SEATTLE, WA – July 7, 2015 – Blaze Bioscience®, a biotechnology company focused on guided cancer therapy, today announced that the company has received Orphan Drug Designation for BLZ-100 from the Office of Orphan Products Development of the U.S. Food and Drug Administration (FDA) for malignant brain tumors.

“Improvements in brain cancer surgery represent one of the highest unmet medical needs for both adults and children with brain cancer,” said Blaze co-founder and CEO Heather Franklin. “We continue to enroll patients in our ongoing Phase 1 studies in adult and pediatric patients with brain cancer and our goal is to rapidly advance the development of BLZ-100 to address the needs of these patients with the added support of the FDA’s Orphan Drug program.”

The FDA grants Orphan Drug Designation status to products for rare diseases and disorders, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Orphan Drug Designation provides the sponsor certain benefits and incentives, including greater access to FDA staff, a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees. The receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval.

About BLZ-100

BLZ-100 is the first product candidate from Blaze’s Tumor Paint platform and consists of an Optide (optimized peptide), which binds and internalizes into cancer cells, 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, enabling more precise, complete resection of cancer throughout surgery. Preclinical utility of Tumor Paint technology has been demonstrated in a wide range of cancer types, including brain, lung, breast, prostate, and colorectal. BLZ-100 is currently in multiple Phase 1 proof-of-concept clinical studies to evaluate the safety and imaging characteristics of BLZ-100 in solid tumor cancers.

About Blaze Bioscience

Blaze Bioscience, Inc. is a privately held biotechnology company focused on guided cancer therapy. 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 member of the executive management team at ZymoGenetics. Blaze is working to develop Tumor Paint products and Optide-based therapeutics. Surgery is first-line therapy for most solid tumor cancers and Tumor Paint products intend 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. In addition to the Tumor Paint platform, Blaze is collaborating with the Fred Hutchinson Cancer Research Center to discover and develop products based on knottin peptides as part of the Optides platform. This program extends the expertise gained in developing the Tumor Paint platform to optimized knottin peptides for therapeutic and imaging applications. For additional information, please visit www.blazebioscience.com.
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