NEWS RELEASE

Merck and Samsung Bioepis Announce Pivotal Phase 3 Studies for Investigational Biosimilars SB4, Enbrel (Etanercept), and SB2, Remicade (Infliximab), Met Primary Endpoints

6/10/2015

Data Presented for the First Time at the EULAR Annual Meeting

Phase 1 Data for SB2, SB4 and SB5, an Investigational Biosimilar of Humira (Adalimumab), also Presented

Merck (NYSE:MRK), known as MSD outside the United States and Canada, and Samsung Bioepis Co., Ltd. today announced that pivotal Phase 3 clinical studies of SB4, an investigational biosimilar of Enbrel (etanercept), and SB2, an investigational biosimilar of Remicade (infliximab), met their primary endpoints, demonstrating equivalence to the originator medicine in patients with moderate to severe rheumatoid arthritis (RA) despite methotrexate therapy. The primary endpoint in the two studies was the American College of Rheumatology 20 percent response criteria (ACR20), at week 24 and at week 30 of treatment, respectively. In these studies, SB4 and SB2 demonstrated a safety profile equivalent to the originator medicines.

These results will be presented for the first time at the European League Against Rheumatism (EULAR) 16th annual meeting in Rome, June 10-13.

“We are excited by the positive results from these two pivotal, head-to-head equivalence studies, which are part of the robust data packages intended to support global regulatory filings for SB4 and SB2,” said Christopher Hansung Ko, CEO of Samsung Bioepis. “As part of our collaboration with Merck, we currently have five biosimilar candidates, including SB5, an adalimumab biosimilar, in our late-stage development pipeline.”

“Our collaboration with Samsung Bioepis to develop and commercialize multiple biosimilar candidates in our partnered markets is making significant progress, with five late-stage biosimilar candidates expected to be filed with regulatory authorities around the world within the next two years,” said Dora Bibila, associate vice president, and general manager, Merck Biosimilars Business. “We are excited by the opportunity to leverage the extensive capabilities of our two companies in the emerging biosimilars marketplace to help meet the growing needs of patients and healthcare systems worldwide.”

SB4 and SB2 Phase 3 data presented at EULAR

Samsung Bioepis conducted two randomized, double-blind, parallel group, multicenter studies evaluating the efficacy, safety, pharmacokinetics and immunogenicity of SB4 biosimilar etanercept and SB2 biosimilar infliximab compared to originator Enbrel and Remicade, respectively, in adult patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. Enbrel and Remicade are TNF inhibitors approved in the U.S. and many other countries for the treatment of rheumatoid arthritis and certain other indications.

In the SB4 biosimilar etanercept study, 596 patients were randomized at 70 sites in 10 countries. In this study, SB4 was shown to be equivalent to Enbrel in terms of ACR20 response rate at week 24 of treatment in the per-protocol set: 78.1 percent (193/247) in the SB4 arm vs. 80.3 percent (188/234) in the Enbrel arm. The adjusted rate difference was −2.22 percent (95 percent confidence interval, −9.41 percent to 4.98 percent), which was within the pre-defined margin (−15 percent, 15 percent).

In the SB2 biosimilar infliximab study, 584 patients were randomized at 73 sites in 11 countries. In this study, SB2 was shown to be equivalent to Remicade in terms of ACR20 response rate at week 30 of treatment in the per-protocol set: 64.1 percent (148/231) in the SB2 arm vs. 66.0 percent (163/247) in the Remicade arm. The adjusted rate difference was −1.88 percent (95 percent confidence interval, −10.26 percent to 6.51 percent), which was within the pre-defined margin (−15 percent, 15 percent).

SB4, SB2 and SB5 Phase 1 data presented at EULAR

Samsung Bioepis presented results of these three randomized, single-blind, three-arm, parallel group Phase 1 studies of SB4, SB2 and SB5 demonstrating the pharmacokinetic (PK) equivalence of each biosimilar candidate to its respective originator product sourced in the U.S. and in the EU. Each of these studies also demonstrated the PK equivalence of the U.S. and EU sourced originator products. An equivalent safety profile to the originator product was demonstrated for each of the three biosimilar products in each of the three studies.

About the EULAR data presentations

A Phase III, Randomised, Double-blind Clinical Study Comparing SB4, an Etanercept Biosimilar, with Etanercept Reference Product (Enbrel) in Patients with Moderate to Severe Rheumatoid Arthritis despite Methotrexate Therapy (FRI0128); 12 p.m. CET, Friday, June 12, Hall 6

A Randomised, Double-blind, Phase III Study Comparing SB2, An Infliximab Biosimilar, To The Infliximab Reference Product (Remicade) In Patients With Moderate To Severe Rheumatoid Arthritis Despite Methotrexate Therapy (SAT0152); 10:15 a.m. CET, Saturday, June 13, Hall 6

A Phase I Pharmacokinetic Study Comparing SB4, an Etanercept Biosimilar, and Etanercept Reference Product (Enbrel) In Healthy Male Subjects (SAT0176); 10:15 a.m. CET, Saturday, June 13, Hall 6

A Phase I Pharmacokinetic Study Comparing SB2, an Infliximab Biosimilar, and Infliximab Reference Product (Remicade) In Healthy Subjects (SAT0144); 10:15 a.m. CET, Saturday, June 13, Hall 6

A Phase I Pharmacokinetic Study Comparing SB5, An Adalimumab Biosimilar, and Adalimumab Reference Product (Humira) in Healthy Subjects (FRI0110); 12 p.m. CET, Friday, June 12, Hall 6

About the Merck and Samsung Bioepis collaboration

Merck and Samsung Bioepis announced in February 2013 a collaboration to develop and commercialize in certain partnered territories multiple biosimilar candidates. In February 2014, the two companies expanded the collaboration to include MK-1293, an insulin glargine biosimilar candidate currently in Phase 3 clinical development for the treatment of patients with type 1 and type 2 diabetes. Under terms of the agreement, Samsung Bioepis is responsible for preclinical and clinical development, process development and manufacturing, clinical trials and regulatory registration, except for MK-1293, which Merck will continue to develop and manufacture. Merck will be responsible in its partnered territories for commercialization of all approved products resulting from the collaboration.

The portfolio includes biosimilar candidates in immunology, oncology and diabetes. There are five candidates in Phase 3 development [Merck partnered territories]:

- SB4 Enbrel (etanercept) [worldwide ex-U.S./EU/Japan]
- SB2 Remicade (infliximab) [worldwide ex-EU/Russia/Turkey]
- SB5 Humira (adalimumab) [worldwide ex-EU/Russia/Turkey]
- SB3 Herceptin (trastuzumab) [worldwide]
- MK-1293 Lantus (insulin glargine) [worldwide]

Each of these five biosimilar candidates is expected to be filed with regulatory authorities around the world between 2015 and 2016.

About Samsung Bioepis

The company was established in 2012 as part of the Samsung group, with the mission to produce affordable, high-quality biopharmaceutical products for many patients in need. The company aims to be the world leading biopharmaceutical company with its heritage of innovation and advanced technologies. Please visit **www.samsungbioepis.com** for more information.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook** and **YouTube**.

Merck Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2014 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

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