# Pulmongene's Expanded Access Policy

## Overview

Pulmongene is a clinical-stage biotechnology company dedicated to developing innovative therapies for pulmonary, fibrotic, and autoimmune diseases, including idiopathic pulmonary fibrosis (IPF). Through advanced translational research and rigorous clinical development, Pulmongene aims to bring safe and effective therapies to patients worldwide and obtain regulatory approvals from authorities such as the U.S. Food and Drug Administration (FDA), the China National Medical Products Administration (NMPA) and other regulatory authorities. Pulmongene conducts clinical trials to evaluate investigational medicines in patients, with the goal of generating robust data on safety and efficacy to support regulatory approval and broader patient access. Investigational medicines are products that have not yet been approved by regulatory authorities; their safety and efficacy have not been fully established.

## Expanded Access

Expanded Access (EA), sometimes referred to as compassionate use, is a potential pathway that allows patients with serious or immediately life-threatening diseases to gain access to investigational therapies outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

The FDA considers Expanded Access potentially appropriate when all the following apply:

- Patient has a serious disease or immediately life-threatening disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational product will not interfere with clinical trials that could support a medical product's development or marketing approval for the treatment indication

For more information about Expanded Access in the United States., please visit the FDA website: https://www.fda.gov/news-events/public-health-focus/expanded-access.

## Pulmongene's Current Expanded Access Policy

At this stage of development, Pulmongene is focused on conducting well-controlled clinical trials to establish the safety and efficacy of its investigational therapies and to

support their timely development and potential regulatory approval.

Given the early stage of clinical development and considerations related to patient safety, investigational product supply, and the need to ensure the integrity and timely completion of clinical trials, Pulmongene does not currently offer Expanded Access or similar programs.

For patients seeking access to Pulmongene's investigational therapies, participation in an ongoing clinical trial remains the most appropriate and recommended pathway. Information on Pulmongene-sponsored clinical trials is available on Company's website or on ClinicalTrials.gov.

Pulmongene will periodically reassess this policy as its clinical development program advances, in accordance with the 21st Century Cures Act. This policy may be revised if circumstances change with respect to investigational product supply, the stage of clinical development, or the regulatory status of its investigational medicines.

**Contact Information**

Patients seeking information about Pulmongene's clinical trials are encouraged to consult their treating physician or specialist. Healthcare providers with questions regarding this policy or Pulmongene's clinical development program may contact us at:

contact@pulmongene.com

**Policy Updates**

This policy is reviewed periodically and updated as appropriate. Any revisions will be reflected in the "Last Reviewed" date above and made publicly available in a timely manner.

*This policy is published in accordance with Section 561A(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-0) and FDA regulations at 21 CFR Part 312, Subpart I.*