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Licensing agreement for ESETEC-based production of antibody fragment PB2452

Wacker Biotech
PhaseBio Pharmaceuticals

Apr 23 2019

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Companies:	Wacker Biotech PhaseBio Pharmaceuticals
Announcement date:	Apr 23 2019
Deal value, US$m:	n/d

Details

Announcement date:	Apr 23 2019
Start date:	Apr 01 2019
Industry sectors:	Biotech Pharmaceutical
Brand name:	ESETEC
Compound name:	PB2452
Asset type:	Compound Technology
Therapy areas:	Cardiovascular Cardiovascular » Myocardial Infarction Antibodies
Technology types:	Cell culture Enabling technology
Deal components:	Licensing

Financials

Deal value, US$m:	n/d

Termsheet

Wacker Biotech and PhaseBio Pharmaceuticals signed a license agreement for the production of antibody fragment PB2452.

PhaseBio obtains the right to use both WACKER’s ESETEC-based production strain and WACKER’s ESETEC technology to manufacture and commercialize the antibody fragment.

Press Release

Wacker Biotech and PhaseBio Sign License Agreement for ESETEC®-Based Production of Antibody Fragment PB2452

Munich and Jena, Apr 23, 2019

WACKER subsidiary Wacker Biotech GmbH and US biopharmaceutical company PhaseBio Pharmaceuticals Inc. signed a license agreement for the production of antibody fragment PB2452. Under the agreement, PhaseBio obtains the right to use both WACKER’s ESETEC®-based production strain and WACKER’s ESETEC® technology to manufacture and commercialize the antibody fragment.

“Our license agreement with PhaseBio underscores the fact that our ESETEC® platform is a key technology for making antibody fragments and developing successful biopharmaceuticals,” says Dr. Susanne Leonhartsberger, managing director of Wacker Biotech GmbH, a WACKER subsidiary based in Jena (Germany). ESETEC® is a patented technology developed by WACKER for the highly efficient synthesis of

pharmaceutical proteins. It has already proven itself in the production of antibody fragments. The effectiveness of the system was highlighted, for example, through WACKER's collaboration with MedImmune, the global biologics R&D arm of AstraZeneca. Within just a few weeks of receiving the corresponding genes, WACKER successfully produced the antibody fragment, or Fab (antigen-binding fragment). The license agreement covers both the use of the strain developed and the manufacturing process, which produces the Fab fragment in superior yields. PhaseBio received the rights to develop PB2452 in 2017 – and has now approached WACKER.

PB2452 is an Fab antibody fragment that serves as a "reversal agent" for ticagrelor, a drug that inhibits platelet aggregation. Marketed by AstraZeneca under the trade names Brilique and Brilinta, ticagrelor is a blood thinner for treatment of patients with Acute Coronary Syndrome or a history of myocardial infarction. PB2452 demonstrated immediate and sustained reversal of the antiplatelet activity of ticagrelor in a clinical phase 1 trial. Wacker Chemie has now licensed its manufacturing process for this antibody fragment to PhaseBio. Under the agreement, PhaseBio gains direct access to WACKER's ESETEC® technology and to WACKER's E.coli strain for producing PB2452.

ESETEC®, a patented technology developed by WACKER, is based on an E.coli strain which secretes the desired proteins into the culture broth in the correct folding conformation during fermentation. Secretion facilitates purification of the target protein, since there is no longer any need for complicated process steps such as homogenization and refolding. This makes the entire manufacturing process significantly more efficient and cost-effective. A number of biopharmaceuticals manufactured with ESETEC® are already being evaluated in preclinical and clinical trials. "Thanks to our ESETEC® technology, we achieved the development breakthrough for antibody fragment PB2452, which needs to be produced as cost-efficiently as possible," says Leonhartsberger.

Jonathan Mow, CEO of PhaseBio, notes that "the ESETEC® system was our choice because it offers significant productivity and time benefits for manufacture of PB2452. This technology outperforms conventional expression and secretion systems using mammalian cells."

Today, Wacker Biotech produces the GMP (Good Manufacturing Practice) batches ordered by PhaseBio at its Amsterdam site, which became part of the WACKER Group in 2018. "A highlight of integrating the new site was that the process transfer between Jena and Amsterdam went so smoothly," stresses Dr. Susanne Leonhartsberger. Furthermore, Wacker Biotech will continue to optimize the production process for PhaseBio.

About Wacker Biotech Wacker Biotech GmbH and Wacker Biotech B.V. are full-service contract manufacturers of biopharmaceutical proteins based on microbial systems. The companies' services range from molecular biology, analytical services and process development through to the GMP-compliant manufacture of clinical test samples and pharmaceutical actives, live microbial products and vaccines for the commercial market at the GMP-compliant, FDA- and EMA-certified production plants in Jena and Halle in Germany and in Amsterdam in the Netherlands. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient production and maximum quality. Wacker Biotech GmbH and Wacker Biotech B.V. are wholly-owned subsidiaries of the Munich-based WACKER Group.

Filing Data

Not available.

Contract

LICENSE AGREEMENT

between Wacker Biotech GmbH

Hans-Knöll-Straße 3

D-07745 Jena

Germany

(value added tax identification number DE199093878)

- hereinafter referred to as „Wacker Biotech" -

and PhaseBio Pharmaceuticals, Inc.

1 Great Valley Parkway, Suite 30

Malvern, PA 19355

USA

- hereinafter referred to as „PhaseBio" –

PhaseBio and Wacker Biotech hereinafter collectively referred to as "Parties" and individually referred to as "Party", as the case might be.

WHEREAS PhaseBio is a biopharmaceutical company with experience in research and development of protein therapeutics.

WHEREAS Wacker Biotech is a biotechnology company with experience in feasibility evaluation, process development, GMP-compliant production of clinical test materials and GMP-compliant bulk production of biopharmaceuticals.

WHEREAS Wacker Biotech has access to a modified microbial production system (“ESETEC®” as hereinafter defined), based on a modified E. coli [***] strain (the “Wacker Secretion Strain” as hereinafter defined) owned by its Affiliate Wacker AG (as hereinafter defined).

WHEREAS ESETEC®, the Wacker Secretion Strain and any information related thereto constitute valuable assets of Wacker Biotech and Wacker AG.

WHEREAS PhaseBio has recently acquired rights to develop the product PB2452 (the “Product”, as hereinafter defined) from MedImmune Limited, a member of the AstraZeneca group (hereinafter “MedImmune”) (the “Transaction”). A manufacturing process for production of Product using ESETEC® has been developed by Wacker Biotech for MedImmune under the MedImmune FSAs and the MedImmune DCSA (as hereinafter defined).

WHEREAS PhaseBio desires to develop the Product for therapeutic use in reversing ticagrelor-mediated platelet inhibition.

WHEREAS Wacker Biotech and PhaseBio have entered into a separate Development and Clinical Supply Agreement (the “PhaseBio DCSA”, as hereinafter defined) in order to further develop and improve the production process and to supply GMP-compliant material of Product by Wacker Biotech to PhaseBio.

WHEREAS PhaseBio desires to obtain a license, with the right to sublicense, as hereinafter set forth under the WACKER Licensed Technology (as hereinafter defined) for the production of Product using the Developed Process (as hereinafter defined) and the Developed Strain (as hereinafter defined) both as developed under the Preceding Service Agreement(s) and the PhaseBio DCSA.

WHEREAS Wacker Biotech is willing to grant said license accordingly on the terms and conditions hereinafter set forth.

WHEREAS PhaseBio is willing to accept such license on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the promises and the mutual covenants hereinafter recited, the Parties agree as follows:

1.

Definitions

In this Agreement, the following terms shall have the meanings set forth in this Article.

1.1

“Affiliate(s)” shall mean a) an organization, which directly or indirectly controls a Party; or b) an organization, which is directly or indirectly controlled by a Party; c) an organization, which is controlled, directly or indirectly, by the ultimate parent company of a Party. Control as per (a) to (c) is defined as owning fifty percent (50%) or more of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization.

1.2

“Agreement” shall mean this agreement including any attached Annexes.

1.3

“Annex” shall mean an annex attached to this Agreement.

1.4

“Annual Minimum Royalty” shall have the meaning as set forth in Section 3.1(b).

1.5

“API” shall mean an active pharmaceutical ingredient derived from a production run which is compliant with GMP in accordance with Part II of Eudralex Vol. 4 “The rules governing medicinal products in the European Union”, titled “ Basic Requirements for Active Substances used as Starting Materials”, intended to be used alone or in mixtures with other substances in the manufacture of a final drug (medicinal) product and that, when used in the production of a final drug (medicinal) product, becomes an active ingredient of the final drug (medicinal) product, whereas such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

1.6

“Background IP” shall mean (i) with respect to Wacker Biotech, any and all IP owned by, licensed to, or controlled by Wacker Biotech/Wacker AG prior to the earlier of the FSA Effective Dates (April 24, 2014) or arising outside of and not related to the performance of the MedImmune FSAs, MedImmune DCSA and PhaseBio DCSA; and/or (ii) with respect to PhaseBio, any and all IP owned by, licensed to, or controlled by PhaseBio prior to the effective date of the PhaseBio DCSA or arising outside of and not related to the performance of the PhaseBio DCSA.

1.7

“Calendar Year” shall mean the period from the Effective Date until December 31 of the same year (the “First Calendar Year”), thereafter the period from January 01 to December 31 of each year of the Gregorian calendar (the “Full Calendar Year”) and - in the last year of the term of this Agreement - the period from January 01 until the expiration of the Royalty Period (the “Last Calendar Year”).

1.8

“cGMP” shall mean the current Good Manufacturing Practices for manufacture, processing or packaging of drug substances and drug products as set forth in the EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use as outlined in the European Commission Directive 2003/94/EC, of 8 October 2003, ICH Guidance for Industry “Q7 Good Manufacturing Practice for Active Pharmaceutical Ingredients”, Requirements of the Code of Federal Regulations of the FDA, relevant and applicable local laws, each as amended from time to time during the term of this Agreement.

1.9

“Combination Product” shall mean the Final Drug Product sold, distributed, transferred, provided or otherwise made available in combination (in the same package, at the same time, as an associated supply, as part of the same action (including where pricing or consideration paid is linked to, dependent on or associated with any other supply or series of supplies) and including as a co-formulation) with one or more other active ingredients that are not the subject of this Agreement (each, an “Other Active”).

1.10

“Confidential Information” shall mean, except as otherwise expressly set forth below, any information (whether in written, oral, visual, graphic, electronic or other form) disclosed or provided by or on behalf of one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”) under this Agreement. The Disclosing Party shall use commercially reasonable efforts to mark as “Confidential” any such information disclosed or provided in written or recorded form and, in the case of orally disclosed information, shall use commercially reasonable efforts to identify such information as confidential at the time of oral disclosure and to confirm the confidential nature of such information in writing within thirty (30) days after oral disclosure. Notwithstanding the foregoing, information which is not marked “Confidential” at the time it is delivered to the Receiving Party, or which is not identified as confidential when disclosed orally and confirmed in writing within thirty (30) days will be deemed to be Confidential Information if the confidential nature of such information would be apparent to, or generally understood by, a reasonable person in the biotechnological industry based on the subject matter thereof, the circumstances under which it was disclosed, or otherwise.

Wacker Biotech’s Confidential Information shall include the WACKER Licensed Process Technology, any information related to ESETEC® and/or the WACKER Secretion Technology, the Developed Strain and the WACKER Secretion Strain (and all material and immaterial aspects of it including their genetic nature and elements).

With respect to PhaseBio’s Confidential Information the following shall apply: The Parties do not anticipate that PhaseBio will directly disclose any additional technical information to Wacker Biotech under this Agreement; the PhaseBio Background IP, PhaseBio Material, and the sequences encoding for Product (including the protein sequence and/or related genetic information as described in Annex 3) are subject to the confidentiality and non-use obligations of the PhaseBio DCSA. Therefore the Parties anticipate that PhaseBio’s Confidential Information (i.e. information where PhaseBio is the Disclosing Party) made available to Wacker Biotech under this Agreement will be limited to any commercial information provided in form of the reporting in accordance with the stipulations of Section 3.7 herein, any list of Permitted Persons or Permitted Entities provided by PhaseBio to Wacker Biotech, any disclosure by the auditor to Wacker Biotech pursuant to Section 3.12, any Expert’s Statement, any manufacturing records made available pursuant to Section 4.6, or any Claim Notice delivered by PhaseBio to Wacker Biotech.

1.11

“Day of First Commercial Sale” shall mean the day of the first sale by PhaseBio, its Affiliates or its Sublicensee(s) to a Third Party of a Final Drug Product for commercial use after obtaining all of the applicable regulatory approvals.

1.12

“Deliverables” shall mean the written documentation of the WACKER Licensed Technology and the Developed Strain as described finally in Annex 2.

1.13

“Developed Process” shall mean the documented process for the cGMP manufacture of Product using a Developed Strain developed under the Preceding Service Agreements or a future agreement between the Parties; the Developed Process is consisting of the Upstream Process and the Downstream Process.

1.14

“Developed Strain(s)” are the modified Wacker Secretion Strains developed under the Preceding Service Agreements or any future agreement between the Parties, for the cGMP manufacture of Product. As of the Effective Date, Developed Strains include the modified Wacker Secretion Strains with the names [***] and [***] (the latter also known as [***] under the MedImmune DCSA) (collectively, the “Existing Developed Strains”). In case a new statement of work under the PhaseBio DCSA to be mutually agreed by the Parties, or a future agreement between the Parties, is directed to the development of a modification of or improvement to an Existing Developed Strain or the development of a new modified Wacker Secretion Strain containing genetic information coding for Product, such modified or improved strain resulting from such development shall constitute a “Developed Strain” for purposes of this Agreement.

1.15

“Distributed Dose” shall mean a Dose sold, distributed, transferred, provided or otherwise made available for the first time by PhaseBio, its Affiliates or Sublicensee(s) to an independent Third Party expressly including distributers, wholesalers managed care organizations, hospitals, other buying groups, any governmental or regulatory authority. A Dose shall be deemed to be made available to an independent Third Party when a Dose is no longer in direct possession of

PhaseBio, its Affiliates or Sublicensee(s) irrespective whether or not any compensation (in cash or otherwise) has been received in return.

For the sake of clarity, a Dose shall be deemed to be a Distributed Dose for the calculation of Running Royalties even if such Dose is made available to an independent Third Party (i) in form of a Combination Product; or (ii) as a replacement for any expired (shelf-life) Dose. However a Dose shall not be deemed to be a Distributed Dose for the calculation of Running Royalties if such Dose is made available to an independent Third Party as a replacement for any rejected, returned (but not due to expiration of shelf-life), recalled, damaged or defective Dose.

1.16

“Dose” shall mean a single-dose of medication containing Final Drug Product intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single treatment in the dosage and packaging configuration approved by the applicable regulatory authority in a jurisdiction of the Territory for the approved indication, whether such approved dosage is contained in a single vial (or other container) in final packaging or in two or more vials (or other containers) packaged together in final packaging.

1.17

“Downstream Process” shall mean that part of the Developed Process that follows the Upstream Process starting with (and expressly including) the following process step: loading of the first chromatographic column and expressly including all chromatographic purification and final conditioning of the Product.

1.18

“Drug Product” shall mean any pharmaceutical product that contains the Product either alone or in combination with other active pharmaceutical ingredients or pharmaceutical product, provided that the Product contained in such Drug Product has been manufactured using WACKER Licensed Technology.

1.19

“Effective Date” shall be the date of the signature of the Party last-to-sign this Agreement.

1.20

“ESETEC®” shall mean Wacker AG’s modified microbial production system, including ESETEC® 1.0 and ESETEC® 2.0, which is suitable for the massive secretion of functional, recombinant proteins into the culture broth based on a selection of modified E. coli [***] strains (the “Wacker Secretion Strain(s)” as hereinafter defined) and a set of modified plasmids carrying specific signal sequences or helper genes which confer correct folding and/or secretion of a protein into the culture medium of a microbial production host (including any future modifications, derivatives, mutations and/or clones thereof made, derived, developed or arisen).

1.21

“Final Drug Product” shall mean Drug Product in the ready-to-sell form provided that a marketing authorization has been obtained for such pharmaceutical product from the U.S. Food and Drug Administration (FDA) or any other competent regulatory authority in the world.

1.22

“Indemnified Wacker Technology” shall mean

(a)

[***]; and

(b)

[***]

both (a) and (b) in unmodified form and in the status of development as of the earlier of the MedImmune FSAs Effective Dates (April 24, 2014). For the sake of clarity, the term “Indemnified Wacker Technology” as used in this Agreement does expressly not comprise (i) any contributions (either material or immaterial) of either MedImmune or PhaseBio to the performance of the Preceding Service Agreements for the development of the Developed Process and/or the Developed Strain, including Product, genetic material or information coding for Product, the Downstream Process and/or PhaseBio Background IP; or (ii) any combinations of such contributions of either MedImmune or PhaseBio with (a) and/or (b) - the term “Indemnified Wacker Technology” as used in this Agreement is strictly limited to (a) and (b) as such.

1.23

“Indirect Taxes” means value added taxes, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice.

1.24

“IP” shall mean any and all technical, scientific and/or analytical information, inventions, discoveries (whether patentable or not), know-how, methods (including without limitation testing methodologies) and Patent Rights.

1.25

“Material” shall mean any tangible biological, chemical, physical material or samples including any DNA, RNA, proteins, plasmids, restriction maps and sequences, reagents, culture supernatant, samples of Product, cells, progeny derived from cells whether modified or not, antibodies, apparatus, manuals, protocols, reports, data sheets, standard operation procedures (“SOP(s)”) or any other material or article of manufacture.

1.26

“MedImmune Background IP” shall have the meaning as set forth in the MedImmune DCSA.

1.27

“MedImmune DCSA” shall mean the service agreement entered into by and between MedImmune and Wacker Biotech with an effective date of July 24, 2015 as amended or updated from time to time.

1.28

“MedImmune FSAs” shall mean the service agreements entered into by and between MedImmune and Wacker Biotech with effective dates of April 24, 2014 and of June 27, 2014 (the “FSA Effective Date(s)”) both as amended or updated from time to time.

1.29

“MedImmune IP” shall have the meaning as set forth in the MedImmune DCSA.

1.30

“Notification Purposes” shall have the meaning as set forth in Section 4.5.

1.31

“Notification Information” shall have the meaning as set forth in Section 4.5.

1.32

“Patent Rights” shall mean any and all patents or patent applications, rights in inventions and any rights of the same or similar nature or effect anywhere in the world, including divisionals, continuations, continuations-in-part, and substitutions thereof and all foreign patent applications

corresponding to the preceding applications; and all patents issuing on any of the preceding applications, including extensions, reissues, and re-examinations.

1.33

“Permitted Persons” shall have the meaning as set forth in Section 4.2.

1.34

“Permitted Entities” shall have the meaning set forth in Section 4.6.

1.35

“PhaseBio Background IP” shall mean the Background IP of PhaseBio. PhaseBio Background IP includes, without limitation, the Downstream Process and all MedImmune Background IP and MedImmune IP as far as (i) the rights thereto have been exclusively licensed to PhaseBio by MedImmune pursuant to the Transaction; and (ii) WACKER has become aware thereof in course of the Preceding Service Agreements.

1.36

“PhaseBio DCSA” shall mean the Development and Clinical Supply Services Agreement entered into by and between PhaseBio and Wacker Biotech with an effective date of June 07, 2018 as amended or updated from time to time.

1.37

“PhaseBio Material” shall mean

(i)

the Material of PhaseBio provided to Wacker Biotech under the PhaseBio DCSA;

(ii)

to the extent still existing and in the possession or control of Wacker Biotech, the Material of MedImmune provided to Wacker Biotech under the MedImmune FSAs and/or MedImmune DCSA.

1.38

“Preceding Service Agreements” shall mean (i) the MedImmune FSAs; (ii) the MedImmune DCSA; and (iii) the PhaseBio DCSA.

1.39

“Product” shall mean anti-ticagrelor antibody fragment known as PB2452 (or in the Preceding Service Agreements as MEDI2452) and defined by the protein sequence and/or related genetic information as described in Annex 3; Product is intended to be used as an API.

1.40

“Promotional Samples” shall have the meaning as set forth in Section 3.5.

1.41

“Royalty Period” shall mean a period commencing on the Effective Date and ending at the later of

(a)

the day on which the manufacture, use, sale or offer for sale of Product no longer infringes a Valid Claim; or

(b)

the [***] anniversary of the Day of First Commercial Sale.

1.42

“Running Royalty” shall have the meaning as set forth in Section 3.1(a).

1.43

“Sublicensee(s)” shall mean the permitted Third Parties as set forth in Section 2.2.

1.44

“Tax” or “Taxation” means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

1.45

“Tax Authority” means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world, authorized to levy Tax.

1.46

“Technical Assistance Agreement” shall have the meaning as set forth in Section 2.4.

1.47

“Territory” shall mean any country in the world expressly excluding [***]. The Territory might be subject to changes according to the stipulations of Section 2.1 last paragraph.

1.48

“Third Party” means any person or entity other than Wacker Biotech, Wacker AG, WBA or PhaseBio or any of the Affiliates of the aforementioned parties.

1.49

“Transaction” shall have the meaning as set forth in the recitals.

1.50

“Upstream Process” shall mean that part of the Developed Process starting with (and expressly including) the following process step: first inoculation of a culture with the Developed Strain up to (but expressly excluding) the following process step: the loading of the first chromatographic column; for the sake of clarity the Upstream Process shall expressly include any fermentation, harvest and clarification of the culture broth.

1.51

“Valid Claim” shall mean a claim of

(a)

an issued, unexpired patent included within the WACKER Licensed Technology, that has not been: (i) held invalid, unpatentable or unenforceable by a final decision, that was not appealed or is unappealable, of a court of competent jurisdiction or of an administrative agency having authority over patents, or (ii) admitted to be invalid, unpatentable or unenforceable by the holder by reissue, disclaimer or otherwise; or

(b)

a pending claim in a pending good faith patent application within WACKER Licensed Technology. Notwithstanding the foregoing clause (a), in the event that a pending claim in a pending application will not issue as a valid and enforceable claim in an issued patent within [***] years after the earliest date from which such patent application claims priority, such a pending claim will not be a Valid Claim, unless and until such pending claim subsequently issues as a valid and enforceable claim in an issued patent, in which case such claim will be reinstated and be deemed to be a Valid Claim as of the date of issuance of such patent.

1.52

“Wacker AG” shall mean Wacker Chemie AG (with offices located at Hanns-Seidel-Platz 4, 81737 Munich, Germany), which is the parent company of Wacker Biotech.

1.53

“WACKER Background IP” shall mean the Background IP of Wacker Biotech and/or Wacker AG, in particular such Background IP of Wacker Biotech and/or Wacker AG related to WACKER Secretion Technology.

1.54

“WACKER Licensed Process Technology” shall mean any and all Confidential Information relating to the Upstream Process and the Developed Strain which either (i) has been contributed by Wacker Biotech to the performance of the Preceding Service Agreements; or (ii) has been assigned to Wacker Biotech under the Preceding Service Agreements and which is reasonably necessary for the implementation of the Upstream Process in accordance with the terms and conditions of the license granted under this Agreement.

1.55

“WACKER Licensed Technology” shall mean the WACKER Licensed Process Technology and the WACKER Patent Rights.

1.56

“WACKER Patent Rights” shall mean the Patent Rights listed in more detail in Annex 1 hereto (and as amended from time to time) and all other Patent Rights owned or controlled by Wacker Biotech that would be infringed by implementing the Developed Process as permitted in accordance with the terms and conditions of the license granted under this Agreement.

1.57

“WACKER Secretion Strain” shall mean (a) the specific proprietary E. coli [***] strain of Wacker Biotech in an unmodified form and which has been selected by Wacker Biotech from ESETEC® in course of the Preceding Service Agreements as the basis for the construction of the Developed Strain(s), or (b) any specific modified or improved strain that may be developed by Wacker Biotech pursuant to a new statement of work under the PhaseBio DCSA to be mutually agreed by the Parties, or a future agreement between the Parties, as the basis for the construction of Developed Strain(s). For the sake of clarity, the term “WACKER Secretion Strain” as used in this Agreement shall expressly not comprise (i) any contributions (either material or immaterial) of MedImmune or PhaseBio under the Preceding Service Agreements, including, in each case, genetic material or information coding for Product, PhaseBio Background IP and/or PhaseBio Material; or (ii) any combinations of such contributions of MedImmune and/or PhaseBio under the Preceding Service Agreements with such specific proprietary E. coli [***] strain. The term “WACKER Secretion Strain” as used in this Agreement is strictly limited to the specific proprietary E. coli [***] strain described in clause (a) of the first sentence of this Section 1.57 as such, or a specific modified or improved strain described in clause (b) of the first sentence of this Section 1.57 as such; which strain, in each case ((a) and (b)), does not contain genetic information coding for Product. For clarity, the WACKER Secretion Strain as such is not able to produce or secrete Product since it does not contain genetic information coding for Product.

1.58

“WACKER Secretion Technology” shall mean Wacker AG’s and/or Wacker Biotech’s Confidential Information related to ESETEC®, to the proprietary E. coli [***] strains (including the WACKER Secretion Strain) and to the molecular design of production hosts, the fermentation of production hosts, the secretion of proteins and their primary isolation from the culture broth.

1.59

“WBA” shall mean Wacker Biotech B.V. (formerly known as SynCo Bio Partners B.V.), whose registered office is at Paasheuvelweg 30, 1105 BJ Amsterdam, the Netherlands, which is a subsidiary of Wacker AG.

1.60

Interpretation

(a)

Whenever any provision of this Agreement uses the term “including” (or “includes”), such term shall be deemed to mean “including without limitation” and “including but not limited to” (or “includes without limitations” and “includes but is not limited to”) regardless of whether the words “without limitation” or “but not limited to” actually follow the term “including” (or “includes”), except if expressly excluded by using the words “solely”, “only” or similar wording;

(b)

The recitals set forth at the start of this Agreement, along with the Annexes to this Agreement, and the terms and conditions incorporated in such recitals and Annexes shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such recitals and Annexes and the terms and conditions incorporated in such recitals and Annexes;

(c)

This Agreement shall be construed as if both Parties drafted it jointly, and shall not be construed against either Party as principal drafter;

(d)

Unless otherwise provided, all references to Sections, Articles and Annexes in this Agreement are to Sections, Articles and Annexes of and to this Agreement;

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(e)

Unless otherwise provided, all references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters or calendar years;

(f)

The above definitions are intended to encompass the defined terms in both the singular and plural forms;

(g)

The Article and Section headings of this Agreement are for convenience of the Parties only and in no way alter, modify, amend, limit, or restrict the contractual obligations of the Parties; and

(h)

The words “in writing” or “written” used in this Agreement shall be deemed to include any communications sent by letter, facsimile or e-mail received by the Receiving Party; and

(i)

The term “shall” used in this Agreement is to be interpreted exclusively as “must”, therefore implying mandatory rights and obligations of the Parties.

2.

License Grant and Technology Transfer

2.1

Subject to the terms and conditions of this Agreement and in consideration of the fees payable by PhaseBio to Wacker Biotech according to Article 3, Wacker Biotech hereby grants to PhaseBio an exclusive right and license under the WACKER Licensed Technology, the Developed Strain and the Deliverables

(a)

to make and have made the Product in the Territory; and

(b)

to use worldwide the Product manufactured in accordance with Section 2.1(a) for the manufacture of the Drug Product; and

(c)

to sell, have sold, offer for sale and import worldwide the Final Drug Product manufactured in accordance with Section 2.1(a) or 2.1(b) respectively.

With respect to the Territory, PhaseBio acknowledges and agrees that Wacker Biotech and Wacker AG are willing to take all necessary measures to protect their valuable WACKER Secretion Technology, in particular the Wacker Secretion Strain. [***]

For the sake of clarity, the rights granted hereunder do not comprise and expressly exclude any activity of PhaseBio or its Sublicensees directed to a modification of the Developed Strain. For the sake of clarity, the rights granted hereunder do not comprise and expressly exclude the right of PhaseBio or its Sublicensees to reproduce and make master cell banks (MCB) and/or working cell banks (WCB), unless Wacker Biotech is not able or willing to provide cell banking services to PhaseBio, in which event the Parties will mutually agree in writing on a specific exemption from such exclusion; Wacker Biotech agrees that all cell banking services provided to PhaseBio for the Developed Strain will be performed as a fee-for-service based on customary and commercially reasonable terms.

2.2

PhaseBio is entitled to grant sublicenses to any Third Party (the “Sublicensee(s)”) under the rights granted hereunder according to Section 2.1. [***]

However, PhaseBio shall impose on the Sublicensee(s) [***] the same obligations as imposed on PhaseBio under this Agreement (including all reporting, accounting and confidentiality obligations and acceptance of all rights of Wacker Biotech (expressly including the rights of auditing and investigation) set forth herein). PhaseBio shall promptly inform Wacker Biotech upon conclusion of such a sublicense agreement. PhaseBio shall be responsible for the compliance of the Sublicensee(s) with the terms and provisions set forth herein.

2.3

Within [***] days after receipt by Wacker Biotech of the complete payment of the first Annual Minimum Royalty in accordance with Sections 3.1(b), 3.6 and 3.10, Wacker Biotech shall disclose and supply the Deliverables to PhaseBio or a Third Party contract manufacturer designated by PhaseBio. In the event that PhaseBio reasonably believes that the Deliverables supplied by Wacker Biotech are incomplete, PhaseBio shall immediately provide written notice thereof to Wacker Biotech detailing the missing parts, and Wacker Biotech shall undertake reasonable efforts to furnish amended Deliverables within thirty (30) days after receipt of such PhaseBio's written notice.

2.4

During a period of [***] calculated from the Effective Date and if requested by PhaseBio, Wacker Biotech shall provide reasonable technical assistance to PhaseBio in relation to the implementation of Developed Process at facilities designated by PhaseBio. Such technical assistance shall be limited to a maximum of [***] per month during the [***] period ([***]) and to a maximum of [***] per month during the [***] period ([***]). Such technical assistance shall be compensated by PhaseBio to Wacker Biotech at a rate of [***]. The details of such technical assistance shall be subject to a separate technical assistance service agreement ("Technical Assistance Agreement").

2.5

Except as expressly provided herein, PhaseBio acknowledges and agrees that nothing in this Agreement shall be construed as granting to PhaseBio by implication, estoppel or otherwise, any licenses, options or any additional or other rights in ESETEC®, Wacker Background IP, WACKER Patent Rights, WACKER Licensed Process Technology, Developed Strain and/or WACKER Secretion Technology; no obligation of Wacker Biotech, Wacker AG or WBA nor any of their affiliated companies, neither expressed nor implied, to grant any additional licenses or any additional rights shall exist. Furthermore, for the sake of clarity, except as provided expressly to the contrary in this Agreement, PhaseBio acknowledges and agrees that no other or additional biologic material including bacterial strains, vectors, plasmids, sequences and/or constructs shall be released or provided to PhaseBio neither by Wacker Biotech, WBA or Wacker AG nor any of their affiliated companies as a deliverable of this Agreement except as expressly stipulated in the Deliverables or the Technical Assistance Agreement.

3.

Consideration and Payment Terms

3.1

For and in consideration of the rights granted under Sections 2.1 and 2.2 PhaseBio shall pay to Wacker Biotech during the term of the Royalty Period:

(a)

subject to Section 3.5, a per-unit (i.e., Distributed Dose) royalty (quota license) in an amount of [***] per Distributed Dose (the "Running Royalty"); and

(b)

subject to Section 3.6, an annual fixed license fee of [***] per Calendar Year (the "Annual Minimum Royalty").

The Running Royalty and the Annual Minimum Royalty shall be reduced by [***].

Debtor of any royalties payable to Wacker Biotech according to this Section 3.1 shall be PhaseBio, irrespective of whether or not the royalties payable to Wacker Biotech result from actions subject to licenses of PhaseBio, its Affiliates or its Sublicensee(s); royalties payable to Wacker Biotech under this Section 3.1 shall be made by PhaseBio as if any action subject to licenses has been made by PhaseBio directly.

3.2

The amount of [***] per Distributed Dose pursuant to Section 3.1(a) shall be valid until and including the calendar year [***]. For the period following the calendar year [***] the per-unit royalty pursuant to Section 3.1(a) shall [***], without further declarations or agreements between the Parties being required. For the avoidance of doubt, for the year [***] the amount of [***] per Distributed Dose pursuant to Section 3.1(a) shall [***]. Notwithstanding the foregoing, but always subject to Section 3.3, beginning with [***], in no event shall the per-unit royalty under Section 3.1(a) [***] the per-unit royalty under Section 3.1(a) for [***] by reason of any and all [***] for the [***], regardless of the [***], without the prior written consent of PhaseBio; provided, however, that in the event of [***] that Wacker Biotech believes in good faith [***], Wacker Biotech and

PhaseBio shall negotiate in good faith [***].

3.3

As of the Effective Date the Parties assume that the amount of Product in a Dose will be [***]. The Parties hereby agree that in case the the amount of Product in a Dose will exceed [***] the Parties will enter into good faith negotiations on [***] to adequately reflect the [***].

3.4

If PhaseBio reasonably determines that it is necessary for the execution of the rights granted under Sections 2.1 and 2.2 [***], the royalties payable to Wacker Biotech under Section 3.1 shall be [***]; provided, however, that in no event shall any royalties payable to Wacker Biotech [***] pursuant to this Section 3.4 [***] of the royalties payable to Wacker Biotech in Section 3.1 above.

3.5

For the avoidance of doubt, there are no Running Royalties due or payable for that share of the Distributed Doses containing solely Product manufactured by Wacker Biotech under a separate supply agreement to be conducted by the Parties.

Furthermore PhaseBio, its Affiliate or its Sublicensee(s) collectively will be allowed to distribute Doses as free promotional samples up to a cumulative total of [***] of all Distributed Doses per Calendar Year (“Promotional Samples”). Any Promotional Samples that have been made available to an independent Third Party up to such percentage in a Calendar Year shall be deemed not to be Distributed Doses and shall not be subject to the obligation to pay Running Royalties. Any Doses which have been made available as free promotional samples to an independent Third Party exceeding such percentage in a Calendar Year shall be deemed to be Distributed Doses and shall be subject to the obligation to pay Running Royalties.

3.6

The Running Royalty of a Calendar Year – if any – shall be fully creditable against the Annual Minimum Royalty of the same Calendar Year.

The Annual Minimum Royalty shall be due beginning with such Calendar Year in which the Developed Strain was transferred to PhaseBio by Wacker Biotech and shall be payable within [***] days of the beginning of a Calendar Year. In the event the First Calendar Year is not a Full Calendar Year the Annual Minimum Royalty for such First Calendar Year shall be paid on a pro rata basis calculated on the basis of 365 calendar days per Calendar Year and shall be due and payable within [***] days after the Effective Date. For each Calendar Year following the First Calendar Year the Annual Minimum Royalty shall be due within [***] days of the beginning of such Calendar Year. In the event the Last Calendar Year is not a Full Calendar Year the Annual Minimum Royalty for such Calendar Year shall be paid on a pro rata basis calculated on the basis of 365 calendar days per Calendar Year; in case of any excess payment Wacker Biotech shall reimburse PhaseBio any amount paid in excess within [***] after the later of (i) the termination date of this Agreement or (ii) the date on which an excess payment has been determined.

3.7

Within [***] days after June 30 and December 31 of each Calendar Year (semi-annually), PhaseBio shall furnish to Wacker Biotech a written report showing in reasonably specific detail

(a)

the amount of Distributed Doses for the preceding six (6) months period; and

(b)

the calculation of the payments due and payable, if any, which shall have accrued hereunder; and

(c)

withholding taxes, if any, required by law to be deducted in respect of any royalties due.

In the report of December 31 of each Calendar Year PhaseBio shall include additionally the amount and percentage (in relation to the amount of Distributed Doses) of Promotional Samples for the preceding twelve (12) months period.

In case no Running Royalties have become due in a reporting period PhaseBio shall inform Wacker Biotech accordingly at the due dates according to the foregoing stipulations.

3.8

The Running Royalty shall be payable on the day the written report according to Section 3.7 is due.

3.9

Any payments due to Wacker Biotech hereunder shall be a net payment, i.e. free of any bank and transfer charges and without deduction of any Taxes (including Indirect Taxes) or other fees payable outside the Federal Republic of Germany, except any withholding tax, if any, imposed on the amount payable under this Agreement which PhaseBio may deduct from payment hereunder and pay to the relevant Tax Authority. In the event withholding taxes shall be due the Parties will reasonably cooperate in completing and filing a request for exemption or reduction of withholding tax required under the provisions of any applicable double taxation or similar treaty or agreement in order to enable PhaseBio to make such payments to Wacker Biotech under this Agreement without any deduction or with reduced withholding. PhaseBio will furnish Wacker Biotech with the certificate of tax receipt issued by the relevant tax office, necessary to have such taxes credited in the Federal Republic of Germany.

3.10

All payments hereunder shall be payable in Euro (EUR) and shall be submitted by PhaseBio to Wacker Biotech to the following account of Wacker Biotech GmbH with Deutsche Bank, München (unless Wacker Biotech informs PhaseBio in writing about a change in the receiving bank):

[***]

adding the remark [***].

The obligation to pay shall only be considered fulfilled on the day on which the complete amount of money is credited to said account.

3.11

Whenever conversion of United States Dollars (USD) to Euro (EUR) shall be required, such conversion shall be calculated using the exchange rates of the European Central Bank (“ECB”) (e.g., https://www.ecb.europa.eu; also available at Reuters page “ECB37”). For the purposes of crediting the Running Royalty of a Calendar Year against the Annual Minimum Royalty of the same Calendar Year the following procedure shall apply: For calculation purposes the Annual Minimum Royalty shall be converted to United States Dollars (USD) on the day on which the respective Annual Minimum Royalty is due using the exchange rate of the ECB of that day; any balance to be paid by PhaseBio between the respective converted Annual Minimum Royalty in United States Dollars (USD) and the credited Running Royalties of the same Calendar Year shall be converted from United States Dollars (USD) to Euro (EUR) using the average exchange rate of the ECB published for the respective six (6) month royalty period during the Calendar Year.

3.12

In the event that PhaseBio is delinquent in the payment due under this Agreement, Wacker Biotech is entitled to charge default interest amounting to [***] above the interest rate of the European Central Bank (ECB). Such interest shall be calculated on a pro rata basis from the day payment was due until the day the payment is credited to the account according to Section 3.10.

3.13

PhaseBio will keep complete and accurate records of account for [***] years preceding the current year for the verification of the royalties to be paid under this Agreement. During the term of this Agreement and within [***] years after termination, such records of account shall be open at all reasonable times – but not more than once each calendar year - to the inspection of an independent certified auditor chosen by Wacker Biotech and acceptable to PhaseBio. The auditor shall keep confidential any information obtained during such inspection and shall report to Wacker Biotech only the payments due and payable.

The costs of such inspection and audit shall be borne by Wacker Biotech, unless it shall be established by Wacker Biotech that as a result of an error in such a report PhaseBio has failed to pay Wacker Biotech at least [***] of the full amount of royalties due and owing under this Agreement, in which event the costs of such inspection shall be borne by PhaseBio. The results of such inspection are binding to the Parties.

3.14

Subject to Section 3.6, last sentence any payments already made by PhaseBio are not refundable in any event, including termination of this Agreement.

4.

Confidentiality and Use Restrictions

4.1

Unless otherwise agreed in this Agreement, the Receiving Party shall keep strictly confidential any Confidential Information of the Disclosing Party and shall not make Confidential Information of the Disclosing Party, in whole or in part, available to any Third Party (including any patent offices or similar authorities). The Receiving Party shall use Confidential Information of the Disclosing Party only for the purpose of exercising its rights (including, in the case of PhaseBio as the Receiving Party, the rights granted hereunder under Section 2.1 and 2.2) and performing its obligations under this Agreement. The Receiving Party shall not use or exploit Confidential Information of the Disclosing Party in any form directly or indirectly, in whole or in part, for any other purposes or for the obtainment of intellectual property rights. All Confidential Information of the Disclosing Party and all rights therein shall remain the Disclosing Party's exclusive property.

In particular PhaseBio shall not deposit, in whole or in part, the Developed Strain with a depositary institution [***]; furthermore PhaseBio shall use the Developed Strain only for the purpose of exercising its rights under this Agreement.

4.2

The Receiving Party shall take all necessary steps to meet the obligations set forth in this Article 4. The Receiving Party shall disclose Confidential Information of the Disclosing Party only to those of its directors, officers, employees, legal representatives, Sublicensee(s) or contract manufacturers (the "Permitted Persons") who have a need to know of such Confidential Information for the exercise of the Receiving Party's rights (including, in the case of PhaseBio as the Receiving Party, the rights granted hereunder under Section 2.1 and 2.2) and the performance of the Receiving Party's obligations hereunder and who have agreed before to be bound by the terms of confidentiality and restricted use consistent with this Agreement, in particular this Article 4, in writing, unless such Permitted Persons are already bound accordingly by the terms of employment, other contracts or by applicable law. The Receiving Party shall be liable for any breach of the provisions of this Agreement by its Permitted Persons.

However, notwithstanding the foregoing PhaseBio shall not disclose or make otherwise available to any Third Party, expressly not to Sublicensee(s) or contract manufacturers, the genotype and/or related genetic information of the Wacker Secretion Strain and/or the Developed Strain, [***].

4.3

PhaseBio shall not analyze, have analyzed, perform or have performed any reverse engineering or decompilation of the Developed Strain or any other Deliverable provided hereunder in order to receive any information on the genotype and/or related genetic information of the Wacker Secretion Strain (which builds also the basis of the Developed Strain) or any aspect thereof; such information shall be deemed to be Confidential Information of Wacker Biotech in each case.

PhaseBio shall expressly instruct in writing any individual within its organization who has access to the Developed Strain to comply with this non-analysis obligation pursuant to this Section 4.3 and oblige the Permitted Entities in writing to impose a similar obligation to those individuals within the Permitted Entities' organizations; for clarity, every individual within PhaseBio's organization or within the organization of the Permitted Entities who has access to the Developed Strain shall have been expressly instructed in writing to comply with this non-analysis obligation pursuant to this Section 4.3.

Furthermore PhaseBio shall not have the right to reconstruct the Developed Strain.

4.4

Subject to (i) the use of Confidential Information reasonably necessary solely for the duration and the performance of PhaseBio's rights according to Section 9.9; and/or (ii) the requirement to retain any Confidential Information for regulatory reasons, in the event of termination of this Agreement PhaseBio shall immediately return or destroy all embodiments of the received Confidential Information, including but not limited to records, data media, product samples, materials or other documents in any form, including any electronic (with respect to electronic files, deleted to the extent reasonably practicable), paper or otherwise embodied copies at Wacker Biotech's request which may be made at any time upon or after termination of this Agreement.

After termination of this Agreement, PhaseBio shall immediately stop using the WACKER Licensed Technology, in particular the Developed Process and the Developed Strain and, subject to Section 9.9, any material, including Product, produced by such use; in particular PhaseBio shall immediately destroy the Developed Strain and any modification, derivative, mutations, clones or progeny thereof.

Complete return or destruction shall be confirmed in writing by PhaseBio. The above shall not apply to back-up copies of electronic data routinely prepared but only for the time for which such back-up copies of similar-type information are customarily retained.

For the sake of clarity, in the event of termination of this Agreement (but not expiration of the Royalty Period), upon expiration of the period of use permitted under Section 9.9, the obligations of this Section 4.4 on complete return and destruction shall apply without limitation or restriction.

4.5

Notwithstanding the obligations of this Article 4, PhaseBio may disclose Confidential Information if it is required to do so in response to a valid order of a competent court or other government authority; provided however, Confidential Information shall not be disclosed without (a) first timely notifying Wacker Biotech in writing to allow Wacker Biotech to safeguard its rights by protective order or equivalent; and (b) cooperating with Wacker Biotech to limit the scope of Confidential

Information disclosed to the greatest extent possible and to ensure that disclosed Confidential Information is (i) treated as confidential by the recipient to the greatest extent possible by law; and (ii) used solely for the purposes for which the order was issued.

Notwithstanding the foregoing, Wacker Biotech acknowledges that PhaseBio intends to establish a contract manufacturing relationship for Product with a contract manufacturer located in [***]. PhaseBio will reimburse Wacker Biotech for (i) all reasonable and documented costs and expenses of said third party consultant as well as (ii) all reasonable internal efforts and documented out-of-pocket expenses incurred by Wacker Biotech directly in course of its supporting efforts at the then effective hourly rate of Wacker Biotech. PhaseBio will be invoiced by Wacker Biotech and the payments are due and payable within thirty (30) days net from the date of an invoice. Wacker Biotech is entitled to charge default interest in accordance with Section 3.12 in the event of delinquency of payment of such invoiced amounts by PhaseBio.

[***]

4.6

PhaseBio agrees and acknowledges that Wacker Biotech or Wacker AG shall have the right once in any calendar year to seek a legally binding written declaration by PhaseBio and each of its Affiliates, Sublicensees, and contract manufacturers of Product that have access to the Developed Strain (collectively, “Permitted Entities”) that the WACKER Licensed Technology or any part of it, in particular the Developed Strain, has only been used for the performance of the rights granted hereunder and/or that products, other than Product, Drug Product and/or Final Drug Product, manufactured or sold by PhaseBio, its Affiliates, its permitted Sublicensee(s) and subcontractors are not made, based upon or using the WACKER Licensed Technology, in particular not ESETEC® and/or the Wacker Secretion Strain.

From time to time upon Wacker Biotech’s request, PhaseBio will provide Wacker Biotech with a list of the Permitted Entities who have access to the Developed Strain, the WACKER Licensed Technology or any part of it.

Furthermore Wacker Biotech and/or Wacker AG shall have the right at any time, at its own cost, to have an independent expert, acceptable to PhaseBio, investigate to verify that neither PhaseBio, nor the Permitted Entities have in any manner become involved, directly or indirectly, in the manufacture or sale of a product, other than the Product, Drug Product or Final Drug Product, based upon or using the WACKER Licensed Technology, in particular ESETEC® and/or the Wacker Secretion Strain (collectively hereinafter a “Misuse of WACKER Licensed Technology”), and such investigation shall [***]. PhaseBio shall cooperate in a reasonable manner with such independent expert in its investigation. The right of investigation under this sub-paragraph shall be strictly limited to the respective product in question.

In connection with this investigation, the independent expert shall only provide to Wacker Biotech and/or Wacker AG a report that [***] (the “Expert’s Statement”). [***] Wacker Biotech and/or Wacker AG shall have the right to use the redacted Expert’s Statement as it deems fit.

Wacker Biotech and/or Wacker AG’s rights of investigation under this Section 4.6 shall not obligate PhaseBio or any Permitted Entity to provide [***].

PhaseBio shall require any of its Permitted Entities who will have access to the Developed Strain in writing to expressly agree to Wacker Biotech and/or Wacker AG’s rights of investigation according to this Section 4.6 prior to any transfer of WACKER Licensed Technology, in particular the Developed Strain, to such Permitted Entities.

In each event the provisions of this Section 4.6 shall survive [***] after any termination or expiration of this Agreement. Upon expiration of said [***] term Wacker Biotech and/or Wacker AG shall [***].

4.7

The obligations of confidentiality and restricted use set forth in this Article 4 shall not apply to any portion of Confidential Information of the Disclosing Party that the Receiving Party can prove by competent evidence:

(a)

is in the public domain at the time of disclosure; or

(a)

after disclosure, becomes part of the public domain by publication or otherwise, except through breach of this Agreement or the PhaseBio DCSA by the Receiving Party; or

(b)

was already in its possession at the time of disclosure, without confidentiality restrictions; or

(c)

is disclosed to the Receiving Party by a Third Party who is entitled to disclose the information without an obligation to maintain the confidentiality thereof; or

(d)

is expressly approved for disclosure by written authorization of the Disclosing Party in each case; or

(e)

is independently developed by personnel of the Receiving Party without recourse or reference to the Confidential Information of the Disclosing Party.

Any combination of features shall not be deemed to be within the foregoing exceptions merely because individual features are within an exception unless the actual combination itself is within an exception. Any specific Confidential Information shall not be deemed to be in the foregoing exceptions merely because it is encompassed by more general information which is within an exception unless the specific Confidential Information itself is within an exception.

4.8

Without limiting the Parties' rights according to Sections 2.2, 6.2 and 10.8, each Party shall keep confidential the terms and conditions of this Agreement.

5.

Prosecution and Maintenance of WACKER Patent Rights and Third Party Infringement

5.1

Wacker Biotech and/or Wacker AG shall not be obliged to prosecute and maintain WACKER Patent Rights or to take any measures which are necessary for the perfection on the WACKER Patent Rights. Wacker Biotech and/or Wacker AG shall not be obliged to offer to PhaseBio the transfer of any of the WACKER Patent Rights in the event that Wacker Biotech and/or Wacker AG elects not to continue prosecuting or maintaining any of the WACKER Patent Rights.

5.2

All costs related to the prosecution and maintenance of WACKER Patent Rights shall be borne by Wacker AG or Wacker Biotech respectively.

5.3

The Parties shall furnish the other with timely written notice of any and all infringements and other unauthorized uses of WACKER Patent Rights that come to their attention during the term of this Agreement.

6.

Press Release, Publicity and Use of Names

6.1

Neither Party shall make use of the name or trademarks of the other Party, nor of any agent of the other Party in connection with any publicity, advertising, promotional material, or otherwise without the prior written approval of the other Party.

6.2

Always subject to Section 4.8, the Parties agree that an initial public announcement of the execution of this Agreement shall be made in the form of a mutual press release. The content of the mutual press release is outlined in Annex 4. Final wording (but not content) and time of the publication is to be agreed upon by the Parties in good faith. After such press release is published, each Party shall be entitled to make or publish any public statement consistent with the contents thereof.

7.

Warranties and Representations

7.1

Warranties and Representations of PhaseBio

PhaseBio represents and warrants that

(a)

the execution, delivery and performance of this Agreement shall not result in a breach or violation of any agreements, contracts or other arrangements to which it is a party;

(b)

it is duly organized and validly existing under the laws of jurisdiction of its organization and it has the legal right to enter into this Agreement;

(c)

it has an exclusive license from MedImmune to the Medimmune Background IP, the MedImmune IP, the Product and in any and all confidential information and Material of MedImmune provided to Wacker Biotech under the Preceding Service Agreement(s);

(d)

it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(e)

this Agreement is a legal and valid obligation binding upon PhaseBio and enforceable in accordance with its terms;

(f)

it shall comply with any applicable supranational, national or local laws, regulations or codes in the performance of its material obligations under this Agreement; and

(g)

as of the Effective Date, [***], the provision of [***] hereunder [***] for reason attributable to: (i) [***]; and/or (iii) [***].

7.2

Warranties and Representations of Wacker Biotech

Wacker Biotech represents and warrants that

(a)

the execution, delivery and performance of this Agreement shall not result in a breach or violation of any agreements, contracts or other arrangements to which it is a party;

(b)

it is duly organized and validly existing under the laws of jurisdiction of its organization, and it has the legal right to enter into this Agreement;

(c)

it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(d)

this Agreement is a legal and valid obligation binding upon Wacker Biotech and enforceable in accordance with its terms;

(e)

as of the Effective Date, [***] the WACKER Secretion Strain as such, [***];

(f)

to the best of Wacker Biotech's knowledge, no person other than those persons named as inventors on any of WACKER Patent Rights is an inventor of the inventions claimed in the WACKER Patent Rights;

(g)

Wacker Biotech has not received written notice (and is not otherwise aware) of any pending lawsuits, judgments, settlements, or legal actions against Wacker Biotech with respect to the WACKER Licensed Technology that, [***]. Except for [***] Wacker Biotech has not received written notice (and is not otherwise aware) of [***]; and

(h)

as of the Effective Date, Wacker Biotech is not pursuing any lawsuits, judgments, settlements, or legal actions with respect to the WACKER Secretion Technology, ESETEC® or the WACKER Licensed Technology that, [***] would have [***].

7.3

Disclaimers

7.3.1

Nothing in this Agreement is or shall be construed neither express nor implied as an obligation of Wacker Biotech, WBA and/or Wacker AG to bring or prosecute actions or suits against any Third Party for infringement of the WACKER Licensed Technology, including the WACKER Patent Rights.

7.3.2

Except for the warranties and representations given under Section 7.2 above, nothing in this Agreement is or shall be construed neither express nor implied as:

(b)

a warranty or representation by Wacker Biotech, WBA and/or Wacker AG as to the validity, enforceability or scope of the WACKER Patent Rights or any claim within the WACKER Patent Rights; or

(c)

a warranty or representation by Wacker Biotech, WBA and/or Wacker AG that the manufacture, use, offer-for-sale or sale of Product, Drug Product or Final Drug Product or the use of the WACKER Licensed Technology (expressly including the Developed Process) or the Deliverables (expressly including the Developed Strain) in accordance with the rights granted under this Agreement is or will be free from infringement of and does and will not intervene in any Patent Rights of any Third Party; or

(d)

granting by implication, estoppel, or otherwise any licenses, sub-licenses or other rights or making covenants not-to-sue under any Patent Rights of Wacker Biotech, WBA, Wacker AG and/or any Third Party, other than the licenses expressly granted as set forth in Article 2; or

(e)

a warranty or representation by Wacker Biotech, WBA and/or Wacker AG as to the accuracy, sufficiency, completeness or fitness for a particular purpose [***].

7.3.3

Except for the express warranties set forth in Section 7.2 Wacker Biotech, WBA AND/OR Wacker AG make NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WITH RESPECT TO the WACKER LICENSED TECHNOLOGY, Deliverables, Confidential Information and/or any other information or materials disclosed, provided or delivered AND/OR RIGHTS OR LICENSES GRANTED by Wacker Biotech AND/OR Wacker AG hereunder or the use thereof, WHETHER EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE. Wacker Biotech HEREBY SPECIFICALLY DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY OR GUARANTEE OF ACCURACY, COMPLETENESS, SUFFICIENCY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, ENFORCEABILITY OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OR ANY OTHER RIGHTS OF THIRD PARTIES.

7.3.4

PhaseBio shall in any case be solely responsible for the use to which it puts WACKER Licensed Technology including any Deliverables and/or any other information or material which it receives from Wacker Biotech and/or Wacker AG hereunder; except to the extent of [***]. PhaseBio shall be solely responsible for the manufacture, use or distribution, offer for sale and sale of Product, Drug Product and Final Drug Product or any other product resulting therefrom. PhaseBio agrees to comply with all laws and regulations applicable to the handling, use, storage and disposal of any materials provided hereunder and to otherwise handle, use and store such materials in a safe, secure and responsible manner.

8.

Indemnification, Liability and Limitation of Liability

8.1

PhaseBio shall indemnify, defend and hold harmless Wacker Biotech, its employees, officers, directors, governors, managers, subsidiaries, Affiliates, agents and principals (partners, shareholders or holders of an ownership interest, as the case may be) (hereinafter collectively "Wacker Biotech Released Parties") from and against any and all losses, damages, costs and expenses, including reasonable attorneys' fees and court costs (hereinafter collectively "Damages"), to which any Wacker Biotech Released Party may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, an "Action"), to the extent such Damages result from or arise out of (i) any breach by PhaseBio of any of its warranties or representations set forth in Section 7.1; (ii) any product liability claims with respect to Product, Drug Product and/or Final Drug Product made by or on behalf of PhaseBio or any of its Affiliates or Sublicensees by exercising the license granted hereunder; (iii) an alleged or actual failure of Product, Drug Product and/or Final Drug Product made by or on behalf of PhaseBio or any of its Affiliates or Sublicensees by exercising the license granted hereunder to conform to requirements of any applicable laws and/or any applicable regulatory approvals, including the failure of PhaseBio to obtain the necessary regulatory approvals; (iv) the use of any Deliverables, the WACKER Licensed Technology or any other information or material disclosed, delivered or provided hereunder [***]; and/or (v) [***].

Such indemnification (as described herein under (i) - (v)), shall not apply if such Action or Damage arises from matters which are subject to Wacker Biotech's indemnification obligations set forth in Section 8.2. Subject to Section 8.4, PhaseBio will defend any Actions covered by this Section 8.1 at its expense and will pay any Damages that may be finally awarded against Wacker Biotech and Wacker Biotech Released Parties; to this extent, PhaseBio waives the defense of time limitation.

8.2

Wacker Biotech shall indemnify, defend and hold harmless PhaseBio, its employees, officers, directors, governors, managers, subsidiaries, Affiliates, agents and principals (partners, shareholders or holders of an ownership interest, as the case may be) (hereinafter collectively "PhaseBio Released Parties") from and against any and all Damages to which any PhaseBio Released Party may become subject as a result of any Action, to the extent such Damages result from or arise out of any breach by Wacker Biotech of any of its warranties or representations set forth in Section 7.2.

Such indemnification shall not apply if and to the extent any Action or Damage arises from matters which are subject to PhaseBio's indemnification obligations set forth in Section 8.1.

Subject to Section 8.4, Wacker Biotech will defend such Actions at its expense and will pay any Damages, that may be finally awarded against PhaseBio and PhaseBio Released Parties.

8.3

If any of the Indemnified Wacker Technology becomes, [***], the subject of a Third Party claim of infringement or litigation Wacker Biotech shall, [***]. For the sake of clarity, this claim of PhaseBio pursuant to this Section 8.3 is [***].

8.4

A Party wishing to seek indemnification hereunder (the "Indemnified Party") shall notify the other Party (the "Indemnifying Party") in writing of any Action as soon as reasonably practicable ("Claim Notice") after the Indemnified Party receives notice of the Action, shall permit the Indemnifying Party to assume direction and control of the defense of the Action (including the right to settle the Action solely for monetary consideration) using counsel reasonably satisfactory to the Indemnified Party, and shall cooperate as requested by the Indemnifying Party's request (at the Indemnifying Party's expense), in the defense of such Action. The Indemnifying Party shall keep the Indemnified Party informed on a current basis of its defense of any such Action. Each Party hereto shall cooperate with the other Party in every reasonable way to facilitate the defence of any such Action. The Indemnified Party shall not agree to any settlement of such Action without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall be free to take any reasonable action as it deems fit, provided however the Indemnifying Party will not settle any Action in any manner or agree to any settlement of such Action or consent to any judgment in respect thereof that (i) does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto; (ii) adversely affects the rights of the Indemnified Party; (iii) admits or imposes any liability or obligation on the Indemnified Party; or (iv) acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party.

The Indemnified Party's failure to provide a Claim Notice to the Indemnifying Party under this Section 8.4 does not relieve the Indemnifying Party of any liability that the Indemnifying Party may have to an Indemnified Party, but in no event shall the Indemnifying Party be liable for any Damages that result from a delay in providing a Claim Notice. Each Claim Notice must contain a description of the Action and the nature and amount of the related Damages (to the extent that the nature and amount of the Damages are known at that time). In the event that a final judgment or order is entered by any court or other tribunal against the Indemnified Party, the Indemnifying Party shall satisfy such judgment or order (and/or reimburse the Indemnified Party for any amounts it pays against such judgment or order) incurred by the Indemnified Party with regard to its defence against the Action or Damage within [***] days of the Indemnified Party providing notice to the Indemnifying Party of the judgment or order.

8.5

Except for [***], as far as legally permitted neither Party shall be liable to the other Party, whether in tort, contract or otherwise, for any consequential, special, incidental, punitive or indirect damages, loss or expenses (including but not limited to business interruption, lost business, lost profits, or lost savings) in connection with this Agreement; provided, however, that this Section 8.5 [***], as applicable.

8.6

Except for [***], as far as legally permitted the entire liability of Wacker Biotech to PhaseBio under this Agreement, whether in tort, contract, under the indemnity contained in Section 8.2 or otherwise shall be limited to [***].

8.7

Nothing in this Agreement shall purport or attempt or serve to exclude or restrict any liability (i) for any fraud or fraudulent misrepresentation, (ii) for wilful misconduct or (iii) under mandatory applicable law, including without limitation mandatory product liability law.

8.8

PhaseBio and Wacker Biotech shall obtain and/or maintain during the term of this Agreement and for a period of [***] years thereafter, liability insurance in amounts which are reasonable and customary in the biopharmaceutical industry for the respective activities (i.e. Wacker Biotech as contract manufacturing organisation and PhaseBio as sponsor/pharmaceutical company) at the respective place of business, but no less than [***], and such liability insurance shall insure against all mandatory liability, including liability for personal injury, physical injury and property damage. Wacker Biotech shall have the right to self-insure at any time.

9.

Term and Termination

9.1

This Agreement shall come into effect on the Effective Date and shall - unless terminated earlier in accordance with the provisions of the Sections 9.2 to 9.7 – be in force for an indefinite period of time.

9.2

Upon regular expiration of the Royalty Period (i.e. without occurrence of an earlier termination in accordance with the stipulations herein) the license granted hereunder to PhaseBio shall be fully-paid up and automatically converts to a non-exclusive license. Irrespective of such expiration the obligations of the Parties according to Articles 4, 6, 7 and 8 shall remain in effect.

9.3

This Agreement (including the rights granted herein) may be terminated by either Party upon any material breach by the other Party of any material obligation or condition, effective [***] days after giving written notice to the breaching Party of such termination, which notice shall describe such breach in reasonable detail. The foregoing notwithstanding, if such default or breach is cured or shown to be non-existent within the aforesaid [***] day period, the notice shall be deemed automatically withdrawn and of no effect; provided, however, that prior to giving any notice for breach, the Parties shall first attempt to amicably resolve any disputes as to the existence of any breach through good faith negotiations between a senior management member from each Party for a period of not less than [***] days.

A material breach of PhaseBio which entitles Wacker Biotech to terminate this Agreement for cause shall include, but not be limited to the default of PhaseBio to pay the consideration according to Article 3 within the remedy periods set out in Section 9.3 or any non-compliance by PhaseBio with the provisions of Article 4.1, 4.2, 4.3, 4.6 and 4.8.

9.4

PhaseBio shall have the right to terminate this Agreement and the rights granted to PhaseBio hereunder earlier with effect to the end of a Calendar Year by giving [***] months prior written notice of termination to Wacker Biotech, provided that any payments due for the period before the effective date of the termination will be paid by PhaseBio even if the due date of such payment would be after the effective date of the termination.

9.5

Wacker Biotech shall have the right to terminate this Agreement and the rights granted to PhaseBio hereunder with immediate effect by giving written notice of termination in the event PhaseBio declares bankruptcy or commences bankruptcy or reorganization proceedings, or if PhaseBio has such proceedings commenced against it which are not dismissed within [***] days after service, or if PhaseBio makes a general assignment for the benefit of creditors or is generally unable to pay its debts as they become due.

9.6

Wacker Biotech shall have the right to terminate this Agreement and the rights granted to PhaseBio hereunder with immediate effect by giving written notice of termination in the event PhaseBio challenges or supports challenge of WACKER Patent Rights.

9.7

Upon any termination of this Agreement, Section 4.4 shall apply. Upon any termination of this Agreement (but, for clarity, not upon expiration of the Royalty Period in accordance with Section 9.2) any and all rights granted to PhaseBio hereunder shall cease and shall automatically revert to Wacker Biotech.

9.8

Furthermore termination of this Agreement or expiration of the Royalty Period for any reason shall not affect and shall be without prejudice to any rights or obligations of either Party which shall have arisen on or before the date of such termination of this Agreement or expiration of the Royalty Period, nor shall it affect the survival of any provisions of this Agreement which are expressly, or by implication, intended to survive the termination of this Agreement or expiration of the Royalty Period, in particular without limitation the rights and obligations of Articles 3, 4, 6, 7, 10 and 11 shall survive any termination of this Agreement or expiration of the Royalty Period (provided that PhaseBio shall have no obligation to pay Running Royalties or any Annual Minimum Royalty for any period after expiration of the Royalty Period. Termination of the Agreement or expiration of the Royalty Period in accordance with the provisions hereof shall not limit any remedies which may be otherwise available.

9.9

In case of termination by PhaseBio under Section 9.3 or 9.4, PhaseBio shall have the right to utilize the stock in its inventory of any Product as permitted by the license granted by Wacker Biotech under this Agreement for a limited period of [***] following the date of termination hereof subject to PhaseBio’s continuing obligation to pay royalties for such [***] period in accordance with the stipulations of Article 3 hereof.

10.

Miscellaneous

10.1

Any change or modification of this Agreement, including this Section 10.1, requires written amendment signed by both parties.

10.2

If any provision in this Agreement is invalid or unenforceable the rest of this Agreement shall remain unaffected. The Parties shall in good faith substitute such provision with a valid and enforceable provision which comes closest to the economic intention of the invalid or unenforceable provision.

10.3

All notices, requests and other communications hereunder shall be in writing and shall be delivered or sent in each case to the respective address specified below, or such other address as may be specified in writing to the other Party hereto via hand delivery or internationally recognized overnight delivery services that maintains records of delivery, and shall be effective either upon receipt, if hand delivered, or on the third delivery day after deposit with an internationally recognized overnight delivery service (unless the receiving Party can prove by reasonable evidence later receipt):

(a)

Wacker Biotech:

Wacker Biotech GmbH

Hans-Knöll-Straße 3

D-07745 Jena

Germany

Attn.: Managing Director

with a copy to:

Wacker Chemie AG

Corporate Department IP - Intellectual Property

Hanns-Seidel-Platz 4

D-81737 Munich

Germany

(b)

PhaseBio:

PhaseBio Pharmaceuticals, Inc.

1 Great Valley Parkway, Suite 30,

Malvern, PA 19355

USA

Attn: Chief Executive Officer

10.4

Both Parties are independent contractors under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute Wacker Biotech or PhaseBio as partners or joint venturers with respect to this Agreement. Except as expressly stipulated herein, neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement, or undertaking with any Third Party. Furthermore nothing herein is intended nor is to be construed so as to assume or create any obligations of a Party to enter into any other contract, agreement, or undertaking with the other Party.

10.5

No waiver of any rights shall be effective unless consented to in writing by the Party to be charged and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

10.6

This Agreement is not a release. This Agreement is not a joint development agreement.

10.7

This Agreement constitutes the entire and exclusive Agreement between the Parties with respect to the subject matter hereof and supersedes and cancels all previous discussions, agreements, commitments and writings in respect thereof; provided, however, that the PhaseBio DCSA shall remain in effect in accordance with its terms. No amendment or addition to this Agreement shall

be effective unless reduced to writing and executed by the authorized representatives of the Parties. In case of any discrepancy between the main body of this Agreement and its Annexes, the main body shall prevail without restriction. In the event of any conflict between this Agreement and the Preceding Service Agreements, this Agreement shall control.

10.8

Neither Party may transfer or assign this Agreement, directly or indirectly, or any of its rights hereunder without the prior written consent of the other Party, other than to an Affiliate, a successor of a Party under a change in control of such Party or to a Third Party in connection with the transfer or sale of all or substantially all of its business relating to the subject matter of this Agreement, always provided that the assignee expressly obligates itself in a written instrument to fully perform all of the obligations of the assignor under this Agreement. However, should PhaseBio [***], PhaseBio shall [***]. Any consent required by either Party under this Section 10.8 shall not be unreasonably withheld. Any other attempted transfer or assignment in violation of this Section 10.8, in particular an assignment of this Agreement without a transfer of the rights and obligations hereunder shall be void. In the event of a permitted change of control, the original Party's (or its successor's) obligations hereunder shall continue. This Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assignees.

10.9

Neither Party will be liable nor deemed to be in default for any delay or failure in performance under this Agreement or other interruption of service deemed resulting directly or indirectly from a cause beyond the reasonable control of either Party, including but not limited to, Acts of God, civil or military authority, acts of public enemy, war, accident, fire, explosion, earthquake, flood, failure of transportation, strike, or other work interruption by either Party's employees or any similar or dissimilar cause (each such event being a "Force Majeure").

10.10

This Agreement may be executed in counterparts, each of which will be deemed to be an original but all of which together will constitute one and the same agreement binding to the Parties; electronic or facsimile signature or signature by electronic image transmission (such as portable document format, PDF) will be as binding and enforceable as an original.

11.

Law and jurisdiction

11.1

Subject to Section 11.3 this Agreement and any dispute, including without limitation any arbitration, arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of the Federal Republic of Germany.

11.2

The Parties will endeavor to settle all disputes amicably in good faith discussions. If an amicable agreement is not achieved, the exclusive place of jurisdiction shall be Munich, subject to Section 11.3.

11.3

All determinations and requirements of inventorship will be determined in accordance with [***].

[Remainder of the page left blank intentionally; signatures follow on the next page]

IN WITNESS WHEREOF, PhaseBio and Wacker Biotech have executed this Agreement in duplicate originals by duly authorized representatives.

Wacker Biotech GmbH PhaseBio Pharmaceuticals, Inc.

Signed Signed

By:

/s/ Susanne Leonharlsberger

By:

/s/ Jonathan P. Mow

Printed Printed

Name:

Dr. Susanne Leonharlsberger

Name:

Jonathan P. Mow

Title:

Managing Director

Title:

Chief Executive Officer

Date: March 25, 2019 Date: April 1, 2019

List of Annexes

Annex 1: List of WACKER Patent Rights

Annex 2: List of Deliverables

Annex 3: Sequence of Product

Annex 4: Content of the Mutual Press Release

Annex 1 – List of WACKER Patent Rights

[***]

Annex 2 - List of Deliverables

Developed Strain in the status of development as of the Effective Date:

1.

Developed Strain: [***]

The Developed Strain will be delivered to PhaseBio as [***].

2.

Confidential Information relating to the Developed Process as of the Effective Date

(to be updated after finalization of the Performance under the PhaseBio DCSA, if necessary)

A.

Process Flow Chart:

[***]

B.

Documents:

[***]

Annex 3 - Sequence of Product

[***]

Annex 4 – Content of the Mutual Press Release

•

PhaseBio selected Wacker Biotech to develop an improved manufacturing process for PB2452 using ESETEC®.

•

PB2452 is a first-in-class antibody fragment to reverse the effects of ticagrelor, which addresses important unmet need for patients requiring antiplatelet therapy

•

ESETEC® was selected based on superior space-time yields for this difficult-to-express antibody fragment, outperforming conventional expression systems including mammalian cells

•

PhaseBio has now acquired a product-specific license for ESETEC®.

•

PhaseBio obtained a license in order to have direct access to the cell line and developed process.

Annex 5 – Information Required for [***]

[***]