Expanded Access and Compassionate Use Policy

Istesso discovers and develops pioneering medicines that enhance the body's ability to repair. Our ambition is to develop new medicines that make a lasting impact on patients' lives, raise treatment expectations and change the way people think about chronic disease.

We conduct clinical trials to assess the efficacy and safety of an investigational medicine before obtaining regulatory approval as part of our work. In doing so, we collaborate with Healthcare Professionals (HCPs), patients and healthy volunteers.

So that we can bring medicines to those who need them, we focus our resources on conducting our trials effectively. This gives us the best chance of achieving the regulatory approvals needed to market and make new medicines accessible to patients.

A company may consider providing a treating HCP with an unlicensed medicine where patients have serious or life-threatening conditions, cannot join a clinical trial, or have no suitable alternative treatments. This use of an unlicensed medicine outside a clinical trial is commonly referred to as "compassionate use" or "expanded access".

Consideration for expanded access depends on the following conditions:

- The patient has a serious life-threatening illness or condition;
- 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;
- The patient is ineligible for, or cannot participate in, a clinical trial;
- The requested investigational drug is in active clinical development;
- Sufficient scientific and clinical evidence demonstrates that the benefits of the investigational drug outweigh the risks;
- Sufficient data are available to determine an appropriate dose and schedule for the patient's specific condition;
- Adequate supply of the investigational drug is available;
- The treating physician/HCP making the request is qualified to administer the investigational medicine and to adhere to applicable laws and regulations.

When Istesso considers the provision of our unlicensed investigational medicines on the grounds of "compassionate use" or "expanded access, we commit to ensuring that:

a) All requests will be considered fairly and equitably;
b) Patients are not put at risk of unnecessary harm;
c) We have a deep enough understanding of the potential benefits and risks of the investigational medicine through the conduct of a rigorously designed, scientifically and medically sound development program;
d) Granting unlicensed 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.

The benefit-risk profile of each investigational drug is reviewed on a regular basis. As each drug in development is unique, the availability of one investigational drug for a particular patient does not guarantee it will be offered to other patients with different medical histories or circumstances. Similarly, this does not imply that a different investigational medicine will be provided under our policy. In general, we do not grant access to an investigational drug until sufficient preliminary safety and efficacy data have been collected from clinical trials.

Notes:

This policy is subject to review 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/HCP must provide detailed information to facilitate evaluation of a request. In addition, the requesting physician/HCP 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 and HCPs seeking unlicensed access for patients with no alternative treatment options should submit their requests to EAP@istesso.co.uk. This mailbox is regularly monitored, and we will do our best to acknowledge each submitted request within 10 business days after receipt. Requests will be considered on an individual 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 trials can be found here*.*