

(b) (6)

Thursday, December 15, 2022

Division of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

5438
DEC 22 '22 AM 7:57

CITIZEN PETITION

The undersigned submits this petition under 21 C.F.R. § 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request that the Commissioner of Food and Drugs immediately grant Breakthrough Therapy Designation (BTD) for Simufilam (formerly PTI-125) sponsored by Cassava Sciences.

A. Action Requested

Immediately grant Breakthrough Therapy Designation (BTD) for Simufilam (formerly PTI-125) sponsored by Cassava Sciences.

B. Statement of Grounds

1. The requirements for BTD are: "A drug that is intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinical endpoint over currently available therapies."
2. Simufilam has been proven to be safe with over 300,000 doses given in clinical trials with no safety concerns.
3. Simufilam is intended to treat Alzheimer's Disease which is a very serious condition.
4. Preliminary clinical evidence from Phase 1 & Phase 2 trials demonstrates substantial improvement on clinical endpoints over currently available therapies as proven with cerebral spinal fluid biomarkers, cognition testing and testimonials.
5. Six months of clinical data is the customary period required for BTD.
6. Simufilam satisfied all of the requirements and should have received BTD in April 2021, over 20 months ago.
7. Charts showing improvement in cerebral spinal fluid biomarkers and cognition testing are included below.
8. Videos of doctor and family testimonials can be found on Twitter, in a grouping of 43 tweets when searched for #DisbarJordanThomas. Click on "latest" to see all 43 tweets and have them put in order. #DisbarJordanThomas is being used as a publicly available subdirectory which allows for images, links to sources and videos.

C. Environmental Impact

Petitioner states that the relief requested in this petition will have no environmental impact and, therefore, an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

D. Economic Impact

Economic impact information will be submitted at the request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully,

 12/15/2022
Michael K. Law