Current Agreements

Dealdoc

Development, licensing and co-marketing agreement for GBR 500

Glenmark Pharmaceuticals
Sanofi

May 16 2011

Development, licensing and co-marketing agreement for GBR 500

Companies:	Glenmark Pharmaceuticals Sanofi
Announcement date:	May 16 2011
Deal value, US$m:	613.0 : sum of upfront and milestone payments

Details

Announcement date:	May 16 2011
Termination date:	Oct 30 2015
Industry sectors:	Bigpharma Biotech Pharmaceutical
Compound name:	Vatelizumab
Asset type:	Compound
Therapy areas:	Central Nervous System » Multiple sclerosis Gastrointestinal » Inflammatory bowel disease » Crohn's disease
Technology types:	Antibodies » Monoclonal antibodies » Humanized mAb Biological compounds
Deal components:	Co-market Co-promotion Development Licensing Marketing Termination
Stages of development:	Phase I
Geographic focus:	Asia » Japan Europe Europe » Russia North America Oceania » Australia Oceania » New Zealand South America » Argentina South America » Brazil South America » Chile South America » Uruguay
Excluded geography:	Asia » India

Financials

Deal value, US$m:	613.0 : sum of upfront and milestone payments
Upfront, US$m:	25.0 : upfront payment upon closing of the transaction 25.0 : contingent upon Sanofi’s positive assessment of certain data to be provided by Glenmark
Milestones, US$m:	563.0 : success■based development, regulatory and commercial milestone payments

Royalty rates, %:	n/d : tiered double■digit royalties on sales

Termsheet

October 2015

Sanofi has backed away from a multiple sclerosis treatment developed alongside Indian drugmaker Glenmark Pharmaceuticals after the antibody came up short in a midstage trial.

May 2011

Agreement to grant Sanofi a license for the development and commercialization of GBR 500, a novel monoclonal antibody for the treatment of Crohn’s Disease and other inflammatory conditions.

Glenmark will receive an upfront payment of US$ 50 million, of which US$ 25 million will be paid upon closing of the transaction and US$ 25 million, which is contingent upon Sanofi’s positive assessment of certain data to be provided by Glenmark.

Glenmark could receive potential success■based development, regulatory and commercial milestone payments.

The total of these payments could reach US$613 Mn.

Glenmark is eligible to receive tiered double■digit royalties on sales of products commercialized under the license.

Sanofi will have exclusive marketing rights for North America, Europe, Japan, Argentina, Chile and Uruguay.

Sanofi and Glenmark will comarket in Russia, Brazil, Australia and New Zealand, and Glenmark will retain exclusive marketing rights in India and other countries in the rest of the world.

Press Release

October 2015

Sanofi dumps a $663M MS deal with India's Glenmark

Sanofi ($SNY) has backed away from a multiple sclerosis treatment developed alongside Indian drugmaker Glenmark Pharmaceuticals after the antibody came up short in a midstage trial.

The therapy, vatelizumab, is designed to beat back the inflammation at the heart of MS by targeting white blood cells. Sanofi partnered up on the drug in 2011 in a deal worth up to $663 million, paying Glenmark $50 million up front.

The antibody was rolling through Phase II study in relapsing-remitting MS before coming upon a preplanned interim analysis. Looking at the data, Sanofi concluded vatelizumab had little chance of meeting its primary endpoint and has now decided not to move forward with the treatment.

In a statement to LiveMint, Glenmark said Sanofi's decision was not tied to any safety concerns related to vatelizumab and that the company is now looking for a new partner to push the treatment forward.

The loss of vatelizumab is a blow to Sanofi's MS operation, leaving only the Phase I GZ402668 in the pipeline. The company markets the intravenous Lemtrada and oral Aubagio, treatments that grew 120% last quarter to bring in about $293 million.

But the MS market is quickly evolving as more agents win approval. Sanofi, through its Genzyme unit, is already contending with therapies from Biogen ($BIIB) and Novartis ($NVS), and Roche ($RHHBY) is moving toward FDA approval with a new injected therapy analysts say could cut into each player's market share.

June 2011

Glenmark Pharmaceuticals Receives $25 Million from Sanofi (France) (SASY.PA) as Upfront Payment

NEW DELHI: Glenmark Pharma today said its USD 613 million (over Rs 2,745 crore) outlicensing deal with Sanofi has been approved by the US authorities and has also received an upfront payment of USD 25 million (over Rs 110 crore) from the French drug-maker.

Last month Glenmark Pharmaceuticals SA, a wholly-owned subsidiary of Glenmark Pharmaceuticals, had outlicensed its novel monoclonal antibody ' GBR 500' aimed at treating digestive system disorders, to French drug-maker Sanofi for as much as USD 613 million.

"The GBR 500 deal signed by Glenmark in May 2011 with Sanofi has received clearance from the Hart-Scott-Rodino Antitrust Improvements Act, US," Glenmark said in a filing to the Bombay Stock Exchange (BSE).

Following that clearance, the deal has now become effective and Glenmark has also received the first upfront payment of USD 25 million, it added.

The Hart-Scott-Rodino Act provides the Federal Trade Commission and the Department of Justice with information about large mergers and acquisitions before they occur.

As per the deal, the Mumbai-based firm would receive an upfront payment of USD 50 million from Sanofi.

In addition, Glenmark could receive potential success- based development, regulatory and commercial payments at different intervals, the company had said earlier.

GBR 500 is currently undergoing early-stage human trials as a treatment for Crohn's disease (a form of inflammatory bowel disease), but is considered to have potential for treatment of other inflammatory conditions, such as multiple sclerosis and ulcerative colitis.

As per the deal, Sanofi will have exclusive marketing rights for products developed using GBR 500 in North America, Europe, Japan, Argentina, Chile and Uruguay, while it will co -market the products with Glenmark in Russia, Brazil, Australia and New Zealand.

Glenmark will retain exclusive marketing rights in India and other countries in the rest of the world.

The company has six different molecules under different stages of development, including GBR 401, GBR 600, GBR 900.

Glenmark had acquired GBR 500 and GBR 600 from a Canadian pharmaceutical company at the early stages of its development, he said.

Shares of Glenmark were today trading at Rs 317.05 on BSE in late afternoon trade, up 1.47 per cent from its previous close.

---

16 May 2011

Glenmark Pharmaceuticals Out-Licenses Novel Monoclonal Antibody, GBR 500, to Sanofi

Sanofi to develop the molecule for Crohn’s Disease and other antiinflammatory conditions such as Multiple Sclerosis

Combined upfront and potential development, regulatory and commercial milestone payments could total US$613 Mn

Mumbai, India, May 16, 2011 – Glenmark Pharmaceuticals S.A (GPSA), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), announced today that it has entered into an agreement with Sanofi to grant Sanofi a license for the development and commercialization of GBR 500, a novel monoclonal antibody for the treatment of Crohn’s Disease and other inflammatory conditions. The transaction is expected to close in the coming month subject to customary closing conditions, including the expiration or early termination of the waiting period under the Hart■Scott■Rodino Antitrust Improvements Act.

Under the terms of the agreement, Glenmark will receive an upfront payment of US$ 50 million, of which US$ 25 million will be paid upon closing of the transaction and US$ 25 million, which is contingent upon Sanofi’s positive assessment of certain data to be provided by Glenmark. In addition, Glenmark could receive potential success■based development, regulatory and commercial milestone payments. The total of these payments could reach US$613 Mn. In addition, Glenmark is eligible to receive tiered double■digit royalties on sales of products commercialized under the license. Sanofi will have exclusive marketing rights for North America, Europe, Japan, Argentina, Chile and Uruguay. Sanofi and Glenmark will comarket in Russia, Brazil, Australia and New Zealand, and Glenmark will retain exclusive marketing rights in India and other countries in the rest of the world.

GBR 500 is an antagonist of the VLA■2 (alpha2■beta1) integrin. It is a first■in■class therapeutic monoclonal antibody and has established proof of concept in animal models across a range of anti■inflammatory conditions. Glenmark has completed Phase I dosing of GBR 500 in the US and the drug has been well tolerated with a good pharmacokinetic profile. Plans are in place to initiate clinical proof of concept studies in Crohn’s Disease. Sanofi has licensed the rights to all therapeutic indications.

“There continues to be a strong medical need for safer and more efficacious products for the treatment of Inflammatory Diseases,” said Elias Zerhouni, M.D., President, Global Research & Development, Sanofi. “GBR500 brings an innovative approach to Sanofi’s Immuno■Inflammation portfolio, which we believe may address a significant gap in treating Inflammatory Diseases which would be of huge benefit to patients”.

According to Glenn Saldanha MD and CEO of GPL, “This collaboration on a novel first■inclass monoclonal antibody validates Glenmark’s world■class innovative R&D capabilities in the drug discovery arena. We are pleased to have this second licensing collaboration with Sanofi, one of the largest pharmaceutical companies in the world and the first one from Glenmark in the field of novel biologics”.

Dr. Michael Buschle, President Biologics for Glenmark commented, “The focus for the Switzerland biologics R&D centre has been to discover and develop exciting novel monoclonal antibodies for the potential treatment of inflammatory and oncology conditions. This deal is a testimony to

the strong biologics platform that Glenmark has established in a relatively short frame of time.”

About Glenmark

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is a leading player in the discovery of new molecules, both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has eight molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis, IBD, etc.] and Pain [neuropathic pain and inflammatory pain].

The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has twelve manufacturing facilities in four countries and has five R&D centres.

About Sanofi

Sanofi, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi is listed in Paris and in New York.

Filing Data

Not available.

Contract

Not available.