Current Agreements

Dealdoc

Distribution and licensing agreement for Generx [Ad5FGF-4]

Huapont Pharma
Angionetics

Jul 11 2016

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Companies:	Huapont Pharma Angionetics
Announcement date:	Jul 11 2016
Deal value, US$m:	3 : sum of equity financing

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Details

Announcement date:	Jul 11 2016
Industry sectors:	Biotech Pharmaceutical
Exclusivity:	Exclusive
Asset type:	Product
Therapy areas:	Cardiovascular » Angina
Technology types:	Gene therapy
Deal components:	Distribution Licensing
Stages of development:	Phase III
Geographic focus:	North America » United States

Financials

Deal value, US$m:	3 : sum of equity financing
Equity, US$m:	1 : first tranche of investment 2 : payable upon the successful clearance from FDA

Termsheet

Angionetics announced that it has entered into an exclusive territorial distribution and license agreement with an entity affiliated with Huapont Life Sciences Co., Ltd. (through sublicense to a technology agreement with Bayer Pharma AG), for Huapont to clinically develop, to market and sell the Generx® [Ad5FGF-4] angiogenic gene therapy product candidate in Mainland China.

The initial medical indication will be for the treatment of patients with refractory angina due to ischemic heart disease.

Under the exclusive distribution and license agreement, Angionetics will be responsible for a planned U.S.-based Phase 3 clinical program, and working in cooperation with researchers at Angionetics, Huapont Life Sciences' affiliated entity will focus on the clinical development, registration, marketing and sales of the Generx product candidate in China.

Huapont's affiliated entity will assume the costs associated with the commercial development of Generx® in China, and Angionetics will be entitled to royalties on net sales, and potentially share economic consideration as a result of a monetization event.

On July 11, 2016, it was reported that an affiliated entity of Huapont had entered into a $3,000,000 private equity financing, and acquired a 15% preferred stock equity interest in Angionetics to support the advancement of Angionetics as a cardiovascular gene therapy company independent of Taxus Cardium.

The equity will be purchased in two tranches, an initial investment of $1,000,000 has been paid, and the remaining $2,000,000 is payable upon the successful clearance by the United States FDA of a Phase 3 clinical trial for Generx®.

Press Release

SAN DIEGO, July 11, 2016 /PRNewswire/ -- Angionetics Inc., a wholly-owned subsidiary of Taxus Cardium Pharmaceuticals Group Inc. (Trading Symbol: CRXM), today announced that it has entered into an exclusive territorial distribution and license agreement with an entity affiliated with Huapont Life Sciences Co., Ltd. (through sublicense to a technology agreement with Bayer Pharma AG), for Huapont to clinically develop, to market and sell the Generx® [Ad5FGF-4] angiogenic gene therapy product candidate in Mainland China. The initial medical indication will be for the treatment of patients with refractory angina due to ischemic heart disease.

Under the exclusive distribution and license agreement, Angionetics will be responsible for a planned U.S.-based Phase 3 clinical program, and working in cooperation with researchers at Angionetics, Huapont Life Sciences' affiliated entity will focus on the clinical development, registration, marketing and sales of the Generx product candidate in China. Huapont's affiliated entity will assume the costs associated with the commercial development of Generx® in China, and Angionetics will be entitled to royalties on net sales, and potentially share economic consideration as a result of a monetization event. This transaction stands in place of a previously announced Generx® license transaction with Shanxi Taxus Pharmaceuticals Co. Ltd. which was not consummated as planned.

On July 11, 2016, it was reported that an affiliated entity of Huapont had entered into a $3,000,000 private equity financing, and acquired a 15% preferred stock equity interest in Angionetics to support the advancement of Angionetics as a cardiovascular gene therapy company independent of Taxus Cardium. The equity will be purchased in two tranches, an initial investment of $1,000,000 has been paid, and the remaining $2,000,000 is payable upon the successful clearance by the United States FDA of a Phase 3 clinical trial for Generx®.

Huapont Life Sciences Huapont Life Sciences is a China-based company focused on the research and development of new and innovative healthcare products, and the manufacture, marketing and sale of leading pharmaceutical products, active pharmaceutical ingredients (known as APIs) and a portfolio of safe and effective agricultural herbicides (including NC16, NC34, NC36, NC125, NC201) serving the agricultural business throughout the US and South American markets. Huapont's pharmaceutical business includes dermatology products, cardiovascular products, anti-tuberculosis agents, autoimmune-related products and oncology-related products. Huapont Life Sciences's API business involves the production and sale of bulk pharmaceutical chemicals, pharmaceutical intermediates and preparations of Western medicines, with current annual revenues of approximately US $1.1 billion, and approximately 7,100 employees operating throughout Mainland China. Huapont is listed on the Shenzhen Stock Exchange (002004.SZ) and carries a current market capitalization of approximately US $3.0 billion. An entity affiliated with Huapont Life Sciences has entered into the equity and license agreements with Angionetics and expects to collaborate with Huapont in the development, approval process and then marketing and sale of Generx®.

Angionetics & Generx® [Ad5-FGF4] Cardiovascular Gene Therapy Angionetics is a biotechnology company, recently-formed by Taxus Cardium, that has been designed to effect an asset "value unlock" of the company's undervalued technology platforms. As Angionetics advances forward with its plan to operate as a company independent of Taxus Cardium, it will focus on the clinical and commercial development of angiogenic, gene- based bio-therapeutics for the treatment of almost 1.0 million patients in the U.S. who have late-stage coronary artery disease and refractory angina and other ischemic heart disorders and medical conditions (visit www.angionetics.com).

Following the formation of Angionetics by Taxus Cardium, the management team initiated a comprehensive review of Taxus Cardium's global Generx® regulatory and clinical dossier, and elected to primarily focus on the clinical advancement and registration of Generx® in the United States and China, which are considered to be the most dynamic medical markets in the world for new and novel breakthrough products like the Generx® product candidate.

Generx® (Ad5FGF-4) is a first in class, disease altering, one-time administered, late-stage clinical product candidate initially for the treatment of patients with myocardial ischemia and refractory angina due to coronary artery disease. Generx® has been biologically engineered to enhance blood flow (perfusion) in ischemic regions of the heart by leveraging cardiac plasticity to promote the natural formation and growth of microvascular coronary structures (collateral vessels). This is achieved by stimulating and augmenting the heart's innate natural capacity to modulate the enlargement of pre-existing collateral arterioles (arteriogenesis), and to form new capillary vessels (angiogenesis) in select ischemic regions downstream from large coronary arteries.

The angiogenic biological process driven by the Generx® product candidate is referred to as "medical revascularization," in contrast to the classic "mechanical revascularization" procedures that include coronary artery bypass surgery (CABG), and percutaneous coronary intervention (PCI) involving angioplasty and stents. Generx® therapy is initially intended to broaden and enhance the spectrum of care for patients with myocardial ischemia-driven refractory angina, who are unresponsive to optimal medical therapy, have low angiographic risk and thus, based on a large number of independent clinical studies (COURAGE, BARI 2D, STICH and PROMISE), are unlikely to receive any prophylactic benefit from early mechanical revascularization. It is estimated that approximately 900,000 Americans have refractory angina. Every year approximately 50,000 to 100,000 new patients are diagnosed with refractory angina. In addition, approximately 200,000 patients in the U.S. have Cardiac Syndrome X, a condition believed to be due to microvascular dysfunction.

Based on recent filings, the FDA Center for Biologics Evaluation and Research (CBER) has accepted and designated Angionetics Inc. as the Sponsor, and acknowledged Angionetics' U.S. activation of the Ad5FGF-4 (Generx) Investigational New Drug Application (IND) pursuant to Section 505(i) of the Federal Food, Drug and Cosmetic Act. The previously granted FDA "Fast Track" designation for the Generx® development program continues forward. In addition, Angionetics has submitted, for FDA clearance, a new U.S.-based Phase 3 clinical study protocol (the "AFFIRM" study) to evaluate the further safety and definitive efficacy of Generx® [Ad5FGF-4] for men and women with advanced ischemic heart disease and refractory angina.

Angionetics has submitted the planned Generx [Ad5FGF-4] Phase 3 AFFIRM clinical study protocol to the FDA as well as updates to all key elements of the Generx IND. The recent submission included an updated Investigator's Brochure and a summary of clinical efficacy and safety data from the four FDA cleared, U.S. and international clinical studies. The clinical data, including patient subset analyses, were used as the basis for the AFFIRM study design and target patient population. The updated long-term safety data totaled over 2,500 patient years, and represented the completed safety dataset for the prior clinical studies. A detailed review of product manufacturing procedures, testing strategies and up-to-date stability data were also provided to the FDA.

The new U.S.-focused AFFIRM clinical study protocol, as submitted to the FDA, incorporates important research innovations that include: (1) enhanced cardiac delivery procedures utilizing standard balloon catheters, supported by research showing that transient ischemia may enhance gene transfer to heart cells; and (2) a more comprehensively characterized target patient population based on Ad5FGF-4 responder data from the four FDA cleared clinical studies. The study patient population includes patients with refractory angina (no longer responsive to anti-anginal medications and not a candidate CABG or PCI), and documented clinical evidence of myocardial ischemia within the past 12 months. Patients must have clinically significant limitation of physical activity due to angina (CCS Class 3 or 4) and angina-limited baseline exercise treadmill test (ETT) duration of 3-7 min. The proposed primary efficacy endpoint will be improvement in ETT duration in Generx®-treated patients compared to a placebo control group. Secondary efficacy endpoints include change in CCS angina class, change in weekly angina frequency and nitroglycerin usage, and change in quality of life, assessed using the Seattle Angina Questionnaire (SAQ).

Our Generx® [Ad5FGF-4] bio-therapeutic product candidate has been developed over the past decade by researchers, clinicians and physicians at Angionetics and its predecessor companies, Collateral Therapeutics, Schering AG (now Bayer Healthcare) and Cardium Therapeutics. Our highly experienced management team has been responsible for advancing Ad5FGF-4 from preclinical research, into late stage clinical development based on a wide array of innovations, clinical research discoveries and commercial insights. Over $250 million has been invested by Angionetics and its predecessor companies to advance Generx® into late-stage clinical study. Collectively, our management team has over 100 years of experience in the development of gene-based cardiovascular therapeutic product candidates, and was involved in the initial discovery and early development of Ad5FGF-4 and the advancement of Ad5FGF-4 from preclinical research to Phase 3 clinical study.

Taxus Cardium Pharmaceuticals Group Taxus Cardium Pharmaceuticals Group Inc. is a holding company that operates a portfolio of equity-based and potential royalty-driven investments as follows: (1) Angionetics, currently a majority-owned business unit focused on the late-stage clinical development and commercialization of Generx®, an angiogenic gene therapy product candidate designed for medical revascularization for the potential treatment of patients with myocardial ischemia and refractory angina due to advanced coronary artery disease); (2) the Excellagen® technology platform, that has broad potential applications as a delivery platform for small molecule drugs, proteins and biologics and as an FDA-cleared flowable dermal matrix for advanced wound care, which is currently being held as an investment for future sale or internal commercialization; (3) LifeAgain, an advanced medical data analytics (ADAPT®) technology platform focused on developing new and innovative products for the life insurance and healthcare sectors; and (4) Healthy Brands Collective, a functional food and nutraceutical company which acquired Taxus Cardium's To Go Brands® business.

Filing Data

Not available.

Contract

Not available.