

Shorla Oncology Announces FDA Filing Acceptance of New Drug Application for Novel Formulation to Treat Breast and Ovarian Cancer

U.S.-Ireland Specialty Pharmaceutical Company's ready-to-dilute form of a drug for the treatment of adenocarcinoma of the breast or ovary

January 9, 2023 - CAMBRIDGE, Mass. - Shorla Oncology ('Shorla'), a U.S.-Ireland specialty pharmaceutical company, announced today that the US Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for a novel formulation to treat breast and ovarian cancer. The Agency assigned a Prescription Drug User Fee Act ("PDUFA") action date of June 29th, 2024.

"This innovative drug ('SH-105') will offer hospital pharmacists and patients access to a differentiated, ready to administer, injectable product with unique characteristics that's expected to facilitate rapid adoption once approved" said Orlaith Ryan, Chief Technical Officer and Co-Founder of Shorla Oncology."

SH-105 is a ready-to-dilute form of a well-established drug that has been used as a freeze-dried powder since the 1950s and has seen supply shortages. SH-105's liquid form eliminates the need for powder to be reconstituted, improving efficiency, and reducing the risks associated with the complexity of preparation.

"This is an important step in improving access to and administration of a drug that will help women suffering from breast and ovarian cancer," said Sharon Cunningham, Chief Executive Officer and Co-Founder of Shorla Oncology. "It also marks a significant milestone regarding Shorla's efforts to bring innovative oncology products to market."

More than 350,000 women will be diagnosed with breast cancer in the U.S in 2023, according to the American Cancer Society.¹ About 19,710 women will be diagnosed with ovarian cancer in the United States.²

SH-105 is one of several oncology drugs in Shorla's advanced pipeline. The company recently raised \$35 million in Series B funding that will allow Shorla to accelerate the growth of its oncology portfolio. Last year, the company launched 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-105

¹ [Breast Cancer Statistics | How Common Is Breast Cancer? | American Cancer Society](#). Accessed January 8, 2024.

² [Ovarian Cancer Statistics | How Common is Ovarian Cancer | American Cancer Society](#). Accessed January 8, 2024.

SH-105 is a ready-to-dilute formulation for the treatment of adenocarcinoma of the breast or ovary. SH-105 is a novel, differentiated liquid formulation that eliminates the need for a complex reconstitution step improving efficiencies and reducing preparation risks.

About Shorla Oncology

Established in 2018 by Sharon Cunningham and Orlaith Ryan, Shorla Oncology is a privately held, U.S. and Ireland- based 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.

For further information, please visit www.shorlaoncology.com

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