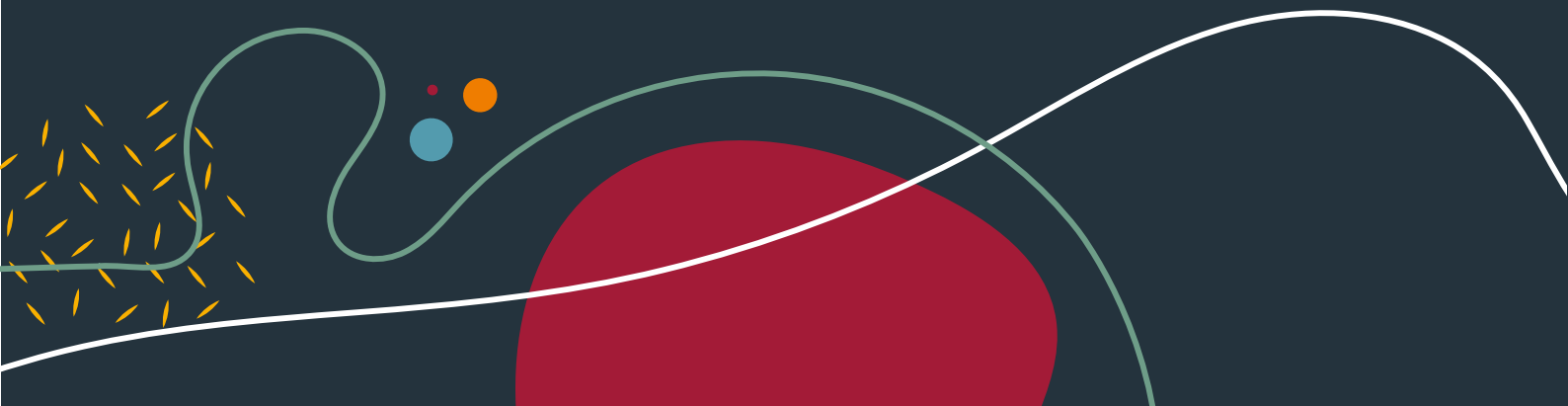
istesso

EXPANDED ACCESS AND COMPASSIONATE USE POLICY

Implemented by Istesso Limited (“the Company”) on 7th October 2020



Background

Expanded access is the use of an investigational new drug prior to approval, and outside of a clinical trial in patients, for the diagnosis, monitoring, or treatment of a serious disease or condition. Compassionate use refers to treatment options that allow the use of a medicine that has not been authorised by the relevant national health authority. Expanded access and compassionate use (together "Pre-Approval Access") are important tools in healthcare, providing they are used ethically and responsibly.

Our position

We are privileged to collaborate with clinical investigators and with patients who participate in our studies to develop new, safe and effective therapies. We believe this approach will serve patients who could be helped by the therapies we are developing. However, we also understand that there are seriously ill patients who will not be eligible for our clinical trials and may not have options for alternative therapies, including investigational therapies in trials being conducted by other sponsors. In these circumstances, we will consider providing a requesting physician with pre-approval access to a specific investigational drug, for the treatment of an individual patient outside of a clinical trial, when certain conditions are met.

We follow several key principles when considering provision of Pre-Approval Access to investigational medicines:

a) All requests will be considered fairly and equitably

b) Patients are not put at risk of unnecessary harm

c) Sufficient understanding of the potential benefits and risks of the investigational medicine has been established through the conduct of a rigorously designed, scientifically and medically sound development program

d) Granting pre-approval access will not jeopardize the development program that may lead to broader public access through marketing authorization

e) Fulfilment of pre-approval access fully complies with applicable laws and regulations

Conditions for consideration of Pre-Approval Access:

1) The patient has a serious of life-threatening illness or condition
2) There must be an unmet medical need; the patient is either no longer responsive to, or no longer able to tolerate, any available treatment option
3) The patient is ineligible for, or cannot participate in, a clinical trial
4) The requested investigational drug is in active clinical development
5) Sufficient scientific and clinical evidence demonstrates that the benefits of the investigational drug outweigh the risks
6) Sufficient data are available to determine an appropriate dose and schedule for the patient's specific condition
7) Providing access to the investigational drug will not jeopardise the initiation, conduct, or completion of clinical trials and the overall development program to support registration of the product for broader patient access
8) Adequate supply of the investigational drug is available
9) The treating physician making the request is qualified to administer the investigational medicine and to adhere to applicable laws and regulations

We continually evaluate the benefit-risk profile of each of our investigational drugs based on evolving clinical data. Each compound under development is different and the fact that one investigational drug is made available for the treatment of a particular patient does not mean it will be made available in response to other requests on behalf of other patients whose circumstances and medical histories may be different, or that a different investigational drug will be made available under our policy. In general, we will not provide access to an investigational drug until sufficient preliminary safety and efficacy information has been obtained in clinical trials.

Application

This policy applies to Istesso Ltd and its subsidiary companies [1].

Notes

We may revise this policy at any time. The posting of this policy does not serve as a guarantee of access to any specific investigational drug for any patient.

The requesting physician must provide detailed information to facilitate evaluation of a request. In addition, the requesting physician must agree to obtain appropriate regulatory and ethics committee approvals and comply with regulatory obligations, including obtaining patient consent, patient monitoring and safety reporting.

Physicians seeking pre-approval access for patients with no alternative treatment options should submit their requests to EAP@istesso.co.uk. We regularly monitor this mailbox and will use our best efforts to acknowledge each submitted request within 10 business days after receipt. Requests will be considered on a case-by-case basis and in each case our decision will be final.

Additional information may be obtained from the U.S. Food and Drug Administration by clicking **here.**

Further information on our clinical trial can be found **here.**