

Jan7Merck Announces U.S. FDA Grants Tentative Approval for LUSDUNA™ Nexvue™ (insulin glargine injection), a Follow-On Biologic Basal Insulin

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Merck (NYSE:MRK), known as MSD outside of the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has granted tentative approval for LUSDUNA™ Nexvue™ (insulin glargine injection) 100 units/mL, a follow-on biologic¹ basal insulin in a pre-filled dosing device. LUSDUNA Nexvue is being developed by Merck with funding from Samsung Bioepis.

With the tentative approval, LUSDUNA Nexvue has met all required regulatory standards for follow-on biologics of clinical and nonclinical safety, efficacy and quality, but is subject to an automatic stay due to a lawsuit from Sanofi claiming patent infringement. Under the Hatch-Waxman Act, the initiation of Sanofi's lawsuit in September 2016 automatically invoked a stay on final FDA approval of LUSDUNA Nexvue for a period of up to 30 months, or in the event a court finds in favor of Merck, whichever comes sooner.

"The tentative approval of LUSDUNA Nexvue is an important milestone, bringing us closer to offering this medicine to patients," said Sam Engel, M.D., associate vice president, Merck clinical research, diabetes, endocrinology and women's health.

The trade name "LUSDUNA Nexvue" was granted provisional approval by the FDA and will be used in the U.S. when the product is made available.

[About Merck](#)

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. 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. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on **Twitter, Facebook, Instagram, 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 2016 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).

1 A follow-on biologic is a similar, but not identical, version of an approved reference product. In the U.S., LUSDUNA

Nexvue is referred to as a follow-on biologic because of its regulatory pathway.

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