

Expanded Access Policy

AC Immune SA, a clinical-stage biopharmaceutical company, is a global leader in developing precision medicine for neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease, and certain rare indications. AC Immune conducts human clinical trials to generate safety and efficacy data required for regulatory approval to make our medicines available broadly to patients as quickly as possible. The data from these trials will be used to support marketing applications submitted to the U.S. Food and Drug Administration (FDA) and other regulatory authorities.

Patients facing serious or life-threatening diseases who are ineligible or unable to participate in a clinical trial and may not have options for alternative therapies, may consider expanded access programs for unapproved therapies. Section 3032 of the 21st Century Cures Act aims to make it easier for patients to understand a drug manufacturer's policies regarding availability of its investigational new drugs for expanded access and how to request access. Specifically, the Cures Act requires pharmaceutical companies or distributors to have publicly accessible expanded access policies for drugs treating serious or life-threatening conditions. Expanded access, also known as compassionate use, is a regulatory pathway in which patients may gain access to an investigational therapy outside the context of participation in clinical trials.

We support the need for expanded access programs and our goal is to provide expanded access to study drugs at the appropriate time in development. The following considerations are evaluated to determine whether to provide expanded access for our investigational products, including the existing evidence on the drug's safety and effectiveness, the availability of sufficient supplies and the impact on any of AC Immune's ongoing clinical development activities.

Expanded Access Policy

AC Immune has determined that given the stage of development of its products, its investigational drugs should be studied in patients as part of controlled clinical trials designed to obtain data on safety and efficacy that may be used to support approval of the product and subsequent wider accessibility to patients. We encourage patients to speak with their physicians and to participate in the available clinical trials. At this time, AC Immune cannot provide investigational drug outside of clinical studies, except under specific circumstances at the request of the treating physician for patients with serious or life-threatening conditions who cannot join a clinical trial and for whom approved alternative therapies are not indicated. The company will reevaluate this policy when sufficient safety and efficacy information has been obtained in controlled clinical trials.

Contact Details

If you have any questions about our investigational products, please contact AC Immune via email at: info@acimmune.com.

Licensed healthcare providers may request additional information about AC Immune's clinical trials or expanded access policy via email at: info@acimmune.com.

Request Procedures

AC Immune is not currently making its investigational products available on an expanded access basis anywhere in the world. In the event that AC Immune decides to consider making

its investigational products available through expanded access programs, requests for expanded access must come from a treating physician.

For Additional Information

For more information on AC Immune's clinical trials, search "AC Immune" at clinicaltrials.gov. Additional information on Expanded Access may be obtained by visiting the U.S. Food and Drug Administration at: [Expanded Access: Information for Physicians](#).

The publication of this policy by AC Immune is not a guarantee of access to any specific investigational drug by any individual patient. AC Immune may revise this expanded access policy at any time.