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FDA Grants Priority Review for Lilly's Olaratumab, an Investigational Medicine for Advanced Soft Tissue Sarcoma

Olaratumab Previously Received Breakthrough Therapy Designation

INDIANAPOLIS, May 4, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the biologics license application (BLA) for olaratumab, a PDGFR α antagonist, in combination with doxorubicin, for the potential treatment of people with advanced soft tissue sarcoma (STS) not amenable to curative treatment with radiotherapy or surgery.

Lilly has received additional designations for olaratumab from the FDA, including Breakthrough Therapy, Fast Track and Orphan Drug, for this indication. According to the FDA, Breakthrough Therapy designation is a process designed to expedite the development of a potential medicine that is intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

"We are encouraged that the FDA has granted Priority Review for olaratumab as a potential treatment for advanced soft tissue sarcoma," said Richard Gaynor, M.D., senior vice president, product development and medical affairs for Lilly Oncology. "We are hopeful that, if approved, olaratumab will provide a meaningful addition to the limited treatment options for this rare and difficult-to-treat disease."

Providing Priority Review status for olaratumab reinforces that olaratumab is a potential medicine that treats a serious condition and can provide significant improvement in the treatment of people with advanced STS. Submission was completed in the first quarter of 2016.

The BLA submission for olaratumab was based upon the results from a pivotal Phase 2 trial, JGDG, an open-label, randomized study that compared olaratumab in combination with doxorubicin chemotherapy to doxorubicin alone in patients with advanced STS not amenable to curative treatment with surgery or radiotherapy. Results from JGDG were presented at the 2015 American Society of Clinical Oncology annual meeting and the 2015 Connective Tissue Oncology Society annual meeting.

Lilly also submitted olaratumab to the European Medicines Agency (EMA) in the first quarter of 2016, and the application is currently being reviewed under an accelerated assessment schedule.

About Olaratumab

Olaratumab is a human IgG1 monoclonal antibody that is designed to disrupt the PDGF Receptor- α (platelet-derived growth factor receptor α) pathway on tumor cells and on cells in the tumor microenvironment. This means it may cause anticancer activity by targeting tumor cells directly, as well as cells that surround and support tumor growth.

A Phase 3 trial of olaratumab and doxorubicin in advanced STS is currently recruiting adult patients ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02451943) Identifier: [NCT02451943](https://clinicaltrials.gov/ct2/show/study/NCT02451943)).

About Sarcomas

Sarcomas are a diverse and relatively rare type of cancer that usually develop in the connective tissue of the body, which include fat, blood vessels, nerves, bones, muscles, deep skin tissues and cartilage. Soft tissue sarcoma (STS) is a complex disease with multiple subtypes, making it very difficult to treat. According to the American Cancer Society, in 2015 an estimated 12,000 new cases of STS were diagnosed, and nearly 5,000 deaths from STS occurred in the U.S. alone.

About Lilly Oncology

For more than 50 years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

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 and newsroom.lilly.com/social-channels. P-LLY

Lilly Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the potential of olaratumab as a potential treatment of advanced soft tissue sarcoma and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results and patient experience will be consistent with the study findings to date. There can also be no guarantee that olaratumab will receive regulatory approval or that, if approved, it will prove to be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements.

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