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Lilly reports results of ANNOUNCE

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Eli Lilly and Company has reported that the results of ANNOUNCE, the Phase 3 study of LARTRUVO (olaratumab), in combination with doxorubicin in patients with advanced or metastatic soft tissue sarcoma (STS), did not confirm the clinical benefit of LARTRUVO in combination with doxorubicin as compared to doxorubicin, a standard of care treatment.

Specifically, the study did not meet the primary endpoints of overall survival (OS) in the full study population or in the leiomyosarcoma (LMS) sub-population; there was no difference in survival between the study arms for either population. LARTRUVO was well tolerated; there were no new safety signals identified and the safety profile was comparable between treatment arms.

LARTRUVO in combination with doxorubicin previously showed an OS benefit in STS in a 133-patient, U.S.-only, randomized Phase 2 trial, which led to accelerated approval by the U.S. Food and Drug Administrationand conditional marketing authorization by the European Medicines Agency. Continued approval is contingent upon verification of clinical benefit in a confirmatory trial.

As ANNOUNCE did not confirm clinical benefit, Lilly is working with global regulators to determine the appropriate next steps for LARTRUVO. While these discussions are ongoing, patients who are currently receiving LARTRUVO may, in consultation with their physician, continue their course of therapy if they are receiving clinical benefit.

For patients who have not previously received LARTRUVO, the results of the Phase 3 trial do not support initiating treatment with LARTRUVO in patients with STS, outside of participation in a clinical trial. At this time, Lilly is suspending promotion of LARTRUVO.

Anne White, president, Lilly Oncology said, "Lilly was surprised and disappointed that LARTRUVO did not improve survival for patients with advanced soft tissue sarcoma in this study. Lilly is committed to helping people who have soft tissue sarcoma and we will carefully study the detailed data in an effort to better understand the different results between the two trials. We are thankful for the patients and physicians who have participated in the ANNOUNCE study."

LARTRUVO is also being studied in an ongoing global, randomized, double-blind, placebo-controlled Phase 2 trial in advanced STS in combination with gemcitabine and docetaxel.

Lilly expects to incur a charge in the first quarter of 2019 related to LARTRUVO. The exact amount of the charge has not yet been determined, but is estimated to be in the range of $70 million to $90 million (pre-tax), or approximately $0.10 per share (after tax).

In addition, the company expects this to have an impact of approximately $0.17 per share on Lilly's full-year 2019 earnings per share guidance. Lilly will provide a full update to its 2019 financial guidance, including the impact of the potential Loxo Oncology acquisition, when it announces Q4 2018 earnings. This announcement does not change Lilly's 2020 minimum financial goals.