Samus Therapeutics Launches PU-AD Clinical Program in Alzheimer's Disease

IND Cleared and First Phase 1 Study Subject Dosed

Boston, MA, July 23, 2019 -- Samus Therapeutics, Inc. ("Samus" or the "Company") today announced the initiation of its clinical program for PU-AD, an oral, brain permeable inhibitor of epichaperomes in Alzheimer's Disease (AD) following clearance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA). Samus is a privately held, Boston-based, biopharmaceutical company developing multiple novel therapeutics targeting epichaperomes to induce degradation of aberrant proteins driving the pathology of neurodegenerative disease and cancer.

PU-AD is designed to inhibit epichaperomes, complexes of regulatory networks that nucleate on Heat Shock Protein 90 (Hsp90) in diseased cells and maintain and drive the pathologic cellular phenotype. Epichaperomes protect against the degradation of mutated and aberrant proteins, such as tau, enabling them to stabilize and aggregate. The presence of epichaperomes has been found to contribute to, or possibly initiate, many neurodegenerative diseases, including Alzheimer's Disease. PU-AD specifically inhibits epichaperomes, eliminating aggregation and hyperphosphorylation of tau, affects downstream events associated with the disease, and initiates degradation of mutant tau by a mechanism distinct from other protein degradation platforms. PU-AD has negligible effect, if any, on housekeeping Hsp90 in normal cells.

"Epichaperomes play a critical role in the pathogenesis and characteristics of neurodegenerative diseases and cancers," said Gabriela Chiosis, PhD, a co-founder of Samus Therapeutics and Tri-Institutional Professor at Memorial Sloan Kettering Cancer Center. "Targeting epichaperomes represents one of the most novel and exciting new pathways toward finding new treatments for these diseases."

Samus' clinical program will begin with a single ascending dose (SAD) Phase 1 study to evaluate the safety and tolerability of PU-AD in healthy subjects, with the first subject now dosed, and is expected to be followed by a multiple ascending dose (MAD) cohort. Assuming the expeditious completion of this study, the Company would begin PU-AD clinical testing of Alzheimer's patients in Phase1b/2a in the first half of 2020.

Dr. Jeffrey Cummings, Research Professor, Department of Brain Health, UNLV and Professor of Medicine at the Cleveland Clinic Lerner College of Medicine, and principal clinical advisor to Samus, added: "Testing of an entirely new target deeply implicated in the progression and even initiation of pervasive neurodegenerative diseases is very exciting. I look forward to understanding full potential of new therapies in an area with enormous public health consequences."

"In AD and tauopathy mouse models, inhibiting the epichaperome with PU-AD effected degradation of mutated hyperphosphorylated and aggregated tau protein," commented Barbara Wallner, PhD, Chief Scientific Officer of Samus Therapeutics. "This is supported by a series of memory tests in treated mice, which indicated improved or restored cognitive functions.

Acceptance of our IND application and initiation of our clinical program are important steps in validating our approach."

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 enhance degradation of aberrant proteins which drive the pathology of diseases such as neurodegenerative disease and cancer. The Company's lead CNS program, epichaperome inhibitor PU-AD, is being developed initially for Alzheimer's Disease and is currently in a Phase 1 study. Samus' lead oncology candidate, epichaperome inhibitor PU-H71, is being evaluated in an oral form in Phase 1 study of myelofibrosis in combination with ruxolitinib. PU-H71 was granted Orphan Drug designation in the United States and has completed early testing in Phase 1b with an IV form for advanced HER2 negative metastatic breast cancer in combination with Abraxane®. Dr. Cummings is a paid 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 and for which indications; 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. Dr. Chiosis is a co-founder of and holds equity interests in Samus Therapeutics. Epichaperome inhibitors, including PU-AD and PU-H71, were developed in Dr. Chiosis' laboratory at Memorial Sloan Kettering Cancer Center.

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