4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1618]

Eli Lilly and Co.; Announcement of the Revocation of the Biologics License for LARTRUVO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the biologics license application (BLA) for LARTRUVO (olaratumab) injection. Eli Lilly and Co. requested withdrawal (revocation) of the biologics license application and has waived its opportunity for a hearing.

DATES: The BLA is revoked as of February 25, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: On October 19, 2016, FDA approved the BLA for LARTRUVO (olaratumab) injection held by Eli Lilly and Co. (Eli Lilly), Lilly Corporate Center, Indianapolis, IN 46285, indicated, 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, under the Agency's accelerated approval regulations at 21 CFR part 601, subpart E. On January 18, 2019, Eli Lilly reported in a press release that the confirmatory study required as a

condition of LARTRUO's accelerated approval, entitled "Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Doxorubicin Plus Olaratumab Versus Doxorubicin Plus Placebo in Patients With Advanced or Metastatic Soft Tissue Sarcoma" (ANNOUNCE trial), "did not meet the primary endpoints of overall survival in the full study population or in the leiomyosarcoma subpopulation." On September 27, 2019, Eli Lilly requested withdrawal (revocation), in writing, of the BLA for LARTRUVO (olaratumab) injection (BLA 761038) under § 601.5(a) (21 CFR 601.5(a)) because the ANNOUNCE trial failed to demonstrate improvement in overall survival for olaratumab in combination with doxorubicin compared to doxorubicin alone. In that letter, Eli Lilly waived its opportunity for a hearing. On February 25, 2020, the Agency issued a letter to Eli Lilly revoking the approval to manufacture and market LARTRUVO (olaratumab) injection (BLA 761038).

Therefore, under § 601.5(a), the Agency revoked the BLA for LARTRUVO (olaratumab) injection (BLA 761038), applicable as of February 25, 2020.

Dated: July 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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