September 16, 2016

CHMP Recommends Approval of Lilly's Olaratumab, in Combination with Doxorubicin, for Advanced Soft Tissue Sarcoma

Positive Opinion is the First Global Regulatory Step Towards Approval for Olaratumab

INDIANAPOLIS, Sept. 16, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending the granting of a conditional marketing authorization for olaratumab, in combination with doxorubicin, for the treatment of adults in the European Union (EU) with advanced soft tissue sarcoma (STS) not amenable to curative treatment with radiotherapy or surgery and who have not been previously treated with doxorubicin. The CHMP reviewed olaratumab under EMA's accelerated assessment program. If approved, olaratumab will be marketed under the trade name LARTRUVO™.

This is the first regulatory step in the world towards approval for olaratumab. The CHMP positive opinion is now referred for final action to the European Commission, which grants marketing authorization in the EU. The Commission usually makes a decision on marketing authorization within two to three months of the CHMP issuing its recommendation.

"Patients with advanced soft tissue sarcoma have been seeking new treatment options that can potentially extend lives, so they can have more time with their families and loved ones," said Richard Gaynor, M.D., senior vice president of product development and medical affairs for Lilly Oncology. "Advanced soft tissue sarcoma is a rare disease that is difficult to treat, and this milestone brings us one step closer to providing physicians in Europe with a new option that they can offer to their patients."

This will be Lilly's first conditional approval in the EU. As part of a conditional marketing authorization, Lilly will need to provide results from an ongoing Phase 3 study. This study, ANNOUNCE, is fully enrolled. Until availability of the full data, the CHMP will review the benefits and risks of olaratumab annually to determine whether the conditional marketing authorization can be maintained.

The EMA previously granted olaratumab with Orphan Drug Designation for the treatment of soft tissue sarcoma in the EU.

The EU submission is based on data from Phase 2 JGDG, an open-label, randomized trial 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 and who have not been previously treated with doxorubicin. Efficacy endpoints included progression-free survival, overall survival and objective response rate.

Lilly has also submitted the results of this study to the U.S. Food and Drug Administration (FDA) for regulatory review. The FDA recently granted Lilly Priority Review status for olaratumab. Lilly also has received additional designations for olaratumab from the FDA for this indication, including Breakthrough Therapy, Fast Track and Orphan Drug.

Notes to Editor

About Olaratumab

Olaratumab is a PDGFRα blocking antibody that specifically binds PDGFRα and prevents receptor activation. Olaratumab exhibited *in vitro* and *in vivo* anti-tumor activity against selected sarcoma cell lines and disrupted the PDGFRα signaling pathway in *in vivo* tumor implant models. Information about additional clinical trials for olaratumab in sarcoma can be found at ClinicalTrials.gov (in the search box on the home page, type in "olaratumab").

A Phase 3 trial of olaratumab and doxorubicin in advanced STS is fully enrolled (ClinicalTrials.gov Identifier: NCT02451943).

About the JGDG Trial

The open-label, randomized Phase 1b/2 study, JGDG, compared olaratumab in combination with doxorubicin chemotherapy to the control arm of doxorubicin alone in patients with unresectable, advanced STS not amenable to curative treatment with surgery or radiotherapy. After confirmation of safety in the Phase 1b portion of the study, 133 doxorubicin-naïve patients were randomized 1:1 in the Phase 2 portion of the study. A total of 66 patients were treated on the olaratumab-doxorubicin arm, and 67 on the placebo-doxorubicin arm. Efficacy endpoints included progression-free survival, overall survival and

objective response rate.

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. STS is a complex disease with multiple subtypes, making it very hard to diagnose and difficult to treat. For decades, there have been no front-line therapeutic advancements for advanced STS that have improved overall survival. An estimated 23,000 people in the EU will be diagnosed with STS this year.

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.

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 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. 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 for any future indications or that 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.

Refer to: Karen Glowacki; kglowacki@lilly.com; 317-370-1177 (media)
Philip L. Johnson; philip_johnson_l@lilly.com; 317-655-6874 (investors)

Logo - http://photos.prnewswire.com/prnh/20031219/LLYLOGO