Alpheus Expanded Access (Compassionate Use) Policy

Introduction

For new medicines and medical devices to be licensed for use, companies must demonstrate their safety and effectiveness through clinical trials. Patients participating in these trials must meet specific criteria and the data collected is compiled and summarized for final trial reporting to regulatory agencies, such as the United States Food and Drug Administration (FDA). Once enough data is collected to support the safety and effectiveness of an investigational treatment, the regulatory agency will consider all available data to determine if the investigational treatment may be approved for use. Prior to this approval, there may be some cases where patients and clinicians seek access to investigational agents, requiring regulators to review each specific case to determine whether the requirements for expanded access are met. This individual use of an investigational product or treatment is often called "compassionate use" or "expanded access" but may go by other names. We refer to these uses collectively as "compassionate use."

Currently expanded access is not available for the CV01 Sonodynamic Therapy system, Alpheus' priority is to conduct clinical trials in order collect the necessary data to determine the potential risks and benefits of treatment with the CV01 Sonodynamic Therapy system. The policy outlined below describes Alpheus' policy on expanded access, including the criteria for evaluating whether expanded access for the CV01 Sonodynamic Therapy system is appropriate.

Purpose

The purpose of this document is to describe the criteria for evaluating whether expanded access for the CV01 Sonodynamic Therapy system is appropriate outside of a clinical trial.

Background

Expanded access for the CV01 Sonodynamic Therapy system (compassionate use) is not currently available given the early stage of clinical development.

This policy defines the Alpheus process to provide access to the CV01 Sonodynamic Therapy system for patients, including the eligibility criteria for the patient and treating physician, how to make a request, and timeline for consideration of the request by Alpheus.

In general, expanded access for the CV01 Sonodynamic Therapy system must be in accordance with all local laws and regulations governing compassionate use programs, including Alpheus policies and procedures. In addition, expanded access for the CV01 Sonodynamic Therapy system may no longer be provided once it becomes commercially available, if Alpheus discontinues clinical development of the product, or if supplies are insufficient to support both the current clinical development plan and expanded access.

Expanded Access Eligibility

The following criteria are required for consideration of expanded access for the CV01 Sonodynamic Therapy system.

- Serious or life-threatening disease with no alternative options or clinical trials available.
    - Other medical criteria may be required upon discussion with Alpheus.
- Treating physician has direct experience with the CV01 Sonodynamic Therapy system.
- There must be sufficient data to support the disease to be treated, the proposed duration of use for the device, and the potential benefit and risk assessment based on the activity and safety data collected thus far in ongoing or completed clinical trials. These data may not be available until the start of a Phase 3 program.
- The compassionate use of the investigational product will not interfere with or compromise the clinical development program; therefore, patients being considered for compassionate use must not be otherwise eligible for a clinical trial open for enrollment at the proposed treating site, or another potential treating site in close geographic proximity to the patient.
- Adequate supply of or access to the CV01 Sonodynamic Therapy system, and the required components for individual patient use, exist to support the compassionate use treatment in addition to the ongoing clinical development program.
- Regulatory authorities, including the site-specific ethics committee or institutional review board approve the use of the investigational device for compassionate use of the requested patient.

Treating Physician Criteria and Responsibilities

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The following criteria are required for the treating physician(s) in order to be considered for expanded access for the CV01 Sonodynamic Therapy system.

- Proper licensure and fully qualified to administer or oversee treatment.
- Prior experience with the CV01 Sonodynamic Therapy system.
- Agreement in writing to follow any legal and regulatory requirements for expanded access for an investigational product in the applicable jurisdiction.
- Agreement to adhere to all Alpheus requirements including but not limited to patient eligibility criteria, device administration (including guidance regarding interruption or delayed treatment), and investigational product supply, storage and administration.
- Alpheus Medical personnel may administer the treatment with the CV01 Sonodynamic Therapy system; in those cases, the Alpheus Medical personnel must be on site to administer the treatment per the treating physician's institutional policy.

Process for Requesting Access

Access may be requested by the patient's treating physician via electronic mail (email): info@alpheusmedical.com. The request should include documentation that the patient meets the above listed criteria and that the treating physician(s) meet the above-specified criteria and responsibilities. Additionally, supporting medical documentation may be requested by Alpheus.

Alpheus Review of Requests for Access

Alpheus will consider all requests using the guidelines listed above. Alpheus Medical personnel experienced with the CV01 Sonodynamic Therapy system will consider the evidence to date to evaluate the potential benefit/risk for each individual patient.

Alpheus will provide a response within 5 business days of receiving all required details to support the request. If a request is approved by Alpheus, the expanded access will still require regulatory review and approval in the country the patient will be treated, in addition to the treating physician's local ethics or institutional review board review and approval.

Learn More

To obtain additional information regarding ongoing clinical trials with the CV01 Sonodynamic Therapy system, visit www.clinicaltrials.gov.

Effective Date

This policy is effective as of June 2022 but may be updated in the future without prior notice.