Current Agreements

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Development, licensing and marketing agreement for early stem cell therapy for patients following myocardial infarction

BioCardia
CellProThera

Oct 30 2018

Development, licensing and marketing agreement for early stem cell therapy for patients following myocardial infarction

Companies:	BioCardia CellProThera
Announcement date:	Oct 30 2018
Amendment date:	Feb 01 2023
Deal value, US$m:	n/d

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Details

Announcement date:	Oct 30 2018
Amendment date:	Feb 01 2023
Industry sectors:	Biotech Drug delivery Services
Asset type:	Technology
Therapy areas:	Cardiovascular Cardiovascular » Myocardial Infarction
Technology types:	Clinical testing Drug delivery Regenerative medicine » Stem cells
Deal components:	Development Licensing Marketing
Stages of development:	Phase III Regulatory
Geographic focus:	Asia » Singapore

Financials

Deal value, US$m:	n/d

Termsheet

Cellprothera and BioCardia announced an agreement to expand their current collaboration to the SIngXpand Clinical Trial in Singapore.

The study will evaluate the safety and efficacy of in vitro expanded peripheral blood CD34+ stem cells output by the StemXpand Automated Process and delivered via BioCardia's Helix Biotherapeutic Delivery System for the treatment of patients soon after a heart attack.

Under the terms of the agreement, CellProThera will fund completion of all regulatory and clinical activities undertaken by both firms for the clinical investigation.

If the study results in regulatory approval of the product, CellProThera will have exclusive commercial rights in Singapore to the Helix Biotherapeutic Delivery System for the delivery of culture expanded CD34+ cells to treat patients who have suffered a recent heart attack.

BioCardia will receive double-digit royalty payments on future sales of the combination product.

Press Release

February 2023

BioCardia and Cellprothera announced an amendment to their Clinical Research Supply and Support Agreement.

The amendment extends the long-term partnership between both organizations.

The agreement relates to CellProthera's use of BioCardia's Helix transendocardial biotherapeutic delivery system for its ongoing Phase I/IIb EXCELLENT study of its lead product candidate ProtheraCytes.

CellProthera and BioCardia have extended the agreement to complete the ongoing Phase I/IIb EXCELLENT study.

The agreement incorporates the intention for both organizations to work together regarding CellProthera's next clinical study, potential early access commercialization, which could begin in 2024, and future full commercialization programs.

CellProthera is not required to partner with BioCardia therapeutic delivery devices for its commercial or subsequent clinical efforts.

However should it not, BioCardia would receive low single digit royalty on net sales of CellProthera's transendocardially delivered ProtheraCytes for its contributions to CellProthera's development efforts.

October 2018

BioCardia and CellProThera Partner for Clinical Trial and Marketing in Singapore of Early Stem Cell Therapy for Patients Following Myocardial Infarction

SAN CARLOS, Calif. & MULHOUSE, France--(BUSINESS WIRE)-- Cellprothera® and BioCardia® [OTC: BCDA] today announced an agreement to expand their current collaboration to the SIngXpand Clinical Trial in Singapore. The study will evaluate the safety and efficacy of in vitro expanded peripheral blood CD34+ stem cells output by the StemXpand® Automated Process and delivered via BioCardia's Helix™ Biotherapeutic Delivery System for the treatment of patients soon after a heart attack. Under the terms of the agreement, CellProThera will fund completion of all regulatory and clinical activities undertaken by both firms for the clinical investigation. If the study results in regulatory approval of the product, CellProThera will have exclusive commercial rights in Singapore to the Helix Biotherapeutic Delivery System for the delivery of culture expanded CD34+ cells to treat patients who have suffered a recent heart attack. BioCardia will receive double-digit royalty payments on future sales of the combination product.

Published data has shown that delivery of stem cell therapy to the heart using the Helix system resulted in superior cell retention and fewer treatment emergent major adverse cardiac events than either percutaneous intra-coronary infusion or direct injection using a straight needle.1,2 In addition, peer reviewed literature on clinical trials of CD34+ cells have noted minimal adverse events, with potential benefit in the treatment of cardiac conditions. The published results of the pilot study conducted by CellProThera have shown meaningful improvement in cardiac functions after injection of CD34+ stem cells into the myocardium following heart attack.3,4

About CellProThera®

CellProThera, headquartered in Mulhouse, France, is developing a cell therapy product for the regeneration of the damaged heart shortly after a severe heart attack. CellProThera has developed a proprietary technology to expand human peripheral blood CD34+ cells and turn them into a stem cell graft ProtheraCytes®. The graft is then directly injected into the heart tissue of the patient during a minimally invasive procedure. A randomized phase I/IIb clinical trial is currently ongoing in several centres in France and in the UK. The innovative approach developed by CellProThera is viewed by experts as one of the most promising to treat AMI and potentially prevent the occurrence of chronic heart failure.

About BioCardia

BioCardia, Inc., headquartered in San Carlos, California, is developing regenerative biologic therapies to treat cardiovascular disease. CardiAMP and CardiALLO cell therapies are the Company's biotherapeutic product candidates in clinical development. The Company's current products include the Helix™ Biotherapeutic Delivery System and the Morph® steerable guide and sheath catheter portfolio. BioCardia also partners with other biotherapeutic companies to provide its Helix systems and clinical support to their programs studying therapies for the treatment of heart failure, chronic myocardial ischemia and acute myocardial infarction. CardiAMP cell therapy uses a patient's own (autologous) bone marrow cells to potentially stimulate the body's natural healing response through a minimally-invasive, catheter-based procedure.

The Helix Biotherapeutic Delivery System is known as the Helical Infusion Catheter outside of the United States.

Filing Data

Not available.

Contract

Not available.