oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before 6 p.m. ET on June 1, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 3, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya or Sussan Paydar (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11668 Filed 5–26–22; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0887]

TG Therapeutics, Inc.; Withdrawal of Approval of New Drug Application for UKONIQ (Umbralisib Tosylate) Tablets, Equivalent to 200 Milligrams Base

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for UKONIQ (umbralisib tosylate) Tablets, equivalent to (EQ) 200 milligrams (mg) Base, held by TG Therapeutics, Inc., 3020 Carrington Mill Blvd., Morrisville, NC 27560. TG Therapeutics, Inc. (TGT) has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of May 31, 2022.

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, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 5, 2021, FDA approved NDA 213176 for UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, for the treatment of adult patients with: (1) Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and (2) relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, for MZL and FL included required postmarketing trials intended to verify the clinical benefit of UKONIQ.

On February 3, 2022, FDA issued a Drug Safety Communication about a possible increased risk of death with UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base. FDA's initial review of data from a phase 3, randomized, controlled clinical trial in patients with chronic lymphocytic leukemia (CLL) who were administered UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, in combination with a monoclonal antibody drug compared to the control arm showed a possible increased risk of death in patients receiving the combination of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, and the monoclonal antibody (UNITY–CLL trial). Those patients receiving the combination also experienced more serious adverse events than those in the control arm. FDA considered the data from the UNITY–CLL trial conducted in patients with CLL to have implications for UKONIQ's approved uses for MZL and FL.

On March 10, 2022 (87 FR 13736), FDA published the **Federal Register** notice ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments,'' announcing that UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, would be discussed at an Oncologic Drugs Advisory Committee (ODAC) meeting scheduled for April 22, 2022.

FDA met with TGT on April 14, 2022, to discuss voluntary withdrawal of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, pursuant to § 314.150(d) (21 CFR 314.150(d)) due to the decrement in overall survival and increased serious adverse events observed with UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, in the UNITY–CLL trial. FDA recommended the applicant voluntarily request withdrawal of approval of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, for the follicular lymphoma and marginal zone lymphoma indications pursuant to § 314.150(d) and requested TGT waive its opportunity for a hearing.

On April 15, 2022, TGT submitted a letter asking FDA to withdraw approval of NDA 213176 for UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, pursuant to § 314.150(d) and waiving its opportunity for a hearing. On April 18, 2022, FDA acknowledged TGT's request for withdrawal of approval of the NDA and waiver of its opportunity for a hearing. FDA also cancelled the ODAC meeting scheduled for April 22, 2022, because the meeting was unnecessary considering the applicant's withdrawal request.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 213176 for UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: May 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11631 Filed 5–27–22; 8:45 am]

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