Expanded Access to Investigational Drugs for Individual Patients

When patients with serious, chronic, or life-threatening diseases have exhausted all approved treatment options and are not eligible to participate in an existing clinical trial they, in conjunction with their physicians, may seek access to novel investigational therapies before they have been approved or become available in their country. Expanded Access Programs (also known as EAPs) provide access to an investigational clinical products outside of a clinical trials before the therapy has been given marketing approval by the country's regulatory agency. An EAP is sometimes referred to as a "Compassionate Use Program" or "Individual Patient Expanded Access (IPEA)". The following refers specifically to individual patient INDs for Replimune's investigational immunotherapies and does not include corporate sponsored expanded access protocols.

Replimune's Commitment to Expanded Access

At Replimune, we are committed to helping patients defeat their cancer by aiming to bring investigational immunotherapies to market, under a marketing authorization, as quickly as possible. Prior to a marketing authorization, the primary way for patients to access our investigational immunotherapies is within the context of a clinical trial; to learn more about available Replimune clinical trials and our investigational immunotherapies, visit https://replimune.com/clinical-trials/. Replimune also recognizes that some patients may have cancer types where a high unmet need exists and may not qualify for our ongoing clinical trials.

To address unmet needs in patients that have exhausted approved therapies and do not qualify for an existing Replimune clinical trial, Replimune has established an IPEA process in accordance with FDA recommendations and standard guidance for companies/sponsors. The IPEA process allows Replimune to consider requests for individual patient access to Replimune's investigational immunotherapy, RP1, outside of Replimune sponsored clinical trials, e.g. in indications or settings where RP1 has shown initial signs of activity yet the patient does not qualify for one of its ongoing clinical trials, or where a strong scientific rationale exists.

Criteria for Replimune's IPEA

Replimune strives to make decisions regarding IPEA requests after thorough and careful consideration of the patient's eligibility criteria, the status of the program, and other available relevant medical and scientific information. Replimune is committed to making these decisions as ethically and fairly as possible, while minimizing risks to patients. Our decision will be guided in part by the following criteria which must be met prior to consideration for IPEA:

- The patient has a serious condition or immediately life-threatening condition or illness
- There are no currently approved therapies
- The patient is not eligible for enrollment in a Replimune clinical trial
- The potential benefits of the investigational therapy outweigh the potential risks to the patient
- There is a strong scientific rationale for the proposed approach

- The physician must be properly licensed and fully qualified to administer the product (i.e. previous/current experience administering RP1 or other intra-tumoral delivery of oncoloytic virus).
- Adequate supply and availability of the investigational therapy exists
- Local laws and regulations where the patient will be treated permit such use

IPEA Application Process

A treating physician may click here to obtain an application form. The completed form or any questions should be submitted via email to: ExpandedAccess@replimune.com

Medical professionals at Replimune will evaluate each request in a timely manner. We will strive to provide a decision within 7 business days, assuming all required information to enable a decision has been provided.