Elion Therapeutics, Inc. ("ELION") Policy for Evaluating and Responding to Expanded Access Requests

1. PURPOSE

The purpose of this policy is to describe ELION's position and process for providing its investigational antifungal drug, SF001, to patients with serious or immediately life-threatening systemic fungal infections.

SF001 is an investigational drug approved by the U.S. Food and Drug Administration (FDA) for testing in human clinical trials under an Investigational New Drug (IND). Importantly, SF001 has not been approved by the FDA under a New Drug Application (NDA) for any commercial use.

This policy may be revised from time to time to reflect advances in the development of SF001 that may occur before full marketing approval from the FDA is obtained, if ever.

2. SCOPE

ELION is currently conducting Phase 1 clinical trials with SF001 to assess its safety, tolerability and pharmacokinetics in healthy adults. In the future, ELION will conduct one or more clinical trials in patients with invasive fungal infections (IFIs) to assess the potential benefits and risks of SF001 in treating certain serious or life-threatening IFIs. During that phase of development and with agreement of the FDA, ELION may consider providing SF001 when preliminary evidence of efficacy and safety are available. In such cases, ELION may provide SF001 to patients who have completed treatment in certain ELION-sponsored clinical trials. Additionally, ELION may provide SF001 to patients who suffer from severe or immediately life-threatening IFIs under one of the following scenarios:

- ineligible or unfeasible to participate in one of ELION's clinical trials or other antifungal clinical trials, or
- ineligible to be treated with commercially available antifungal drugs, or
- unable to tolerate currently available antifungal drugs, or
- no other comparable or satisfactory alternative therapy is available to treat the IFI.

3. POLICY

3.1. Criteria

ELION is currently not accepting expanded access requests.

When sufficient preliminary evidence of efficacy and safety are available, ELION will consider requests for expanded access to SF001 using the following criteria.

1. Before considering early access, ELION recognizes that it is required to meet a minimum threshold of evidence that treatment with SF001 may benefit the patient and not present undue risk.

2. ELION recognizes that it has a responsibility to ensure that development of SF001 should not be delayed due to insufficient SF001 inventory for those patients who are participating in ELION's clinical trials.
3. The FDA, foreign regulatory agencies and Institutional Review Boards/Ethics Committees as appropriate, agree with ELION that access to its investigational drug, SF001 is permitted.
4. Any access program conducted by ELION will comply with US federal laws and regulations as well as the laws and regulations of any other country involved in the expanded access program.

3.2. Contact Information and Procedure for Requests

For information on ELION's Expanded Access Program, please contact ELION by phone at +1 (443) 423-1785 or email at info@eliontx.com.

Requests for expanded access should include the following information and be submitted to info@eliontx.com:

- Name
- Contact Information
- A brief description of the need for SF001 expanded access without use of identifiable patient information

ELION will make every effort to acknowledge receipt of expanded access requests within 48 hours of receipt.

3.3. Exclusions

Phase 1 trials of investigational drugs are exempt from the registration and results submission requirements for the *ClinicalTrial.gov* registry (HHS 2016).

4. References

Food and Drug Administration, *Expanded Access to Investigational Drugs for Treatment Use. Questions and Answers*, Draft Guidance for Industry (November 2022, Revision 1).

Health and Human Services, Federal Register Final Rule, *Clinical Trials Registration and Results Information Submission*, 81 FR 64982, September 21, 2016.