Wellstat Therapeutics’ New Drug Application for Uridine Triacetate as Antidote to Overexposure to Chemotherapy Drug 5-Fluorouracil (5-FU) Accepted for Review by FDA

Gaithersburg, MD - September 10, 2015 - The U.S. Food and Drug Administration (FDA) has accepted for review Wellstat Therapeutics Corporation’s new drug application (NDA) for the company’s investigational drug uridine triacetate. The NDA seeks regulatory approval of uridine triacetate as an antidote for patients at risk of serious toxicity following an overdose of chemotherapy agent 5-fluorouracil (5-FU), and patients who exhibit serious toxicity within 96 hours of being treated with 5-FU. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in March 2016.

The chemotherapy drug 5-FU has been used for decades in combination with other chemotherapy agents and/or radiation to treat solid tumors including those of the breast, colon, stomach, pancreas, head and neck. Published literature suggests that each year, 250,000 to 300,000 patients in the U.S. receive multiple treatments of 5-FU, typically administered at or near what is considered the maximum tolerated dose, of which approximately 0.5% die from 5-FU toxicity. Overexposure to 5-FU can occur if the drug has been administered at a dose or rate greater than intended, or when a patient has genetic variations, impaired clearance or other biochemical factors that increase sensitivity to the drug.

An estimated ten to twenty percent of patients treated with 5-FU develop serious, sometimes life threatening, 5-FU toxicity. Administration of uridine triacetate can reduce the ability of toxic 5-FU metabolites to incorporate into the genetic material of healthy cells, enabling cellular recover after overexposure to 5-FU and preventing cell death.

In 2009, uridine triacetate received orphan drug status by the FDA as an antidote in the treatment of 5-FU poisoning, and by the European Medicines Agency (EMA) as a treatment for 5-FU overdose. Under an expanded access protocol and under FDA emergency treatment provisions in the U.S., uridine triacetate is currently provided to patients at risk of excess 5-FU toxicity due to overdose and patients exhibiting serious toxicities to 5-FU within 96 hours of 5-FU administration. Under similar emergency use provisions uridine triacetate is also currently provided to patients in Europe and the rest of the world.

The NDA for uridine triacetate contains safety and efficacy data from patients receiving the drug under these expanded access protocols and emergency treatment provisions. Wellstat is working closely with the FDA during the NDA review process.
About Wellstat Therapeutics

Wellstat Therapeutics Corporation is a privately-held biopharmaceutical company located in Gaithersburg, Maryland. Wellstat Therapeutics is committed to discovering, developing and commercializing products that will provide new and improved treatments for patients in the fields of oncology and metabolic, neurometabolic and neurodegenerative diseases. For more information, please visit the website at http://www.wellstattherapeutics.com. Wellstat Therapeutics is part of the Wellstat group of companies (http://www.wellstat.com).

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