Expanded Access Policy for SER-155

Clinicaltrials.gov ID: NCT04995653

Seres Therapeutics ("**Seres**") believes that the best approach to enable all patients to access medicines is through established regulatory approval processes and commercial availability of that medicine. However, an expanded access program (also known as "**EAP**") and sometimes called "compassionate use" program, is a potential way for a patient with an immediately life-threatening or serious disease or condition to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapeutic options are available.

As part of our sustained commitment to patients, Seres may be able to provide access to an investigational medicine, under certain limited conditions, through our EAP. Seres' main objective when initiating an EAP is to equitably serve the patient community with compassion and dignity. Seres aims to accomplish this by thoughtfully balancing requests for treatment with the need to protect patient safety and ensure ethical and compliant access to medications.

It is important to remember that investigational products have not been approved or cleared by regulatory bodies like the FDA for their specific use. Doctors and patients should consider all possible benefits and risks when seeking expanded access to an investigational product.

Seres will consider granting expanded access to investigational drug only if the following criteria are met (along with other defined eligibility parameters for disease under study):

- Sufficient clinical data from its existing clinical trial(s) exists to assess preliminary safety and efficacy.
- The patient has a serious or life-threatening illness with no comparable or satisfactory alternative therapies; the patient is no longer responsive to, or able to tolerate, available therapies; or the patient has a relevant medical condition, that in the opinion of the physician, makes an approved agent unsuitable for the patient.
- The patient is ineligible for, or otherwise unable to, participate in a clinical trial.
- The patient has a disease for which there is sufficient evidence indicating that the potential benefits of expanded access outweigh the known or anticipated risks to the patient (and such risks are not unreasonable in the context of the disease or condition to be treated).
- The investigational drug is currently in clinical development (that is, it is currently being studied in humans) and providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical trials.

If you are a patient or healthcare provider interested in learning more about SER-155 or are interested in Seres clinical studies, or EAP, please contact us at:

Email: clinicalstudies@serestherapeutics.com
Phone : 617-945-9626, option 3

Seres will acknowledge receipt of Expanded Access inquiries within 2 business days of receipt.

Disclaimer

There is no guarantee of access to an investigational medicine for any individual. Seres may revise or stop this program at any time.

This information is not intended to replace the advice of a healthcare professional and should not be considered as a recommendation. Patients should always seek medical advice before making any decisions on their treatment. Healthcare professional should always refer to the specific labeling information approved for the patient's country. The information on the website should not be considered as prescribing advice.