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Merck wins tentative U.S. FDA approval for Lusduna

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LUSDUNA Nexvue is subject to an automatic stay due to a lawsuit from Sanofi claiming patent infringement.



Merck announced in a press release 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 biologic 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.

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 its prescription medicines, vaccines, biologic therapies and animal health products, it works with customers and operates in more than 140 countries to deliver innovative health solutions. It also demonstrates their 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.