Expanded Access Program

About SanBio Group

SanBio Group is a regenerative medicine company with cell-based programs focused on neurological disorders in various stages of research, clinical development, and commercialization. The Company's lead asset, SB623, is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury (TBI).

Clinical Trials

The clinical development process is extremely complex and challenging, and requires an investigational medicine to be tested in a laboratory as well as in rigorous, controlled testing in a sufficient number of humans in multiple clinical trials. We conduct clinical trials independently and in collaboration with industry partners to assess the safety and efficacy of our investigational medicines. If the clinical trial proves successful and the investigational medicine is proven to be safe and effective, we can submit this data to the U.S. Food and Drug Administration (FDA) or other regulatory authorities for review. If the investigational medicine is then approved by a regulatory authority, we are able to provide patients with access to these medicines from their physician.

For most patients, the only way to access investigational medicines is to participate in clinical trials. To learn more about available clinical trials, visit clinicaltrials.gov and search by company, disease, or medicine.

Expanded Access / Compassionate Use

As described by the FDA, expanded access, sometimes called "compassionate use" or other similar names, is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. In extremely rare cases when patients are not eligible for clinical trials and have no available treatment options or have undergone appropriate standard treatment without success, regulators, such as the FDA, may grant permission for SanBio to provide a treating physician with an unapproved medicine.

Because it is not known during clinical development and prior to regulatory authorization whether an investigational medicine is safe or effective, expanded access may present numerous risks for the patient and for the clinical development program. For patients, expanded access may carry potential safety risks or a false sense that the medicine will provide benefit. For the clinical development program, it can delay or jeopardize the approval of a new medicine.

For additional information from the FDA about expanded access in the U.S., click here.

Expanded Access Eligibility Criteria

Please note that at this time, the medicine for use in any patient in the US is not available and this information is provided as general information. The below criteria are those that SanBio would consider in determining whether to offer expanded access for any of their investigational programs, when the medicine is available . However, SanBio cannot guarantee that an expanded access program will be available. And, if an expanded access program is offered, SanBio cannot guarantee that the investigational medicine will be available to a particular patient.

1) The patient has a serious or immediately life-threatening disease or condition.
2) There is no comparable or satisfactory alternative therapy for the disease or condition, or the patient has undergone appropriate standard treatment without success.
3) The patient is ineligible for participation in any ongoing clinical study of the investigational medicine.
4) There is sufficient evidence or understanding of a potential patient benefit from the use of the investigational medicine to justify its potential risks.
5) The medicine must be part of an active and ongoing development process, and expanded access would not interfere with its development or marketing approval for the treatment indication.
6) There is an adequate supply of the medicine to perform necessary clinical studies as well as provide expanded access.

If all these conditions are met, SanBio will consider expanded access requests from treating physicians subject to local/national laws and regulations.

Patients seeking expanded access to SanBio's investigational medicines should consult their physician. The request for expanded access must be made by the patient's treating physician, unsolicited by SanBio or any other individual or organization. This request will provide evidence that the patient will have continual access to the level of medical supervision appropriate to safeguard the patient while being exposed to an experimental therapy. Procedures for acknowledging receipt by SanBio of a request for expanded access may take up to one month.

All requests will be evaluated in a fair, unbiased manner. For patients that meet this criteria, treating physicians may make a request at: clinicaltrials@sanbio.com.

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