Current Agreements

Dealdoc

Co-development, licensing and marketing agreement for PCI-32765

Pharmacyclics
Janssen Biotech

Dec 08 2011

Co-development, licensing and marketing agreement for PCI-32765

Companies:	Pharmacyclics Janssen Biotech
Announcement date:	Dec 08 2011
Amendment date:	Nov 20 2013
Deal value, US$m:	975.0 : sum of upfront and milestone payments

Details

Announcement date:	Dec 08 2011
Amendment date:	Nov 20 2013
Industry sectors:	Bigpharma Biotech Pharmaceutical
Compound name:	Ibrutinib
Asset type:	Compound
Therapy areas:	Oncology » Leukemia » Chronic lymphocytic leukemia Oncology » Lymphoma » Non Hodgkin's lymphoma
Technology types:	Small molecules
Deal components:	Co-development Co-market Co-promotion Licensing Marketing
Stages of development:	Regulatory
Geographic focus:	Worldwide

Financials

Deal value, US$m:	975.0 : sum of upfront and milestone payments
Upfront, US$m:	150.0 : upfront payment
Milestones, US$m:	825.0 : sum of additional payments based upon the achievement of certain development and regulatory milestones 50 : second milestone payment 75 : third milestone achieved 60 : fourth milestone payment for FDA approval 50 : fifth milestone payment for European medicines agency approval
Royalty rates, %:	50.0 : profit revenue share

Termsheet

20 November 2013

A step toward European approval of the blood cancer drug Imbruvica will net Pharmacyclics a $50 million payment from partner Johnson & Johnson.

The European Medicines Agency told Janssen that its application seeking approval of the drug is valid.

That triggers the milestone payment to Pharmacyclics.

The payment is on top of $60 million that Pharmacyclics earned from Janssen Biotech when FDA approved Imbruvica for mantle cell lymphoma patients previously treated with other drugs.

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29 August 2013

Pharmacyclics announced that the U.S. Food and Drug Administration has accepted for filing its New Drug Application for the investigational oral Bruton's tyrosine kinase inhibitor ibrutinib, for two B-cell malignancy indications: previously treated mantle cell lymphoma and previously treated chronic lymphocytic leukemia/small lymphocytic lymphoma.

On June 28, 2013 Pharmacyclics submitted a New Drug Application under section 505(b) of the Food, Drug & Cosmetic Act for ibrutinib.

On Aug 27, 2013 the FDA notified Pharmacyclics that they have completed their filing review and determined that the application is sufficiently complete to permit a substantive review.

The FDA's acceptance of the NDA triggers a $75 million milestone payment to Pharmacyclics under its Collaboration Agreement with Janssen Biotech Inc.

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20 August 2012

The enrollment of the fifth patient has subsequently triggered a second $50 million milestone payment obligation from Janssen Biotech, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, worldwide collaborator on ibrutinib in oncology and sponsor of this MCL trial. As Pharmacyclics or Janssen initiate specific clinical trials and enroll the 5th patient, additional milestone payments of $50 million may be triggered up to a total of $250 million.

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8 December 2011

Agreement with Pharmacyclics to jointly develop and market the anti-cancer compound, PCI-32765.

A number of Phase 1 and 2 studies with PCI-32765 are ongoing across a panel of B-cell malignancy disorders, including chronic lymphocytic leukemia, mantle cell lymphoma, and diffuse large B-cell lymphoma.

The companies have entered into a worldwide 50/50 profit-loss agreement, sharing development and commercialization activities.

Janssen has made an upfront payment of $150 million which will be recorded in the fourth quarter, and will make additional payments based upon the achievement of certain development and regulatory milestones.

Press Release

20 November 2013

Pharmacyclics snags $50 million as cancer drug moves toward European approval

A step toward European approval of the blood cancer drug Imbruvica will net Pharmacyclics Inc. a $50 million payment from partner Johnson & Johnson. The European Medicines Agency on Tuesday told Janssen-Cilag NV, a subsidiary of Johnson & Johnson (NYSE: JNJ), that its application seeking approval of the drug is valid. That triggers the milestone payment to Sunnyvale-based Pharmacyclics (NASDAQ: PCYC). The payment is on top of $60 million that Pharmacyclics, led by CEO Robert Duggan, earned from Janssen Biotech Inc. when the Food and Drug Administration last week approved Imbruvica for mantle cell lymphoma patients previously treated with other drugs. The company received another $75 million from Janssen Biotech in September, when the FDA accepted Imbruvica's application.

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29 August 2013

New Drug Application Filing for Ibrutinib Accepted in Two B-cell Malignancies by the U.S. FDA

New Drug Application Filing for Ibrutinib Accepted in Two B-cell Malignancies by the U.S. FDA

SUNNYVALE, Calif., Aug. 29, 2013 -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its New Drug Application (NDA) for the investigational oral Bruton's tyrosine kinase (BTK) inhibitor ibrutinib, for two B-cell malignancy indications: previously treated mantle cell lymphoma (MCL) and previously treated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). On June 28, 2013 Pharmacyclics submitted a New Drug Application (NDA) under section 505(b) of the Food, Drug

& Cosmetic Act for ibrutinib. On Aug 27, 2013 the FDA notified Pharmacyclics that they have completed their filing review and determined that the application is sufficiently complete to permit a substantive review. The FDA's acceptance of the NDA triggers a $75 million milestone payment to Pharmacyclics under its Collaboration Agreement with Janssen Biotech Inc.

"We are very excited to have received the official FDA acceptance of our first NDA filing for ibrutinib," said Dr. Urte Gayko, Senior Vice President of Global Regulatory Affairs, Pharmacyclics. "We look forward to continuing to work with the FDA as they complete their review of the ibrutinib application which includes the new Breakthrough Therapy Designation process."

About CLL / SLL

CLL, a B-cell malignancy, is a slow-growing blood cancer of the white blood cells (lymphocytes), most commonly from B-cells. CLL is the second most common adult leukemia. Approximately 16,000 patients in the US are diagnosed each year with CLL. The prevalence of CLL is approximately 113,000 in the U.S. CLL is a chronic disease that predominantly occurs in the elderly with a five-year survival of approximately 82 percent.1 Patients commonly receive multiple lines of treatment over the course of their disease. When cancer cells are located mostly in the lymph nodes, the disease is called SLL. CLL and SLL are considered to be different manifestations of the same underlying disease; they share similarities in signs and symptoms, genetic features, disease progression and treatment.

About Mantle Cell Lymphoma

MCL is a B-cell malignancy, an aggressive type of B-cell non-Hodgkin lymphoma (NHL) that usually occurs in older adults.2 The disease typically begins in the lymph nodes, but can spread to other tissues, such as bone marrow, liver, and spleen3. Patients typically survive an average of five years.4 In the U.S., there are approximately 2,500 new cases of MCL each year and a prevalence of approximately 10,000 (Decision Resources 2012).

About Ibrutinib

Ibrutinib is an investigational agent designed to provide potent and sustained inhibition of an enzyme called Bruton's tyrosine kinase (BTK). BTK is a key mediator of at least three critical B-cell pro-survival mechanisms occurring in parallel — regulation of apoptosis, adhesion, and cell migration and homing. Through these multiple signals, BTK regulation helps to direct malignant B-cells to lymphoid tissues, thus allowing access to a micro-environment necessary for survival.

The effectiveness of ibrutinib alone or in combination with other treatments is being studied in several B-cell malignancies, including chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, Waldenstrom's macroglobulinemia and multiple myeloma. To date, 7 Phase III trials have been initiated with ibrutinib and a total of 31 trials are currently registered on www.clinicaltrials.gov. Janssen and Pharmacyclics entered a collaboration and license agreement in December 2011 to co-develop and co-commercialize ibrutinib.

About Pharmacyclics

Pharmacyclics® is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune mediated diseases. Our mission and goal is to build a viable biopharmaceutical company that designs, develops and commercializes novel therapies intended to improve quality of life, increase duration of life and resolve serious unmet medical healthcare needs; and to identify promising product candidates based on scientific development and administrational expertise, develop our products in a rapid, cost-efficient manner and pursue commercialization and/or development partners when and where appropriate.

Presently, Pharmacyclics has three product candidates in clinical development and several preclinical molecules in lead optimization. The company is committed to high standards of ethics, scientific rigor, and operational efficiency as it moves each of these programs to viable commercialization.

Pharmacyclics is headquartered in Sunnyvale, California and is listed on NASDAQ under the symbol PCYC. To learn more about how Pharmacyclics advances science to improve human healthcare visit us at http://www.pharmacyclics.com.

NOTE: This announcement may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements, among others, relating to our future capital requirements, including our expected liquidity position and timing of the receipt of certain milestone payments, and the sufficiency of our current assets to meet these requirements, our future results of operations, our expectations for and timing of ongoing or future clinical trials and regulatory approvals for any of our product candidates, and our plans, objectives, expectations and intentions. Because these statements apply to future events, they are subject to risks and uncertainties. When used in this announcement, the words "anticipate", "believe", "estimate", "expect", "expectation", "goal", "should", "would", "project", "plan", "predict", "intend", "target" and similar expressions are intended to identify such forward-looking statements. These forward-looking statements are based on information currently available to us and are subject to a number of risks, uncertainties and other factors that could cause our actual results, performance, expected liquidity or achievements to differ materially from those projected in, or implied by, these forward-looking statements. Factors that may cause such a difference include, without limitation, our need for substantial additional financing and the availability and terms of any such financing, the safety and/or efficacy results of clinical trials of our product candidates, our failure to obtain regulatory approvals or comply with ongoing governmental regulation, our ability to commercialize, manufacture and achieve market acceptance of any of our product candidates, for which we rely heavily

on collaboration with third parties, and our ability to protect and enforce our intellectual property rights and to operate without infringing upon the proprietary rights of third parties. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance or achievements and no assurance can be given that the actual results will be consistent with these forward-looking statements. For more information about the risks and uncertainties that may affect our results, please see the Risk Factors section of our filings with the Securities and Exchange Commission, including our transition report on Form 10-K for the six month period ended December 31, 2012 and quarterly reports on Form 10-Q. We do not intend to update any of the forward-looking statements after the date of this announcement to conform these statements to actual results, to changes in management's expectations or otherwise, except as may be required by law.

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20 August 2012

Pharmacyclics, Inc. (PCYC) Gets $50 Million Milestone Payment From Johnson & Johnson (JNJ)

8/20/2012 7:51:11 AM

SUNNYVALE, Calif., Aug. 20, 2012 /PRNewswire/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) announced today that the clinical trial, SPARK (MCL2001), of ibrutinib in patients with relapsed or refractory mantle cell lymphoma (MCL) has enrolled its fifth patient. The enrollment of the fifth patient has subsequently triggered a second $50 million milestone payment obligation from Janssen Biotech, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, worldwide collaborator on ibrutinib in oncology and sponsor of this MCL trial. As Pharmacyclics or Janssen initiate specific clinical trials and enroll the 5th patient, additional milestone payments of $50 million may be triggered up to a total of $250 million.

"We formed this partnership with Janssen, with the intention to broadly expand and propel the clinical development of ibrutinib. The speed at which we have moved into important clinical trials in CLL and now MCL is a validation of this joint venture's ability to convert plans into actualities," said Bob Duggan, Chairman and CEO of Pharmacyclics. "We are satisfied with the early progress this partnership is generating and we look forward to providing a material update in December, during the American Society of Hematology Meeting."

SPARKTrial Design (MCL2001)

The SPARKstudy is a single-arm, multi-center Phase II trial of ibrutinib in MCL patients who received at least one prior rituximab-containing chemotherapy regimen and who progressed after bortezomib therapy. The primary endpoint of the study is overall response rate. The key secondary endpoints include overall survival rate, progression-free survival rate, and pharmacokinetic data of ibrutinib. This global study conducted by Janssen is planned to enroll 110 patients worldwide.

Further information about this trial can be found at www.clinitrials.gov:

NCT01599949 "A Study to Evaluate the Efficacy and Safety of Ibrutinib, in Patients With Mantle Cell Lymphoma Who Progress After Bortezomib Therapy"

About Janssen Collaboration

As previously announced on December 8, 2011, Pharmacyclics entered into a worldwide collaboration with Janssen to develop and commercialize ibrutinib, a novel, oral, first-in-class Bruton's Tyrosine Kinase (BTK) inhibitor. Pharmacyclics received from Janssen an upfront payment totaling $150 million upon signing the contract. With the dosing of a fifth patient in the SPARK Study, as announced today, a milestone payment of $50 million has been earned. Pharmacyclics may receive up to an additional $725 million in development and regulatory milestone payments; for total potential upfront and milestone payments of $975 million.

Following regulatory approval, both Pharmacyclics and Janssen will book revenue and co-commercialize ibrutinib. In the US, Pharmacyclics will book sales and take the lead role in US commercial strategy development. Both Pharmacyclics and Janssen will share in commercialization activities. Outside the United States, Janssen will book sales and lead and perform commercialization activities. Profits and losses from the commercialization activities will be split 50/50 on a worldwide basis. Development and commercialization activities under the collaboration will be managed through a shared governance structure. Each company will lead development for specific indications as stipulated in a global development plan, with development costs shared on a 40/60 basis (Pharmacyclics 40% and Janssen 60%).

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8 December 2011

Pharmacyclics, Inc. (PCYC) Could Get $975 Million in Johnson & Johnson (JNJ) License Deal

HORSHAM, Pa., Dec. 8, 2011 /PRNewswire-FirstCall/ -- Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (NYSE: JNJ), announced today that it has executed an agreement with Pharmacyclics, Inc. (Nasdaq: PCYC) to jointly develop and market the anti-cancer compound, PCI-32765. A number of Phase 1 and 2 studies with PCI-32765 are ongoing across a panel of B-cell malignancy disorders, including chronic lymphocytic leukemia, mantle cell lymphoma, and diffuse large B-cell lymphoma. Interim data were reported at the 2011 American Society of Clinical Oncology Annual Meeting and oral presentations on two separate Phase 2 studies will be presented at the upcoming American Society of Hematology Meeting in December, along with several other poster presentations.

"The agreement with Pharmacyclics is an opportunity to bring a new form of oral therapy to patients with B-cell malignancies," said William N. Hait, M.D., Ph.D., Global Therapeutic Head, Oncology, for Janssen. "PCI-32765 is an innovative compound, with broad applicability and the potential to help a large number of patients with B-cell malignancies."

According to the terms of the agreement, the companies have entered into a worldwide 50/50 profit-loss agreement, sharing development and commercialization activities. Janssen has made an upfront payment of $150 million which will be recorded in the fourth quarter, and will make additional payments based upon the achievement of certain development and regulatory milestones. This transaction is expected to have a dilutive impact to Johnson & Johnson's 2011 earnings per share of approximately $0.04 - $0.05.

About PCI-32765

PCI-32765 is an orally active, small molecule inhibitor of Bruton's tyrosine kinase (Btk), an essential element of the B-cell antigen receptor (BCR) signaling pathway. BCR signaling is a critical pathway required for tumor expansion and proliferation, and PCI-32765 exerts its anti-tumor function by blocking BCR signaling and thereby inducing cell death.

About Janssen Pharmaceutical Companies of Johnson & Johnson

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g., multiple myeloma and prostate cancer), immunology (e.g., psoriasis), neuroscience (e.g., schizophrenia, dementia and pain), infectious disease (e.g., HIV/AIDS, Hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g., diabetes).

Filing Data

Not available.

Contract

Not available.