



## **Samus Therapeutics Announces PU-H71 Granted Orphan Drug Designation and First Patient Dosed in Phase 1b Study in Myelofibrosis**

**Boston, MA, June 13, 2018** -- Samus Therapeutics, Inc. ("Samus" or the "Company"), a privately held Boston-based biopharmaceutical company developing novel therapeutics and biomarkers targeting the epichaperome, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to PU-H71 for the treatment of myelofibrosis. The Company also announced today that it has dosed the first patient in a Phase 1b dose-escalation study of PU-H71 in patients with myelofibrosis.

PU-H71, along with PU-AD, are novel therapeutics that, with high specificity, target the epichaperome, a foundational protein complex present in multiple disease states, including cancer and neurological disorders. Under conditions of abnormal stress, cells become biochemically 'rewired' to form a network of high-molecular-weight complexes known as epichaperomes. In cancer, these can function as a network to enhance cellular survival, irrespective of tissue of origin or genetic background. PU-H71 specifically targets the epichaperome, present in over half of all cancers tested by Samus and the Chiosis group at Memorial Sloan Kettering Cancer Center, to precisely interfere with the epichaperome function in diseased cells and to not affect normal cells ([Nature Reviews Cancer, 2018, doi:10.1038/s41568-018-0020-9](#); [Nature, 538, 397-401, 2016](#)).

PU-H71 is now being studied in Phase 1b combination trials in myelofibrosis and advanced metastatic breast cancer. A second compound, PU-AD, which targets the epichaperome in neurodegenerative diseases, is being developed for the treatment of Alzheimer's disease (AD), with a Phase 0 PU-AD PET/SPECT biomarker brain imaging study currently ongoing and a Phase 1 therapeutics study expected to initiate later this year in an AD program.

"Targeting the epichaperome offers an exciting new avenue for treating myelofibrosis and related diseases," said Srdan Verstovsek, M.D., Ph.D., Chief, Section for Myeloproliferative Neoplasms (MPNs) in the Leukemia Department, and Director of the Clinical Research Center for MPNs at the MD Anderson Cancer Center and lead Clinical Research Advisor for the Phase 1b myelofibrosis study. "In myelofibrosis, the epichaperome plays a central role in optimizing the JAK-STAT pathway, allowing JAK2 to form dimers that evade inhibition with a JAK2 inhibitor such as ruxolitinib. By inhibiting epichaperome function and breaking this mechanism, we believe PU-H71 can increase anti-cancer activity of JAK2 inhibitors. I look forward to seeing how the combination of these therapies can affect outcomes in patients for whom this resistance is associated with poor prognoses."

The multicenter Phase 1b study is designed to assess the safety, tolerability, PK and preliminary efficacy of PU-H71 in subjects taking concomitant ruxolitinib.

"New science emerging from Samus and the Chiosis group has led to a greater understanding of the role the epichaperome plays in cancer and Alzheimer's disease, as well as our ability to disrupt

a biologic mechanism fundamental to these diseases,” said Barbara Wallner, Ph.D., Chief Scientific Officer of Samus Therapeutics. “PU-H71 and PU-AD inhibit with high specificity the epichaperome complex in diseased cells and thereby mitigate the adverse effects of disease enhancing proteins without affecting normal cells. We look forward to results from the myelofibrosis study, as well as the ongoing studies of PU-H71 in breast cancer and PU-AD in Alzheimer’s disease.”

Orphan drug designation is granted by the FDA to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain incentives which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity.

### **About Samus Therapeutics**

Samus Therapeutics is a privately held Boston-based biopharmaceutical company developing novel therapeutics targeting the epichaperome, a foundational protein complex emergent from multiple disease states, including cancer and neurological disorders, such as Alzheimer’s, Parkinson’s and chronic traumatic encephalopathy. Samus was established by Drs. Gabriela Chiosis and Larry Norton on research conducted at the Chiosis Laboratory at the Memorial Sloan Kettering Cancer Center, and at Rockefeller University and Weill Cornell Medicine, and is led by Jonathan Lewis, MD, PhD, Chief Executive Officer. The Company’s lead oncology program, epichaperome inhibitor PU-H71, is being evaluated in Phase 1b and 1b/2 clinical studies in breast cancer and myelofibrosis. The Company’s lead CNS neurodegenerative program epichaperome inhibitor, PU-AD, is being studied in a Phase 0 biomarker study evaluating the distribution of the epichaperome in the brain of subjects with Alzheimer’s disease, with a Phase 1 therapeutic study to follow in Q4 2018. In parallel with its therapeutics program, Samus is advancing companion biomarkers PU-PET (for measuring epichaperome in solid tumors and the brain) and PU-CYT (flow cytometry for measuring epichaperome in circulating cells in the blood).

*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 pre-clinical 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.*

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