

Expanded Access Policy

Cassava Sciences is focused on discovering and developing pioneering innovations for the treatment and detection of Alzheimer's disease.

Expanded access, also known as compassionate use, refers to a pathway in which patients with serious or immediately life-threatening diseases or conditions may gain access to an investigational therapy outside the context of participation in clinical trials designed to evaluate safety and efficacy. The following is Cassava Sciences' expanded access policy for evaluating and responding to requests for expanded access for individual patients.

General Criteria

Cassava Sciences believes that investigational therapies for Alzheimer's disease should be studied in patients as part of clinical trials designed to generate comprehensive safety and efficacy data that may be used to support approval of the product, which would ultimately lead to wider availability for all patients. Cassava Sciences strongly encourages patients with Alzheimer's disease and caregivers to speak with their treating physicians and, when possible, to participate in clinical trials.

Cassava Sciences is aware that in certain circumstances, patients may not meet the eligibility criteria to participate in a clinical trial and may have exhausted all available treatment options. Cassava Sciences does not currently have an expanded access program that would allow patients to have access to our investigational therapies outside enrollment in our clinical trials. At this time, participation in one of our clinical trials is the only way to access our investigational therapies.

Contact Details

If you have any questions about our investigational drug candidates or expanded access policy, please contact Cassava Sciences at the following email address: ExpandedAccess@CassavaSciences.com.

Timing of Acknowledgement

Cassava Sciences anticipates that it will acknowledge receipt of any questions on or requests for expanded access within five business days of receipt.

As authorized by the 21st Century Cures Act, Cassava Sciences may revise this expanded access policy at any time. Additionally, the posting of this policy by Cassava Sciences shall not serve as a guarantee of access to any specific investigational product candidate by any individual patient.

In the United States, physicians may find additional information regarding expanded access to investigational therapies by visiting the FDA's website, Expanded Access: Information for Physicians (https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians). Non-U.S. physicians must follow local laws and regulations appropriate for the country originating the request.

For information on Cassava Sciences' clinical trials, including eligibility criteria for participating in ongoing studies, please visit www.clinicaltrials.gov.