



Samus Therapeutics Presents Phase 1 PU-AD Study Results at AAIC 2020 Advancing the Company's Platform for Treating Neurodegenerative Diseases

PU-AD well-tolerated with blood brain barrier penetration and favorable PK profile in healthy volunteers

Phase 2a trial has initiated in AD, ALS Initiation Expected 2H'20

Boston, MA, July 29, 2020 -- Samus Therapeutics, Inc., a privately held, biopharmaceutical company developing small molecule epichaperome inhibitors, today announced the presentation of safety and pharmacokinetic data from the Company's recently completed PU-AD healthy volunteer Phase 1 study at the Alzheimer's Association International Conference (AAIC 2020). PU-AD is Samus' orally bioavailable, small molecule epichaperome inhibitor designed to cause degradation of aberrant proteins associated with the progression of Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS), and other major neurodegenerative diseases. The Phase 1 study results presented today support Samus' advancement of PU-AD into its now initiated Phase 2a study in AD, and its upcoming Phase 2a study in ALS expected to initiate later this year.

"The data presented today underscore the potential of the Samus' epichaperome inhibitor platform to address the unmet medical needs of AD patients and most of the other major neurodegenerative diseases involving multiple disease-associated aberrant proteins," said Richard Bagley, President and Chief Executive Officer of Samus Therapeutics. "We expect to initiate a Phase 2a study of PU-AD in ALS in the second half of 2020, while we continue to advance our ongoing study in Alzheimer's."

The Phase 1 double-blinded, placebo-controlled, single-and multiple-ascending dose study evaluated the safety and pharmacokinetics of PU-AD in healthy volunteers. Subjects were randomized to cohorts of eight subjects to receive treatment with PU-AD or placebo in a 6:2 ratio. Subjects aged 18-60 were administered single doses of 10, 20 and 30 mg. Subjects older than 60 years of age were administered 20 and 30 mg doses daily for seven days. PU-AD was well-tolerated at all doses, with an adverse event profile comparable to that of placebo. There were no other clinically significant safety findings to report. PU-AD's pharmacokinetic profile was favorable and dose-proportional between 10 mg to 30 mg and showed minimal accumulation with repeated dosing. PU-AD detected in cerebrospinal fluid samples provided evidence of blood brain barrier penetration.

Dr. Barbara Wallner, Chief Scientific Officer of Samus Therapeutics, added, "Neurodegenerative diseases are linked to the breakdown of regulatory pathways that prevent the aggregation and accumulation of disease-associated proteins." Dr. Wallner continued, "Epichaperome inhibition



has been demonstrated preclinically to restore cellular proteostasis and neuronal function and the results presented today at AAIC demonstrate that PU-AD is safe at CNS penetrant doses and suggest the potential to treat several neurodegenerative diseases.”

PU-AD is an orally bioavailable small molecule inhibitor, specific to the epichaperome, which has exhibited little or no effect on normal cell proteostasis. The drug has previously shown beneficial effects in animal models, including reduced levels of pathological tau and improved spatial memory/learning. Epichaperomes are believed to maintain and drive the pathologic cellular phenotype by preventing aberrant protein degradation, and in some cases, aiding in their aggregation, among other functions.

Details for the AAIC 2020 presentation are as follows:

Title: A Single- and Multiple-Ascending Dose Study to Evaluate the Safety and Pharmacokinetics of Oral PU-AD, an Epichaperome Inhibitor to Treat Alzheimer’s Disease

Lead author: Dr. Michael H. Silverman

Poster #: 41144

Session: P3 [Posters: Drug Development] Human / Trial design

Date and Time: Wednesday, July 29, 2020: 12:00 AM – 11:59 AM

About Samus Therapeutics

Samus Therapeutics is a privately held biopharmaceutical company developing novel epichaperome inhibitor therapeutics primarily targeting the treatment of neurodegenerative diseases but also in certain blood cancers. Selective inhibition of the epichaperome prevents the stabilization and aggregation of disease-associated aberrant proteins and initiates their degradation. The Company’s lead central nervous system program candidate, PU-AD, is an orally administered small molecule being developed initially for amyotrophic lateral sclerosis (ALS) and Alzheimer’s disease, and has potential application in other neurodegenerative diseases. Samus’ lead oncology candidate, orally administered PU-H71, is being evaluated in a Phase 1b study of myelofibrosis in combination with ruxolitinib. Samus is based in Boston, MA and more information can be found at www.samustherapeutics.com.

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 such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company including but not limited to war, terrorism, natural disaster or pandemic, 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.

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