

Dealdoc

Co-development, marketing and distribution agreement for Generx

Angionetics Taxus Cardium Pharmaceuticals Dr. Reddy's Laboratories

Apr 07 2015

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Angionetics

Companies: <u>Taxus Cardium Pharmaceuticals</u>

Dr. Reddy's Laboratories

Announcement date: Apr 07 2015

Deal value, US\$m: n/d

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Details

Announcement date: Apr 07 2015
Industry sectors: Pharmaceutical
Brand name: Generx
Exclusivity: Exclusive

Exclusivity: Exclusive Asset type: Compound

Therapy areas:

Cardiovascular » Angina

Cardiovascular » Myocardial Infarction

Technology types: Gene therapy

Co-development Distribution

Deal components: Distributio

Marketing

viarketing

Stages of development: Phase III

Asia

Geographic focus:

Asia » Myanmar
Asia » Vietnam
Europe » Russia
South America

South America » Venezuela

Financials

Deal value, US\$m: n/d

Termsheet

Taxus Cardium Pharmaceuticals has entered into a binding term sheet with Dr. Reddy's Laboratories for an exclusive territorial license covering the co-development, marketing and sales of the Generx [Ad5FGF-4] angiogenic microvascular gene therapy Phase 3 product candidate for patients with refractory angina, and myocardial ischemia due to cardiac microvascular insufficiency (CMI).

The agreement initially covers certain territories and international markets, including Russia, the Commonwealth of Independent States (CIS), Venezuela, Vietnam and Myanmar, and provides the right of first refusal for Dr. Reddy's Laboratories to negotiate additional exclusive license agreements to market and sell the Generx gene therapy product candidate in over 30 other countries in Latin America and the Association of Southeast Asian Nations.

Dr. Reddy's Laboratories will assist with local country patient recruitment and relationship building with key opinion leaders to accelerate the Angionetics' international Phase 3 ASPIRE clinical study.

Positive safety and efficacy findings from the ASPIRE study were announced at the Annual 2014 Biotechnology Industry Organization Conference following completion of a protocol-specified interim data analysis.

In addition, Dr. Reddy's Laboratories will assist with product registrations and regulatory compliance with local country health authorities.

The agreement provides economic support that will be used to advance the international Phase 3 clinical study, a cost sharing arrangement for a planned Phase 4 post-marketing clinical study (intended to expand product labeling), and volume-based royalties on net sales. Dr. Reddy's Laboratories' Russian-based business unit markets and sells prescription products through its team of medical representatives and managers who promote the products to physicians across Russia.

Additionally, Dr. Reddy's Laboratories also has a separate Hospital division and an OTC division.

Press Release

Taxus Cardium (CRXM) Announces Agreement With Dr. Reddy's Laboratories Ltd. (RDY) To Co-Develop, Market & Sell Generx Angiogenic Microvascular Gene Therapy In Certain International Markets

SAN DIEGO, April 7, 2015 /PRNewswire/ -- Taxus Cardium Pharmaceuticals Group Inc. (trading symbol: CRXM) today announced that it has entered into a binding term sheet with Dr. Reddy's Laboratories Ltd. (NYSE: RDY) for an exclusive territorial license covering the co-development, marketing and sales of the Generx® [Ad5FGF-4] angiogenic microvascular gene therapy Phase 3 product candidate for patients with refractory angina, and myocardial ischemia due to cardiac microvascular insufficiency (CMI).

Logo. The agreement initially covers certain territories and international markets, including Russia, the Commonwealth of Independent States (CIS), Venezuela, Vietnam and Myanmar, and provides the right of first refusal for Dr. Reddy's Laboratories to negotiate additional exclusive license agreements to market and sell the Generx gene therapy product candidate in over 30 other countries in Latin America and the Association of Southeast Asian Nations.

Angionetics Inc., a wholly-owned operating unit of Taxus Cardium, is now responsible for the worldwide commercialization of the Generx gene therapy product candidate. Angionetics retains the full Generx commercialization rights for North America, Europe, Japan, China, the Middle East, and Africa. It is planned that Angionetics will advance forward as a company independent from Taxus Cardium and seek to externally finance the Generx U.S.-based FDA-cleared AWARE Phase 3 clinical study, the international ASPIRE Phase 3 clinical development program and additional U.S.-based and international clinical studies for other potential Generx medical indications.

As an international co-development partner, Dr. Reddy's Laboratories will assist with local country patient recruitment and relationship building with key opinion leaders to accelerate the Angionetics' international Phase 3 ASPIRE clinical study. Positive safety and efficacy findings from the ASPIRE study were announced at the Annual 2014 Biotechnology Industry Organization Conference following completion of a protocol-specified interim data analysis. In addition, Dr. Reddy's Laboratories will assist with product registrations and regulatory compliance with local country health authorities. The agreement provides economic support that will be used to advance the international Phase 3 clinical study, a cost sharing arrangement for a planned Phase 4 post-marketing clinical study (intended to expand product labeling), and volume-based royalties on net sales. Dr. Reddy's Laboratories' Russian-based business unit markets and sells prescription products through its team of medical representatives and managers who promote the products to physicians across Russia. Additionally, Dr. Reddy's Laboratories also has a separate Hospital division and an OTC division.

About Dr. Reddy's Laboratories Dr. Reddy's Laboratories Ltd. (NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses, Pharmaceutical Services & Active Ingredients, Global Generics, and Proprietary Products, Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Major therapeutic areas of focus are gastro-intestinal, cardiovascular, diabetology, oncology, pain management and anti-infectives. Dr. Reddy's operates in markets across the globe. Major markets include the United States, Russia and CIS, and India. For more information, visit www.drreddys.com.

About Angionetics Inc. Angionetics, an operating unit of Taxus Cardium Pharmaceuticals Group, is a late-stage biotechnology company that is developing new and innovative gene therapy-based, cardiovascular therapeutics. Angionetics is focused on the development and commercialization of novel DNA-based therapeutics designed to promote the heart's innate natural capacity to modulate the formation and growth of cardiac microvascular circulation to enhance blood flow (perfusion) in patients with a variety of ischemia-driven disease conditions and refractory angina and myocardial ischemia due to cardiac microvascular insufficiency (CMI), and other cardiovascular disease conditions. For more information, visit www.angionetics.com.

Angionetics' lead product candidate, Generx® (alferminogene tadenovec [Ad5FGF-4]), is a first in class, single-dose, disease altering therapeutic specifically targeted to the cardiac micro-vasculature. The Generx gene therapy product candidate is designed to stimulate and augment the formation of new biologic structures that increase the coronary microvascular network, to enhance cardiac perfusion, and improve cardiac performance, as measured by exercise tolerance and the occurrence and severity of myocardial ischemia-driven angina. Current therapies for patients with refractory angina and CMI are limited to pharmacologic anti-anginal medications to relieve angina chest pain, which are dosed daily or episodically and can cause adverse side effects, and surgical and percutaneous interventions that address large vessel coronary artery disease. Angionetics' product candidates are designed to easily fit within the current practice of medicine, as single-dose

treatments, which are administered by interventional cardiologists using standard cardiac catheters, during an approximately one-hour, out-patient, angiogram-like procedure which is conducted in a hospital or medical center.

In November 2014, Taxus Cardium reported the formation of Angionetics, which is now responsible for the worldwide commercialization of the Generx gene therapy product candidate, and retains the full commercialization rights for North America, Europe, Japan, China, the Middle East, and Africa. It is planned that Angionetics will seek to externally finance the Generx clinical development program and operate as a company independent from Taxus Cardium. For more information about Taxus Cardium, visit the Company's website www.cardiumthx.com.

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Not available.

Contract

Not available.