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Data in The Lancet Show Olaratumab Plus Doxorubicin Offered 11.8-Month Increase in Overall Survival in Patients with Advanced Soft Tissue Sarcoma, as Reported by Lilly and Memorial Sloan Kettering Researchers

- The study met its primary endpoint of progression-free survival (PFS) and showed a statistically significant improvement in overall survival (OS), a key secondary endpoint.
- U.S. Food and Drug Administration (FDA) previously granted olaratumab with Priority Review, Fast Track, Orphan Drug and Breakthrough Therapy designations.
- European Medicines Agency (EMA) is currently reviewing olaratumab under an accelerated assessment schedule.

INDIANAPOLIS, June 9, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that *The Lancet* published detailed results from a Phase 2 study evaluating the efficacy and safety of olaratumab, an investigational compound, in combination with doxorubicin chemotherapy in patients with advanced soft tissue sarcoma (STS) not amenable to curative treatment with radiotherapy or surgery. STS is a rare cancer for which patients have limited treatment options. The study met its primary endpoint of progression-free survival (PFS) and showed a statistically significant improvement in overall survival (OS), a key secondary endpoint.

"Olaratumab is the first agent added to doxorubicin to demonstrate improved overall survival in advanced soft tissue sarcoma in a randomized trial," said William D. Tap, M.D., chief of the sarcoma medical oncology service at Memorial Sloan Kettering Cancer Center in New York and the study's principal investigator. "This work represents a promising development for this patient population. We are encouraged by the results we've seen and are eager to continue working to provide new treatment options to this community of patients."

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. The primary endpoint of the study was PFS. Key secondary endpoints included OS and objective response rate (ORR).

Randomization was balanced by ECOG performance status, histological tumor type, PDGFR expression and previous lines of treatment.

Patients treated on the olaratumab and doxorubicin arm achieved 6.6 months of median PFS compared to 4.1 months on the placebo and doxorubicin arm (stratified hazard ratio [HR], 95 percent confidence interval [CI]: 0.672 [0.442-1.021]; $p=0.0615$). The investigator-assessed PFS was confirmed by independent review (HR=0.670; 95 percent CI: [0.04-1.12]; $p=0.1208$) with a median PFS of 8.2 months vs. 4.4 months. OS was statistically significant, with patients treated on the olaratumab and doxorubicin arm having achieved a median OS of 26.5 months (95 percent CI, 20.9-31.7) compared to 14.7 months (95 percent CI, 9.2-17.1) with doxorubicin (stratified HR, 0.463; 95 percent CI, 0.301-0.710; $p=0.0003$). The ORR was 18.2 percent (95 percent CI; [9.8-29.6]) with olaratumab plus doxorubicin and 11.9 percent (95 percent CI: [5.3-22.2]) with doxorubicin ($p=0.3421$).

"We are encouraged to see the positive progression-free survival results and the increase in overall survival, which is something we haven't seen in combination or against doxorubicin in the advanced soft tissue sarcoma setting in decades," said Robert Ilaria, Jr., M.D., senior medical director for Lilly Oncology. "Advanced soft tissue sarcoma is a rare cancer that is notoriously difficult to treat, and patients desperately need new treatment options."

The most common (greater than 5 percent incidence) grade 3 or higher adverse events identified in the study were neutropenia (53.2 percent on the olaratumab combination arm vs. 32.3 percent on the placebo plus doxorubicin arm), anemia (12.5 percent vs. 9.2 percent) fatigue (9.4 percent vs. 3.1 percent) and musculoskeletal pain (8 percent vs. 2 percent). There were no increases in febrile neutropenia (12.5 percent on the olaratumab-doxorubicin arm vs. 13.8 percent on the placebo-doxorubicin arm), infections (7.8 percent vs. 10.8 percent) and patient discontinuations (13 percent vs. 19

percent). Grade 3 or higher infusion-related reactions occurred in 3 percent of patients on the olaratumab-doxorubicin arm vs. 0 percent on the placebo-doxorubicin arm.

Lilly has submitted the results of this study to the U.S. Food Drug Administration (FDA) and European Medicines Agency (EMA) for regulatory review. The FDA recently granted Lilly Priority Review status for olaratumab. Lilly also has received additional designations for olaratumab from the FDA, including Breakthrough Therapy, Fast Track and Orphan Drug, for this indication. Additionally, the EMA is currently reviewing olaratumab under an accelerated assessment schedule.

About Sarcoma

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 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.

The 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 Lilly Oncology

For more than fifty 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 will be consistent with the study findings to date or 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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