Current Agreements

Dealdoc

Development and licensing agreement for rHuPH20 (recombinant human hyaluronidase) in development of subcutaneous injectable formulation of recombinant human alpha 1-antitrypsin (rHuA1AT)

Halozyme Therapeutics
Intrexon

Jun 07 2011

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Companies:	Halozyme Therapeutics Intrexon
Announcement date:	Jun 07 2011
Deal value, US$m:	63.0 : sum of upfront and milestone payments

Details

Announcement date:	Jun 07 2011
Industry sectors:	Pharmaceutical Biotech Drug delivery
Therapy areas:	Genetic disorders Biological compounds
Technology types:	Drug delivery » Parenteral » Injectable Small molecules
Deal components:	Development Licensing
Stages of development:	Phase I Formulation
Geographic focus:	Worldwide

Financials

Deal value, US$m:	63.0 : sum of upfront and milestone payments
Upfront, US$m:	9.0 : upfront payment
Milestones, US$m:	54.0 : dependent upon the achievement of clinical and regulatory targets
Royalty rates, %:	11.0 : up to royalty on future sales of combination of rHuA1AT with rHuPH20

Termsheet

Worldwide exclusive licensing agreement for the use of rHuPH20 (recombinant human hyaluronidase) in the development of a subcutaneous (under the skin) injectable formulation of Intrexon Corporation's recombinant human alpha 1-antitrypsin (rHuA1AT).

Halozyme may receive up to $63 million, commencing with an upfront payment of $9 million and total potential future milestone payments of $54 million dependent upon the achievement of clinical and regulatory targets, plus up to 11% royalty on future sales of the combination of rHuA1AT with rHuPH20.

The license provides Intrexon Corporation, a next generation synthetic biology company, with exclusivity to alpha 1-antitrypsin, for the indications resulting from A1AT deficiency.

Additional terms of the transaction have not been disclosed.

Press Release

Halozyme Therapeutics, Inc. (HALO) and Intrexon Corporation Announce Collaboration to Develop First Subcutaneous Recombinant Alpha 1-Antitrypsin Replacement Therapy 6/7/2011

SAN DIEGO and FOSTER CITY, Calif., June 6, 2011 /PRNewswire via COMTEX/ -- Halozyme Therapeutics, Inc. (Nasdaq: HALO) and Intrexon Corporation, today announced the signing of a worldwide exclusive licensing agreement for the use of rHuPH20 (recombinant human hyaluronidase) in the development of a subcutaneous (under the skin) injectable formulation of Intrexon Corporation's recombinant human alpha 1-antitrypsin (rHuA1AT). Under terms of the agreement, Halozyme may receive up to $63 million, commencing with an upfront payment of $9 million and total potential future milestone payments of $54 million dependent upon the achievement of clinical and regulatory targets, plus up to 11% royalty on future sales of the combination of rHuA1AT with rHuPH20. The license provides Intrexon Corporation, a next generation synthetic biology company, with exclusivity to alpha 1-antitrypsin, for the indications resulting from A1AT deficiency. Additional terms of the transaction have not been disclosed.

Alpha 1-antitrypsin is a protease inhibitor that provides a protective effect from inflammatory cell proteases, especially neutrophil elastase. Intrexon is using its synthetic DNA platform for high-level expression of recombinant A1AT for the potential treatment of diseases resulting from genetic alpha 1-antitrypsin deficiency such as genetic emphysema. A1AT may also benefit patients with chronic obstructive pulmonary disease (COPD) and cystic fibrosis. Currently there is no A1AT recombinant protein available and, as a result, treatment for deficiency is limited and expensive. Intrexon will fund all development and commercialization expenses for the program, which is currently in the scale-up phase of process development.

"We are pleased to collaborate with Intrexon on this exciting new endeavor for patients with A1AT deficiency," stated Gregory I. Frost, Ph.D., Halozyme's president and CEO. "The combination of Intrexon's synthetic DNA platform for high-level A1AT production with Halozyme's subcutaneous enzyme technology may enable the first recombinant human A1AT replacement therapy with a more patient-friendly administration profile."

"Halozyme's Enhanze technology is the perfect fit for our recombinant human alpha 1-antitrypsin program," stated Randal J. Kirk, CEO and chairman of the board of Intrexon and board member of Halozyme. Mr. Kirk's comment is seconded by Gerardo Zapata, Ph.D., president of Intrexon's Protein Production Division. "This collaboration allows us to utilize Halozyme's proprietary protein delivery technology with a subcutaneous recombinant human version of the A1AT protein, an innovative potential therapy for genetic emphysema, COPD, and other diseases caused by A1AT deficiency, and will facilitate our ability to bring a promising novel synthetic biologic treatment alternative to the currently available plasma-derived intravenous products," stated Zapata.

About rHuPH20 Enzyme Technology

Halozyme's proprietary rHuPH20 enzyme facilitates the absorption and dispersion of drugs or fluids that are injected under the skin. When injected under the skin, rHuPH20 transiently generates channels in tissues underlying the outer layers of the skin to increase the absorption and spread of injected drugs. When combined with rHuPH20, molecules as large as 200 nanometers may pass freely through the extracellular matrix, which recovers its normal density within approximately 24 hours, leading to a drug delivery platform that does not permanently alter the architecture of the skin. Halozyme's technology platform focuses on the use of rHuPH20 to facilitate subcutaneous administration for large molecule biological therapeutics, many of which currently require intravenous administration.

About Alpha 1-Antitrypsin Deficiency

Alpha 1-antitrypsin (A1AT) is a protease inhibitor made in the liver that works to protect the lungs and the liver. Deficient production of this protein is caused by a genetic defect and it can lead to chronic lung diseases such as emphysema, and liver disease. Many people with the deficiency are undiagnosed. Symptoms of A1AT deficiency include shortness of breath with and without exertion, additional symptoms of chronic obstructive pulmonary disease, and severe liver disease or cirrhosis, and it can be diagnosed with a chest x-ray, blood tests, genetic testing and lung function tests. Treatment involves replacement of the missing A1AT protein administered intravenously (IV or through a vein) once weekly for most patients and it is considered ongoing and lifelong therapy. Several intravenous A1AT products have received FDA approval in the U.S. Currently the A1AT protein is gathered and processed from plasma collected from healthy human donors. For additional information about A1AT deficiency please visit the Alpha-1 Foundation Web site.

About Halozyme

Halozyme Therapeutics is a biopharmaceutical company developing and commercializing products targeting the extracellular matrix for the insulin, cancer, dermatology and drug delivery markets. The company's product portfolio is based primarily on intellectual property covering the family of human enzymes known as hyaluronidases and additional enzymes that affect the extracellular matrix. Halozyme's Enhanze(TM) technology is a novel drug delivery platform designed to increase the absorption and dispersion of biologics. The company has key partnerships with Roche, Baxter, ViroPharma and Intrexon to apply Enhanze technology to therapeutic biologics including Herceptin®, MabThera®, immunoglobulin, Cinryze® and alpha 1-antitrypsin. Halozyme's Ultrafast Insulin program combines its rHuPH20 enzyme with mealtime insulins, which may produce more rapid absorption, faster action, and improved glycemic control. The product candidates in Halozyme's pipeline target multiple areas of significant unmet medical need. For more information visit www.halozyme.com.

About Intrexon Corporation

Intrexon Corporation is a privately held synthetic biology company that employs modular DNA control systems to enhance capabilities, improve safety and lower cost in human therapeutics, protein production, industrial products, animal sciences and agricultural biotechnology. The company's advanced transgene engineering platform enables Better DNA(TM) by combining breakthroughs in DNA control systems with corresponding advancements in modular transgene design, assembly and optimization. The company is currently using these advanced capabilities to undertake foremost challenges across the spectrum for biological applications. More information about Intrexon is available at www.DNA.com.

Filing Data

Not available.

Contract

Not available.