Lartruvo® (olaratumab) – Safety communication

- On January 24, 2019, the FDA released a statement recommending that patients who are currently receiving Lartruvo (olaratumab) should consult with their healthcare provider about whether to remain on treatment. In addition, the FDA recommends that Lartruvo should not be initiated in new patients outside of an investigational study.

- The FDA approved Lartruvo, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

- Lartruvo was approved under the FDA's accelerated approval program in October 2016. As a condition of approval, Eli Lilly conducted a larger study, designed to confirm the clinical benefit of Lartruvo in these patients.

- The recently completed larger study (ANNOUNCE) did not confirm the clinical benefit of Lartruvo. Specifically, the study did not meet the primary endpoint of improvement in overall survival for Lartruvo and doxorubicin as compared to placebo and doxorubicin.

- The FDA is currently reviewing the data and working with the company to determine appropriate next steps.