Blaze Bioscience Announces the Initiation of Pivotal Clinical Trial for Tumor Paint: BLZ-100 (tozuleristide) and the Canvas Imaging System

Multi-site clinical study brings together the best in class tumor-targeting imaging agent for brain cancer and the highest sensitivity NIR microscope-based detection device in late stage development

SEATTLE, WA – November 28, 2018 – 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, today announced they have enrolled the first patient at Seattle Children’s Hospital in their Phase 2/3 pivotal study entitled “A randomized, blinded study of fluorescence detection of pediatric primary central nervous system tumors in subjects receiving tozuleristide and imaged with the Canvas System.”

The randomized, blinded, multi-center, single dose Phase 2/3 study in pediatric patients with central nervous system tumors will assess the safety and efficacy of BLZ-100 as well as the performance of the Canvas System. The trial is expected to enroll 114 patients at fifteen (15) leading U.S. pediatric cancer surgery centers throughout the U.S. that are participants in the Pacific Pediatric Neuro-Oncology Consortium (PNOC).

“Successful neurosurgery means maximizing safe removal of tumor tissue while minimizing damage to healthy brain, and we see a great opportunity to improve outcome if we can put better tools in the expert hands of our surgeons to help them distinguish tumor from non-tumor. We are so excited to be evaluating BLZ-100 as potentially the first tumor-targeted imaging agent for pediatric brain tumors.” said Sarah M. Leary, M.D., M.S., Seattle Children’s Hospital Pediatric Neuro-Oncologist, and Study Chair for the BB-006 (PNOC012) clinical trial. “Our partnership with Blaze and PNOC, and funding from the Norcliffe Foundation and Gateway for Cancer Research, have made this focus on children with brain tumors possible.”

“Treating our first patient in a pivotal trial is the next step in realizing Blaze’s vision to improving cancer surgery for all solid tumor patients. The CDC reports that brain cancer is the number one cancer killer of children making this a compelling place to start. The ability of BLZ-100 to detect pediatric tumors sets it apart from other fluorescence-based agents,” said Heather Franklin, CEO of Blaze Bioscience.

For more information refer to www.clinicaltrials.gov, using the NCT identifier NCT03579602.

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 range. Tumor Paint products are designed to provide real-time, high-resolution intraoperative visualization of cancer cells, potentially enabling more precise, complete resection of cancer and sparing of normal adjacent tissue throughout surgery. 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 Phase 2/3 clinical study in pediatric CNS tumors. More details about on-going trials are available at www.clinicaltrials.gov.

About the Canvas Imaging System

The Canvas Imaging System developed and manufactured by Teal Light Surgical, Inc. (a wholly-owned subsidiary of Blaze Bioscience Inc.) is designed to provide high-sensitivity detection of NIR light in the operating
theater under ambient light conditions. 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. The ability to see cancer cells in real time and high resolution throughout surgery should enable better detection and more complete and precise surgical removal of cancer—while sparing surrounding normal tissue. For additional information, please visit www.blazebioscience.com.

About Gateway for Cancer Research

Gateway for Cancer Research℠ is a nonprofit 501(c)(3) organization committed to funding innovative cancer research that helps people living with cancer to feel better, live longer and conquer cancer TODAY! Thanks to generous underwriting, 99 cents of every dollar Gateway receives directly funds Phase I and Phase II cancer clinical trials at leading research institutions across the world. Over the past 27 years Gateway has raised more than $80 million for cancer research and funded 160+ clinical trials. Get involved today by visiting www.GatewayCR.org, like us on Facebook at facebook.com/demandcures and join the conversation on Twitter at @DemandCures, #BeAGateway.

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