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## Eli Lilly and Company Provides Statement in Response to Sanofi U.S. Lawsuit

INDIANAPOLIS, Jan. 31, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) has provided the following statement regarding a lawsuit filed by Sanofi in the United States District Court for the District of Delaware alleging patent infringement with respect to LY2963016, a new insulin glargine product for which Lilly is currently seeking approval from the U.S. Food and Drug Administration (FDA).

"Lilly respects the intellectual property of others and does not believe the application for approval of its new insulin glargine product infringes any valid claim of the asserted patents," said Doug Norman, vice president and general patent counsel, Eli Lilly and Company.

Lilly, and its alliance partner Boehringer Ingelheim, recently announced the FDA had accepted the filing of the New Drug Application (NDA) for LY2963016, an investigational basal (long-acting) insulin.

LY2963016 is a new insulin glargine product developed for the treatment of patients with type 1 and type 2 diabetes. The NDA was filed through the 505(b)(2) regulatory pathway, which allows the FDA to reference previous findings of safety and efficacy for an already-approved product (insulin glargine) in addition to the studies of LY2963016.

Under the Hatch-Waxman act, the initiation of the lawsuit automatically invokes a stay on FDA approval of the product for a period of 30 months, or until a court finds in favor of Lilly, whichever is sooner. It is too early to speculate whether a resolution would occur before the end of the 30-month litigation stay in mid-2016.

In July 2013, the companies announced the marketing authorization application (MAA) for LY2963016 was accepted for review by the European Medicines Agency (EMA).

### About Diabetes

Approximately 24.4 million Americans and an estimated 382 million people worldwide have type 1 or type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 85 to 95 percent of all diabetes cases. Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin. Diabetes was estimated to cost the U.S. \$263 billion in 2013.<sup>1</sup>

### About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and <http://newsroom.lilly.com/social-channels>. P-LLY

*This press release contains forward-looking statements about LY2963016 for the treatment of diabetes. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that LY2963016 will receive regulatory approval or prove to be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.*

### REFERENCES

1. International Diabetes Federation. IDF Diabetes Atlas, 6th edn. Brussels, Belgium: International Diabetes Federation, 2013. <http://www.idf.org/diabetesatlas>. Accessed on December 18, 2013.

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