



NEWS RELEASE

Merck Announces FDA Accepts Samsung Bioepis' Biologics License Application (BLA) for SB2 (Infliximab), an Investigational Biosimilar of Remicade

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First BLA Filed by Samsung Bioepis as Part of Its Partnership with Merck

KENILWORTH, N.J. – Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) submitted by Samsung Bioepis Co., Ltd. for SB2 (infliximab), an investigational biosimilar candidate of Remicade.

This BLA is the first application filed in the United States by Samsung Bioepis as part of its partnership with Merck to offer biosimilar alternatives to existing biologic medicines. The application seeks approval for use in all therapeutic indications currently approved for Remicade for which marketing exclusivity has expired.

“The acceptance of this biosimilar application by the U.S. FDA is an exciting milestone in the progression of our collaboration with Samsung Bioepis,” said Dora Bibila, general manager, Merck Biosimilars. “If approved, SB2 would offer an important therapeutic option to help meet the needs of U.S. physicians, patients and the healthcare system in the treatment of certain serious inflammatory diseases.”

About the Merck and Samsung Bioepis collaboration

Merck and Samsung Bioepis announced in February 2013 a development and commercialization agreement under which Merck will commercialize multiple biosimilar candidates in certain partnered territories. Under terms of the agreement, Samsung Bioepis is responsible for preclinical and clinical development, process development and



manufacturing, clinical trials and regulatory registration. Merck has full responsibility for commercialization of approved products resulting from the agreement.

About Merck

For 125 years, Merck has been a global health care 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 health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#), [YouTube](#) and [LinkedIn](#).

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’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 health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’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 the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company 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 the company’s 2015 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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