Shorla Oncology Announces FDA Filing Acceptance of New Drug Application to Treat Certain Forms of Leukemia and Other Cancers

Second FDA Acceptance for an NDA Filing by Shorla Oncology Announced in 2024
New Oral Liquid Drug from the U.S.-Ireland Pharmaceutical Company Slows or Stops the Growth of Certain Types of Leukemia and Other Cancers

April 08, 2024 7:00 AM Eastern Daylight Time

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Shorla Oncology ('Shorla'), a U.S.-Ireland specialty pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for SH-201, the first palatable oral liquid of the related chemotherapeutic agent to treat certain forms of leukemia and other cancers. The Agency assigned a Prescription Drug User Fee Act ("PDUFA") action date of November 30, 2024.

"With this NDA acceptance for SH-201, we are a step closer to providing an alternative treatment to thousands of U.S. patients diagnosed with leukemia and other cancers who do not currently have the option of an oral liquid," said Sharon Cunningham, Chief Executive Officer and Co-Founder of Shorla Oncology. "Submitting this drug to the FDA for review is more than just a milestone for our company, it's an important moment for all those impacted by this disease including patients, caregivers and clinicians."

SH-201 is an oral liquid treatment that slows or stops the growth of certain forms of leukemia and other cancers such as:

- Chronic Myeloid Leukemia - Affects approximately 9,280 new patients each year in the U.S.[1]
- Acute Lymphoblastic Leukemia - Impacts approximately 6,550 new patients each year in the U.S.[2]

"The FDA's action today ensures that Shorla is well positioned to bring this innovative oral drug to market," said Orlaith Ryan, Chief Technical Officer and Co-Founder of Shorla Oncology. "SH-201 addresses key areas of unmet need by providing a palatable liquid treatment option for patients suffering with cancer."

This milestone for SH-201 follows acceptance to file announced in January of this year for SH-105, a novel, differentiated ready-to-dilute formulation for the treatment of adenocarcinoma of the breast or ovary. It is progressing through FDA review. The company recently raised $35 million in Series B funding that has allowed Shorla to accelerate the growth of its oncology portfolio. Last year, the company launched

Contacts

Media
Dawn Fallon
New Dawn
Communications LLC
dfallon@newdawncomms.co
732-771-7808

Nelarabine for the treatment of T-cell Leukemia and JYLAMVO, the first and only oral methotrexate solution approved in the United States for use in adults for the treatment of acute lymphoblastic leukemia and other indications.

About SH-201

SH-201 is the first palatable oral liquid of the related chemotherapeutic agent in the U.S. SH-201 is an oral liquid treatment that slows or stops the growth of certain forms of leukemia (such as acute lymphoblastic leukemia and chronic myeloid leukemia) and other cancers.

About Shorla Oncology

Established in 2018 by Sharon Cunningham and Orlaith Ryan, Shorla Oncology is a privately held, U.S. and Ireland-based commercial stage specialty pharmaceutical company with an advanced pipeline of innovative oncology drugs for orphan and pediatric cancers. The company concentrates on indications where existing treatments are limited, in shortage or the drug applications are inadequate for the target population. Shorla's growing portfolio brings accessible, affordable and life-saving treatments to patients, delivering a major contribution to patient care. The company currently markets two products, Nelarabine for the treatment of T-cell Leukemia and JYLAMVO for the treatment of acute lymphoblastic leukemia and other indications. Additionally, the company has two NDAs under FDA review with a view to additional launches within the next twelve months.

For further information, please visit www.shorlaoncology.com.

_____

[1, 2] American Cancer Society. Cancer Facts & Figures, 2024

Contacts

Media
Dawn Fallon
New Dawn Communications LLC
dfallon@newdawncomms.com
732-771-7808