Request of Early Access to Investigational Medicinal Products_Version 02/February 2021

Kedrion's mission is to discover, develop and distribute innovative therapies to treat people suffering from rare and debilitating conditions. To do this, we conduct clinical trials to evaluate the safety and efficacy of Investigational Medicinal Products (IMPs) to collect clinical data to support the approvals from regulatory authorities and make the product commercially available.

For patients with serious or life-threatening disease conditions, for which no satisfactory approved therapies are available and participation in an on-going clinical trial is not an option, Kedrion may consider providing an IMP outside the frame of a clinical trial in compliance with applicable laws and regulations. The use of an IMP outside of a clinical trial is known as "Early Access", "Pre-Approval Access" or Expanded Access.

Kedrion will consider granting Early Access to an investigational medicinal product only if all the following criteria are met:

- Disease/condition being treated is life threatening or seriously debilitating, no approved effective treatment options exist and the product is not commercially available in the country of the requester.
- Patient is ineligible or unable to participate in any on-going clinical trial.
- Providing the investigational medicine for the requested use will not interfere with the initiation, conduct, or completion of clinical trial.
- Along with the health care provider and medical specialists, Kedrion will take into consideration what is currently known about the investigational drug and weigh the potential benefits and risks of providing the investigational drug.
- All requests must be unsolicited and made by the Health Care Professionals (HCPs) treating the patient.

In addition, the following aspects will be taken into account:

- Evidence of potential benefit for the patient requesting the treatment (context of disease or condition to be treated).
- Patient must meet all medical criteria established by Kedrion medical experts working on the product development program.
- Early Access treatment will only be available in countries with appropriate medical oversight.

- Treating HCP must confirm that patient meets all medical criteria and commits to report any adverse events.
- Adequate supply of IMP is available.

HCPs treating patients who meet Kedrion's criteria, can submit their request by clicking on this link. Kedrion may request additional patient information in order to evaluate each request (evaluated on a case by case basis). Kedrion will acknowledge receipt of each request within ten (10) business days.

Kedrion cannot guarantee that an Early Access Program (EAP) will be available for every investigational product. If an EAP is available, Kedrion cannot guarantee that all requests will be granted and approvals will be at Kedrion's discretion. After confirmation that a patient meets all inclusion/exclusion criteria, it will be at Kedrion's discretion to include the patient in a Cohort (such programs are managed by Kedrion and follow a specific protocol, which is developed in consultation with a regulatory agency for the use of the investigational medicine) or provide the treatment to an individual (when allowed by local regulations and Kedrion's Early Access criteria). Individual patient Early Access is managed by the patient's physician.

Once a request is acknowledged, Kedrion will contact the requesting HCP. All participating HCPs must comply with the following:

- any applicable country-specific laws and regulations, including obtaining appropriate regulatory and Ethics Committee / Institutional Review Board (IRB) approvals, medical importation requirements, patient consent, patient monitoring and safety reporting.
- any Kedrion requirements regarding obtaining patient's informed/data handling consent including sharing safety and monitoring data (e.g. outcome, baseline and historical data) with Kedrion.

All subject data will be treated anonymously.

If allowed by country-specific laws and regulations, a site specific agreement with the treating center or hospital will be signed detailing the management of the Early Access Program.

When the IMP provided through the Early Access Program is approved by regulatory authorities and becomes available commercially, all existing Early Access programs in the concerned country/countries will be phased out.

Kedrion can also terminate the Early Access Program in the event it is no longer able to supply the product, or for any other reason, as Kedrion deems appropriate.

Additional information about Kedrion Early Access Programs in the U.S. is available on clinicaltrials.gov.