



## **EXPANDED ACCESS POLICY**

Krystal Biotech, Inc. (Krystal) is dedicated to developing transformative new gene therapies to combat some of the world's most serious skin diseases, providing hope to patients, patient families and communities. Consistent with Krystal's mission to bring innovative medicines to patients with serious or life-threatening skin conditions, we are focused on enrolling and conducting the clinical trials necessary to gain regulatory approvals to make our medicines available broadly to patients as quickly as possible. We are privileged to collaborate with clinical investigators and patients who participate in our studies to develop these new, safe and effective therapies. At the same time, we understand that there are patients who will not be eligible for our clinical trials and may not have options for effective alternative therapies. In these circumstances, Krystal will consider providing a requesting physician with pre-approval access to a specific Krystal investigational drug for the treatment of an individual patient outside of a clinical trial when certain conditions are met. These conditions include, but are not limited to, the following:

- The patient's serious or life-threatening condition limits their ability to comply with certain clinical trial requirements, such as travel;
- The investigational drug is in active clinical development with sufficient data available to determine an appropriate dose and schedule for the patient's specific condition;
- A benefit-risk analysis, based on both the available clinical data as well as the requesting physician's assessment of the individual patient's condition and medical history, supports making the investigational drug available;
- Making the investigational drug available will not negatively impact or delay the conduct of clinical trials, regulatory review, or approval of the investigational drug for broader patient access; and
- Adequate supply of the investigational drug is available.

We continually evaluate the safety and efficacy profile of each of our investigational drugs based on evolving clinical data. Each disease, patient, and investigational drug under development is unique, and as such, requests will be considered on a case-by-case basis.

Krystal is committed to evaluating all requests in a fair and equitable manner. All requests must be submitted by the patient's treating physician; Krystal may require more detailed information in order to fully evaluate a request. 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. Each request will be given careful consideration by Krystal, whose decisions are final.

Physicians seeking pre-approval access for patients with no alternative treatment options should submit their requests to [expandedaccess@krystalbio.com](mailto:expandedaccess@krystalbio.com). We regularly monitor this mailbox and will use our best efforts to acknowledge each submitted request within 5 business days after receipt.