BLAZE BIOSCIENCE POLICY:
EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Executive Summary

Blaze Bioscience, Inc. (the "***Company***") is a biotechnology company developing technology for surgical resection of tumors. As part of the 21st Century Cures Act[1], the manufacturer or distributor of one or more investigational drugs for the treatment of one or more serious diseases or conditions shall make available its policy on how it evaluates and responds to requests submitted under section 561 of the Federal Food, Drug and Cosmetic Act ("***FDCA***")[2] for provision of such a drug, namely the investigational drug tozuleristide. Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials.[3] The U.S. Food and Drug Administration ("***FDA***") regulations promoting expanded access are a suggested or recommended guidance for companies and other entities undergoing clinical trials on investigational drugs, but are not legally required. They are, among other things, intended to increase awareness and knowledge about expanded access and the procedures for obtaining investigational drugs for treatment use for eligible patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives. The regulations were also intended to facilitate the availability, when appropriate, of investigational new drugs for treatment use while protecting patient safety and avoiding interference with the development of investigational drugs for marketing under approved applications. Consequently, in the spirit of the 21st Century Cures Act, Company has established this policy on expanded access for its investigational drugs and made it available on its website.[4]

Expanded Access Policy

The following is Company's expanded access policy for its investigational drug tozuleristide intended for patients with life-threatening diseases or conditions who have exhausted approved treatment options and are unable to participate in a clinical trial involving the investigational drug tozuleristide.

(1) **Contact information:** A licensed treating physician may submit questions or requests on behalf of a patient regarding expanded access to Company

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[1] PUBLIC LAW 114–255, 114th Congress, enacted DEC. 13, 2016.

[2] Section 561(b) of FDCA Chapter V, see also Title 21 U.S.C. §360bbb, and 21 C.F.R. §312.300-320.

[3] Under FDA's current regulations, there are three general categories of expanded access:
(i) Expanded access for individual patients, including for emergency use (21 CFR 312.310)
(ii) Expanded access for intermediate-size patient populations (generally smaller than those typical of a treatment IND or treatment protocol — a treatment protocol is submitted as a protocol to an existing IND by the sponsor of the existing IND)9 (21 CFR 312.315)
(iii) Expanded access for widespread treatment use through a treatment IND or treatment protocol (designed for use in larger patient populations) (21 CFR 312.320)

[4] This policy is subject to revocation or change at any time.

investigational drugs ("***Expanded Access Request(s)***") to be evaluated in accordance with the Request Procedures in this policy. Physician Expanded Access Requests should be submitted in writing to the following to expandedaccess@blazebioscience.com and include "Expanded Access Request" in the subject.

(2) **Request Procedures:**

(a) General Criteria: Company will evaluate and respond to each Expanded Access Request individually and on a case-by-case basis. Criteria Company will use in its evaluation of whether to grant an Expanded Access Request include:

1) Adequate supply of the investigational drug tozuleristide must be available above and beyond the supply needed for Company clinical trials;
2) There is sufficient clinical data to identify an appropriate dose of the investigational drug;
3) There is a good understanding of the patient's clinical situation and investigational drug proposed use for surgery including the proposed fluorescence detection device;
4) All available therapeutic approaches for the patient's disease have been exhausted by the patient and their physicians;
5) The investigational drug is considered an "eligible investigational drug" under Section 561(B)(2) of the FDCA at the time of the Expanded Access Request;
6) Providing the investigational drug is compliant with all applicable rules and laws;
7) Appropriate Institutional Review Board/Ethics Committee and FDA authorization requested expanded access has been obtained;
8) Treating physician understands and is willing to be responsible for ensuring that the patient informed consent requirements are met; and
9) Treating physician understands and is willing to be the holder of a treatment IND with FDA.

(b) Timing of Acknowledgement: Company endeavors to acknowledge requests within ten (10) business days of receipt of an Expanded Access Request.

(c) Clinical trials: Company lists its active clinical trials on clinicaltrials.gov. Before granting an Expanded Access Request for tozuleristide, written confirmation by the treating physician that the patient is not eligible for an active Company clinical trial is needed prior to consideration of the Expanded Access Request.

As authorized by the 21st Century Cures Act, Company may revise this expanded access policy at any time. Additionally, the posting of this policy by Company shall not serve as a guarantee of access to any Company investigational drug, including tozuleristide by any individual patient or patient population. Company may deny an Expanded Access Request. Moreover, the Company granting of access to a Company investigational drug shall not serve as a guarantee of further access to a Company investigational drug in the future.