



## **Samus Therapeutics Announces Presentation of PU-AD Phase 1 Data for Alzheimer's Disease at CTAD Congress**

**Boston, MA, December 5, 2019** -- Samus Therapeutics, Inc. ("Samus" or the "Company"), a privately held, Boston-based, biopharmaceutical company developing epichaperome inhibitors to intervene in pathological processes and initiate the degradation of disease-associated proteins, today announced the presentation of initial Phase 1 data for Alzheimer's Disease at the 12<sup>th</sup> annual Clinical Trials in Alzheimer's Disease (CTAD) Congress, being held December 4 –7 in San Diego, California. The data being reported are from a single ascending dose Phase 1 study in healthy volunteers evaluating the safety and pharmacokinetics of PU-AD, the Company's lead epichaperome inhibitor for Alzheimer's disease. PU-AD is a small-molecule, orally administered, brain permeable inhibitor selective for the epichaperome.

"Neurodegenerative diseases, such as Alzheimer's Disease (AD), are strongly associated with the breakdown of regulatory pathways designed to prevent aggregation and accumulation of disease-associated proteins," said Dr. Jeffrey Cummings, Research Professor, Department of Brain Health, UNLV and Professor of Medicine at the Cleveland Clinic Lerner College of Medicine, and a principal clinical advisor to Samus Therapeutics. "In certain diseases, epichaperomes form to stabilize and protect aberrant proteins, contributing to the pathophysiology of diseases such as Alzheimer's, ALS, Huntington's, Parkinson's and other neurodegenerative diseases," added Barbara Wallner, Chief Scientific Officer of Samus. "For example, in Alzheimer's disease, the epichaperome supports processes that enable the accumulation of hyperphosphorylated tau and contributes to other downstream effects associated with neurodegenerative diseases. Preclinical studies indicate that epichaperome inhibition with PU-AD initiates degradation of pathologic tau species and rescues neuronal functions."

The Phase 1, double-blind, placebo-controlled, single ascending dose study evaluated the safety and pharmacokinetics (PK) of single doses of PU-AD in healthy volunteers. All subjects were treated with a single oral dose of either 10, 20, or 30 mg of PU-AD or placebo in three cohorts. PU-AD was well-tolerated after single oral doses, with any adverse events being mild and self-limited, and demonstrated pharmacokinetic linearity. Multiple dosing over seven days has been initiated in elderly healthy volunteers and the 20 mg cohort has been completed with PU-AD being well-tolerated, without the occurrence of adverse events requiring interruption of dosing. Following the completion of this Phase 1 study, the Company expects to initiate a Phase 2a trial in early Alzheimer's disease patients in the first half of 2020.

"Our approach for the regulation of protein function and degradation offers an entirely new mechanistic approach, one not simply focused on a single protein pathway," said Dick Bagley, President and Interim CEO of Samus Therapeutics. "We are also directing attention to the regulation of oncogenic pathways with our myelofibrosis Phase 1 trial with PU-H71 while addressing preclinically other neurodegenerative diseases and brain cancer with PU-AD."

## **Details for the CTAD 2019 poster presentation are as follows:**

**Title:** A Single Ascending Dose Study to Evaluate the Safety and Pharmacokinetics of PU-AD, an Anti-Alzheimer's Disease Epichaperome Inhibitor

**Lead author:** Michael H. Silverman, M.D., FACP, Samus Therapeutics Inc

**Poster #:** P214

**Session:** Theme11: New therapies and clinical trials

**Date:** Friday, December 6, 2019

**Poster presentation time:** 7:30 AM PT on Friday, December 6, 2019 – 1:00 PM PT on Saturday, December 7, 2019

**Location:** Hilton Bayfront San Diego

## **About Samus Therapeutics**

Samus Therapeutics is a privately held Boston-based biopharmaceutical company developing novel therapeutics targeting Hsp90 in the epichaperome, also termed the stress chaperome, to address the breakdown of regulatory pathways that prevent aggregation and accumulation of disease associated aberrant proteins in CNS diseases and with oncogenic pathways in oncology. Selective inhibition of the epichaperome prevents the stabilization and aggregation of disease-associated aberrant proteins and initiates and enhances their degradation. The Company's lead CNS program, small molecule orally administered PU-AD, is being developed initially for Alzheimer's Disease and is currently in a Phase 1 study. Samus' lead oncology candidate, orally administered PU-H71, is being evaluated in a Phase 1 study of myelofibrosis in combination with ruxolitinib.

Dr. Cummings is compensated for his time as a consultant to Samus Therapeutics.

*This press release contains certain forward-looking information about Samus Therapeutics, Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," "forecasts," and "believes." These statements include, but are not limited to, statements regarding the progress, timing and results of preclinical and clinical trials involving the Company's drug candidates, and the progress of the Company's research and development programs. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied by, the forward-looking statements. These risks and uncertainties include, but are not limited to whether any of our therapeutic candidates will advance further in the preclinical or clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies, whether our products will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; and competition from other pharmaceutical and biotechnology companies. While Samus may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by law.*

Media Inquiries:

David Rosen

Argot Partners

212-600-1902

[david.rosen@argotpartners.com](mailto:david.rosen@argotpartners.com)

Investor Inquiries:

David Pitts

Argot Partners

212-600-1902

[david@argotpartners.com](mailto:david@argotpartners.com)