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Shorla Oncology Announces FDA Approval for TEPYLUTE, A Novel Formulation to Treat Breast and Ovarian Cancer

TEPYLUTE is a ready-to-dilute formulation of thiotepa that significantly reduces preparation time and enables accurate dosing

CAMBRIDGE, Mass., June 28, 2024 - [Shorla Oncology \('Shorla'\)](#), a U.S.-Ireland specialty pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has approved the company's New Drug Application (NDA) for TEPYLUTE, a ready-to-dilute formulation to treat breast and ovarian cancer in an easier to prepare, injectable product that enables dosing accuracy.¹

"This approval fulfills an unmet need by addressing the shortcomings and handling complexities of the current lyophilized powder formulation," said Sharon Cunningham, Chief Executive Officer and Co-Founder of Shorla Oncology. "We have taken a vital oncology drug and made it easier for oncology clinics and hospitals to use, while also reducing medical personnel exposure to a hazardous drug."

TEPYLUTE, formerly SH-105, is the third FDA-approved drug for Shorla, and a significant milestone for the company as it seeks approval for several cancer-fighting drugs for the U.S. market.

"The approval of TEPYLUTE represents an important milestone for Shorla as our first in-house developed NDA," said Orlaith Ryan, Chief Technical Officer and Co-Founder of Shorla Oncology.

TEPYLUTE is a liquid form of a well-established, standard of care oncology drug, thiotepa. The new formulation eliminates the need for complex and time-consuming reconstitution. It provides consistent dosing accuracy and allows for "just in time" preparation.²

"Among TEPYLUTE's many benefits, it removes the necessity to reconstitute which can introduce additional risks of drug preparation errors," emphasized Rayna Herman, Chief Commercial Officer. "We look forward to providing an update on our launch plans for TEPYLUTE in the near future."

¹ Carasu M, Carton M, Darlix A, Pasquier D, Leheurteur M, Debled M, Mouret-Reynier MA, Goncalves A, Dalenc F, Verret B, Campone M. Breast cancer patients treated with intrathecal therapy for leptomeningeal metastases in a large real-life database. ESMO Open 6: 100150.

² Reinhardt H, Otte P, Eggleton AG, Ruch M, Wöhrl S, Ajayi S, Duyster J, Jung M, Hug MJ, Engelhardt M. Avoiding chemotherapy prescribing errors: analysis and innovative strategies. Cancer. 2019 May 1;125(9):1547-57.

The American Cancer Society estimates that more than 300,000 women will be diagnosed with breast cancer in the U.S in 2024.³ About 19,680 women will be diagnosed with ovarian cancer in the United States.⁴

Shorla Oncology is currently marketing two products with a robust pipeline including SH-201, the first palatable oral liquid treatment for certain forms of leukemia and other cancers. In April, the company announced the FDA had accepted SH-201 for an NDA review with an expected action date of November 30, 2024.

About Shorla Oncology

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

For further information, please visit www.shorlaoncology.com

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Media Contact

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

Source: Shorla Oncology

³ [Breast Cancer Statistics | How Common Is Breast Cancer? | American Cancer Society](#), Accessed June 27, 2024

⁴ [Ovarian Cancer Statistics | How Common is Ovarian Cancer | American Cancer Society](#), Accessed June 27, 2024