INDIVIDUAL PATIENT EXPANDED ACCESS POLICY

1 PURPOSE

IGM Biosciences has implemented this policy for the purpose of providing a process for the intake and review of Individual Patient Expanded Access (IPEA) requests for IGM Biosciences investigational drugs under clinical development.

2 SCOPE

This policy applies to the provision of access to investigational drugs under clinical development by IGM Biosciences.

3 POLICY STATEMENT

IGM Biosciences is committed to the development of safe and effective medicines for the treatment and prevention of human disease. IGM Biosciences also recognizes that wherever appropriate, use of an investigational drug by a patient should be in the context of a well-designed clinical trial. Some patients, however, may have exhausted all standard treatment options and may be ineligible to participate in an ongoing clinical trial.

IGM Biosciences has established an IPEA Committee to consider requests for individual patient access to IGM Biosciences' investigational drugs, outside of clinical trials, where appropriate. The IPEA Committee is composed of medical and drug development professionals who are familiar with the investigational drug(s) under development at IGM Biosciences. IGM Biosciences strives to make decisions regarding expanded access after thorough and careful consideration of the risks and benefits relative to each situation. Key factors that will be considered include patient's eligibility criteria, the status of the program, and all available relevant medical and scientific information. IGM Biosciences is committed to making these decisions as ethically and fairly as possible, while minimizing risks to current and future patients.

4 POLICY PRINCIPLES

IGM Biosciences recognizes that in some circumstances, access to investigational drugs may be warranted provided the following are met:

- Drug is unapproved and in active development.
- Drug has completed first in human testing.
- Adequate drug supply for individual patient expanded access use is available.
- There is strong scientific rationale to support the potential benefit of the investigational drug in the proposed indication, recognizing that the strongest evidence of possible benefit is the prior demonstration of clinical activity in the same or similar clinical situation.
- Providing a patient with access to the investigational drug is in compliance with local laws and regulations governing such programs.
- A treating physician has requested access on behalf of a patient and agrees to comply with the responsibilities in section 6.
- Once a regulatory agency has approved a medicine for commercial use, existing expanded access programs will be phased out.

5 PATIENT ELIGIBILITY CRITERIA

IGM Biosciences will consider expanded access to an investigational drug for individual patients only if they meet the following criteria:

- Patient suffers from a serious or immediately life-threatening disease and requires continued investigational drug treatment for his or her well-being.
- There is no comparable or satisfactory alternative therapy or treatment available to the patient.
- Patient is unable to participate in an ongoing clinical study of the investigational drug.
- Patient is willing to give informed consent that they understand the risks of receiving the investigational drug. For patients unable to give informed consent, the consent of a legally authorized representative, as well as assent for minor patients, will be obtained by the sponsor physician, as applicable.
- The potential benefit justifies the potential risks of the treatment, and those potential risks are not unreasonable in the context of the disease or condition to be treated.
- The request for access to the investigational drug comes from the patient's licensed, qualified physician.

6 TREATING PHYSICIAN CRITERIA AND RESPONSIBILITIES

The treating physician requesting access to an investigational drug for their patient must meet the following criteria:

- The physician must be properly licensed and fully qualified to administer the product.
- The physician must comply with any applicable country-specific legal and regulatory requirements related to providing an investigational product under Expanded Access.
    - In the US, IGM Biosciences follows the FDA guidance (Form FDA 3926) for providing physicians with investigational drug for treating individual patients.
- The physician must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition.
- The physician must have the approval of the Institutional Review Board (or equivalent ethics committee that approves and monitors clinical trials involving humans) at the patient's treating hospital or clinic.
- The physician must agree to any IGM Biosciences requirements in terms of medical criteria, safety reporting, drug supply/use, protection of intellectual property and public disclosure/publications. A treating physician may submit questions or requests regarding expanded access to IGM Biosciences (expandedaccess@igmbio.com).

7 IPEA PROCESS

If expanded access is felt to be the best option for a patient, the treating physician should contact IGM Biosciences (expandedaccess@igmbio.com) to make a formal request on behalf of the patient.

The request for access can only be considered if the patient's treating physician is committed to and supportive of the requested treatment. Qualified physicians seeking access on behalf of a patient will be instructed to submit sufficient, relevant redacted medical information about the intended patient to assess the potential risks and benefits of the investigational drug. Ensure that all PHI (protected health information) has been removed prior to sending. All patient information received will be kept confidential per local regulations from country of origin.

IGM Biosciences will confirm receipt of IPEA requests within 2 business days and a decision will be made and communicated as soon as possible. Requests originating in countries outside the United States of America are handled according to regulatory requirements and laws of the country where the request originates.

All requests received will be reviewed on a case-by-case basis by the IGM Biosciences IPEA Committee which has sole approval authority.

8 ADDITIONAL INFORMATION FOR ONGOING CLINICAL TRIALS

Information regarding IGM Biosciences' ongoing clinical trials and development program may be found on the IGM Biosciences company website under Pipeline & Programs.

9 CONTACT FOR QUESTIONS

Questions regarding this policy may be directed to IGM Biosciences at expandedaccess@igmbio.com.