KOWA
RESEARCH INSTITUTE, INC.

K-001 Expanded Access Policy

Kowa Research Institute, Inc. ("KRI") undertakes clinical trials of investigational drug products. An "investigational" drug product is one that is currently being tested in clinical trials and has not yet been approved for marketing by the United States Food and Drug Administration (FDA).

KRI believes that the best way to access our investigational drug K-001 is through participation in a K-001 clinical trial. However, in rare circumstances, a patient may not meet criteria for participating in an ongoing K-001 clinical trial, and may have exhausted all other treatment options. In these cases, the patient's treating physician may contact KRI to seek special access to the investigational drug K-001 through KRI's K-001 expanded access program.

Generally speaking, KRI does not provide expanded access for products that are in an early phase of clinical development, such as K-001. As the development program of K-001 progresses, KRI will consider expanded access requests for K-001 on a case-by-case basis, in a fair and equitable manner, based on the following criteria:

- The patient has a serious disease or condition, or whose life is immediately threatened by his/her disease or condition
- There is no comparable or satisfactory alternative therapy to treat the disease or condition
- There are no other treatment options, including participation in clinical trials of other investigational drugs
- There is sufficient scientific evidence that the potential patient benefit from the investigational treatment outweighs the potential risks of the treatment
- Providing the investigational drug will not interfere with clinical trials that could support the development of the investigational drug or marketing approval for the treatment indication
- There is adequate supply to support both the ongoing clinical trials and previously approved expanded access requests
- There is a regulatory mechanism in the country or region that allows and supports expanded access programs, and there are plans to market the product, once approved, in that country

or region. The expanded access program must be discontinued as soon as feasible when approval of the drug is achieved in the country or region

A patient that meets all the criteria outlined above may submit a K-001 expanded access request to KRI through a duly licensed and qualified physician in charge of their care. Requests must contain an explanation of how the patient meets all the criteria listed above, and should include sufficient supporting information. KRI reserves the right to request additional information, including patient history, to fully evaluate the request. The physician must submit the request by contacting ExpandedAccess@kowaus.com. KRI will acknowledge such requests within 7 business days of receipt. The physician making the request must be licensed and qualified to administer K-001.

More information about ongoing clinical trials can be found at https://clinicaltrials.gov/.

This policy shall not serve as a guarantee of access to any KRI investigational drug.
KRI may revise this policy at any time.