Statement of Cassava Sciences, Inc.
in Response to an Inquiry from *Science*
March 8, 2024

You have asked Cassava Sciences to comment on FDA's inspection of a lab at City University of New York (CUNY). This lab does academic research focused on the advancement of knowledge and on generating new ideas, principles, and theories in neurodegeneration. In order to conduct exploratory research, the CUNY lab is not required to be compliant with FDA's Good Laboratory Practices (GLP) standard and does not claim to be. The research that this lab conducted on behalf of Cassava has been validated by subsequent work performed at academic institutions that are unrelated to CUNY.

The academic research lab at CUNY is not involved in any manner with the conduct or analysis of our ongoing Phase 3 clinical trials of simufilam, a drug candidate for people with Alzheimer's disease dementia.

The FDA's unannounced inspection of CUNY in 2022 is a matter of public record.[1] This was one of almost 12,000 inspections conducted by the FDA in 2022 and reported on the FDA website.[2]

We understand that CUNY responded to the FDA with respect to all conditions and practices noted in the agency's inspection report. The FDA closed its inspection with a classification of "Voluntary Action Indicated."[3] That is, the FDA did not take any administrative or regulatory action—the agency did not issue a warning letter and did not seek an injunction. For comparison, FDA records show that forty percent (40%) of the 1,344 nonclinical labs inspected *under GLP* between 2000 and 2023 likewise received a classification of Voluntary Action Indicated.[4]

The FDA inspection at CUNY resulted in no material change to the data generated for our benefit by this academic research lab.

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[1] FDA Data Dashboard, https://datadashboard.fda.gov/ora/firmprofile.htm?FEIi=3006508031&/identity/3006508031
[2] FDA Data Dashboard, https://datadashboard.fda.gov/ora/cd/inspections.htm
[3] FDA Data Dashboard, https://datadashboard.fda.gov/ora/firmprofile.htm?FEIi=3006508031&/identity/3006508031
[4] Nonclinical Laboratories Inspected under Good Laboratory Practices, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/nonclinical-laboratories-inspected-under-good-laboratory-practices