



Blaze Bioscience Announces FDA has Granted Fast Track Designation to BLZ-100 (tozuleristide) for Pediatric Central Nervous System Tumors

- Phase 2/3 pivotal trial ongoing in patients up to 30 years of age undergoing surgery for pediatric central nervous system tumors

SEATTLE, WA – April 7, 2020 – [Blaze Bioscience, Inc.](#), the Tumor Paint Company®, a biotechnology company dedicated to improving the lives of cancer patients through development and commercialization of products for fluorescence guided surgery, announced today that its clinical program evaluating tozuleristide (BLZ-100) for pediatric brain tumors, has been granted Fast Track designation from the U.S. Food and Drug Administration (FDA).

BLZ-100 (tozuleristide) is a tumor-targeting optical imaging agent, designed to provide real-time, high-resolution visualization of cancer cells during surgery, potentially enabling more effective removal of cancerous tissue while sparing healthy tissue. Greater precision in surgery can be curative or improve downstream treatment options for people with cancer. BLZ-100 and the high-sensitivity Canvas Imaging System are currently being tested in a Phase 2/3 clinical trial enrolling patients from age 0-30 undergoing surgery for pediatric central nervous system tumors.

Fast track is a designation granted by the FDA that is intended to facilitate and expedite development and review of new drugs to address an unmet medical need in the treatment of a serious life threatening condition and for which nonclinical or clinical data has demonstrated the potential to address this unmet medical need. Developers of drugs that receive Fast Track designation benefit from access to FDA expertise, and Fast Track drugs that meet FDA criteria are eligible for priority review and accelerated approval. The designation allows for expedited regulatory review of clinical data, with the goal to speed promising therapies to market.

“Receiving Fast Track designation is an important recognition of the importance of our pediatric brain cancer surgery program and the promise of tozuleristide in this patient population,” said Dr. Dennis Miller, Blaze Bioscience Executive Vice President of Development. “Pediatric brain tumors remain the leading cause of cancer-related death among children and adolescents. We look forward to our continued collaborative relationship with FDA as we work to complete the clinical and other product development work needed to speed the product to approval.”

About BLZ-100 (tozuleristide)

BLZ-100 (tozuleristide) is the first product candidate from Blaze’s Tumor Paint platform and consists of a targeting peptide and a fluorescent dye, which emits light in the near-infrared (NIR) range. Tumor Paint products are designed to provide real-time, high-resolution intraoperative visualization of cancer cells throughout surgery, potentially enabling more precise, complete resection of cancer while sparing normal adjacent tissue. BLZ-100 has been tested in four Phase 1 clinical trials and has demonstrated clinical proof of concept in brain, breast and skin cancers. Additional potential applications of BLZ-100 include prostate, lung, colorectal and other solid tumor cancers. BLZ-100, an investigational agent, is being evaluated in a pivotal Phase 2/3 clinical study in pediatric central nervous system tumors (NCT03579602). More details about ongoing trials are available at www.clinicaltrials.gov.

About the Canvas Imaging System

The Canvas Imaging System is an investigational medical device designed to provide high-sensitivity detection of NIR light in the operating room under ambient light conditions. The Canvas Imaging System was developed and is manufactured by Teal Light Surgical, Inc. (a wholly owned subsidiary of Blaze Bioscience, Inc.). The first Canvas Imaging System under development is adapted for use with surgical microscopes and detects both BLZ-100 and indocyanine green (ICG).

About Blaze Bioscience

Blaze Bioscience, Inc. is a privately held biotechnology company dedicated to improving the lives of cancer patients. Blaze was founded in 2010 by Dr. Jim Olson, a pediatric neuro-oncologist at the Fred Hutchinson Cancer Research Center and Seattle Children's Hospital, and Heather Franklin, a former senior executive at ZymoGenetics. Blaze is working to develop Tumor Paint products and related therapeutics. Surgery is first-line therapy for most solid tumor cancers and Tumor Paint products have the potential to improve cancer surgery by providing real-time, high-resolution visualization of cancer cells throughout surgery. For additional information, please visit www.blazebioscience.com.

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