

## **Expanded Access/Compassionate Use Policy**

### **Updated May 6, 2020**

Insméd is dedicated to improving the lives of patients battling serious and rare diseases. These patients sometimes need medical products that are not yet approved for the treatment of their disease or have been approved but may not be commercially available in their country. Insméd's Expanded Access Programs ("EAPs") can help to address these needs by making certain investigational medical products (e.g., drug or medical device) or unapproved products (unlicensed medicines) available to eligible patients, in accordance with applicable local laws.

To be considered for EAP/Compassionate Use,

- The patient must have a serious or life-threatening condition for which there are no alternative available treatments for the condition or all available treatments have been tried or are contraindicated.
- The requesting physician is qualified and experienced and agrees to comply with local laws and regulations.
- The patient does not meet criteria for a clinical trial or is unable to participate.
- The requesting physician and Insméd Medical team agree the potential benefit outweighs the potential risk to the patient.
- Fulfillment of the request for the investigational product will not interfere with completion of the ongoing registrational clinical trials and/or the overall development program.
- Medical criteria specific to the disease defined by the Insméd Medical team must be met.
- Country laws and regulations permit patient use of the investigational or unapproved product.

Upon receipt of all necessary information, all requests for Expanded Access/Compassionate Use are reviewed and evaluated promptly by Insméd Medical experts, where applicable. Insméd is committed to a fair and impartial evaluation of each request for access to investigational or unapproved products. All decisions are based on clinical evaluation and criteria listed above.

To submit a request for Expanded Access/Compassionate Use, physicians should email [compassionateuse@insmed.com](mailto:compassionateuse@insmed.com)

Receipt of a request will be acknowledged within 5 business days.