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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1647]

Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR). The general function of the committee is to provide advice and recommendations to the Agency on research being conducted at the NCTR. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on August 18, 2020, from 8 a.m. to 5:55 p.m. (CST), and on August 19, 2020, from 8 a.m. to 11:30 a.m. (CST).

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The meeting will be webcast both days and will be available at the following link: *https://collaboration.fda.gov/nctr1000/.*

FOR FURTHER INFORMATION CONTACT: Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On August 18, 2020, the SAB Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the SAB Subcommittee Site Visit Report and a response to this review. The Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, Center for Tobacco Products, and Office of Regulatory Affairs will each briefly discuss their specific research strategic needs and potential areas of collaboration.

On August 19, 2020, there will be updates from the NCTR Research Divisions and a public comment session. Following an open discussion of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at the NCTR at the end of the day.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On August 18, 2020, from 8 a.m. to 5:55 p.m., and on August 19, 2020, from 8 a.m. to 11:30 a.m. (CST),