



Curtana Pharmaceuticals Successfully Completes Pre-IND Submission for CT-179 for the Treatment of Malignant Gliomas

Clinical Development to Begin in First Half of 2018

AUSTIN, TX – August 22, 2017 – Curtana Pharmaceuticals, a privately-held, preclinical-stage biopharmaceutical company, today announced that it has completed a pre-investigational new drug (IND) meeting with the U.S. Food and Drug Administration (FDA). The purpose of the meeting was to discuss the proposed clinical development program for treating newly diagnosed adult glioblastoma (GBM) patients with Curtana’s lead product candidate, CT-179, including the Phase 1 clinical study design. In addition, a clinical development plan for CT-179 in pediatric patients with newly diagnosed high grade glioma (HGG) was proposed.

Curtana submitted their meeting package to the FDA on May 19, 2017. In written responses, the FDA addressed the company’s questions related to the design of the first-in-human Phase 1 study in adult patients with newly diagnosed GBM. The FDA also provided greater clarity on the data collection requirements in pediatric patients. Last, the Agency provided guidance regarding Curtana’s submission for fast track (FT) designation. Curtana anticipates submitting this IND application in the first half of 2018.

“We are very excited by the FDA’s response and general acceptance of our clinical trial design to study CT-179 in newly diagnosed GBM patients in combination with the standard of care treatments, temozolomide and radiation,” said Gregory Stein, M.D., MBA, and Chief Executive Officer. “This is a much-needed departure from the typical development process, which is to first test a new drug as monotherapy in patients with recurrent disease, a strategy that provides safety data, but is frequently unsuccessful in providing adequate evidence of activity. Our goal is to get CT-179 as quickly as possible to adult and pediatric patients with these devastating brain cancers. We applaud the FDA’s acknowledgement of the difficulty treating gliomas and their willingness to be innovative and we will continue to work diligently with the Agency to move our lead product candidate into clinical trials.”

Glioblastoma is the most common and most aggressive of the malignant primary brain tumors in adults. According to the American Brain Tumor Association, an estimated 12,390 new cases of GBM are predicted in 2017. Conventional therapeutic approaches for GBM, including surgery, chemotherapy and radiation therapy, target the tumor bulk, but have limited effect on the glioma cancer stem cells (CSCs), which are responsible for the recurrence of disease that occurs in most



GBM patients. Accordingly, GBM represents a significant unmet clinical need as the median survival is less than 15 months and five-year survival rate is less than 10%.

Curtana's lead clinical candidate, CT-179, is a highly potent inhibitor of Olig2, a transcription factor that is not actively expressed in the vast majority of normal adult brain cells or in normal tissues outside the brain. However, Olig2 is markedly over-expressed in GBM; specifically, in the cancer stem cells (CSCs) that have been shown to be an important factor in tumorigenesis, driving tumor growth, invasion into normal brain tissue, and recurrence. The drug is orally bioavailable, readily crosses the blood-brain barrier, achieves very high concentrations in the brain, and significantly prolongs survival in animal models of brain cancer. When combined with standard of care temozolomide and radiation, CT-179 dramatically inhibits tumor growth and prolongs survival compared to either treatment alone, in relevant animal models.

About Curtana Pharmaceuticals

Curtana Pharmaceuticals, founded in 2013, is a privately held, preclinical-stage biopharmaceutical company headquartered in Austin, Texas. Current investors include [Thynk Capital](#), [angelMD](#), [Biosense Global](#), [DEFTA Partners](#), and other anonymous investors. In 2014, the company was awarded a \$7.6 million grant from the Cancer Prevention and Research Institute of Texas (CPRIT). Curtana focuses on the development of novel first-in-class, small molecule therapeutics targeting cancer stem cells in the central nervous system for the treatment of glioblastoma and other brain cancers. For more information, visit www.curtanapharma.com.

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