



Samus Therapeutics Announces Launch of Expanded Clinical Development Programs for Novel Anti-Epichaperome Small Molecules to Diagnose and Treat Cancer and Neurodegenerative Disease

Studies Initiating in Myelofibrosis, Pancreatic and Breast Cancer Together with Potential PET Scan Diagnostic

Diagnostic and Therapeutic in Development for Alzheimer's and Chronic Traumatic Encephalopathy

Company Appoints Drs. James Armitage and Daniel D. Von Hoff as Oncology Advisors, Dr. Geoffrey Ling as Neurologic Disease Advisor

Boston, MA, March 30, 2017 -- Samus Therapeutics, Inc. ("Samus" or the "Company"), a privately held Boston-based biopharmaceutical company developing novel therapeutics and diagnostics targeting the epichaperome, today announced the launch of an expanded development program for the Company's lead anti-epichaperome candidates, including PU-H71 in various cancers and PU-AD in neurodegenerative diseases.

Samus was established in concert with the Memorial Sloan Kettering Cancer Center (MSKCC) in 2011 by Larry Norton, MD, and Gabriela Chiosis, PhD, based on research from the Chiosis Laboratory at the Sloan Kettering Institute ("SKI"), together with collaborators at Rockefeller University and Weill Cornell Medicine. Jonathan Lewis, MD, PhD, was recruited to Samus in 2016 to serve as Executive Chairman and Chief Executive Officer to lead and accelerate the development of the Company's epichaperome platform.

Epichaperomes are foundational protein complexes that emerge from multiple diseases, including cancer and neurological disorders, the Company's initial areas of focus. Following various forms of cellular stress, chaperome units are rewired into the epichaperome network. Targeting the epichaperome in cancer results in cell death, and, in neurodegenerative diseases, neuronal survival, with no effect in normal cells. Recent, seminal research on the molecular characteristics and composition of the epichaperome and PU-H71 in cancer were published by the Chiosis lab in the journal [Nature](#) (Rodina, A. et al., 538, 397–401, 20 October 2016). This research revealed a direct correlation between the abundance of epichaperomes in cancer cells, and their responsiveness to the cell killing effects of PU-H71, in a manner that is independent of the mutational diversity of the tumor cells, suggesting that PU-H71 may have activity in a wide range of human tumors.

"Samus Therapeutics was founded on novel insights into the structure and function of the epichaperome complex, the modulation of which has been shown to have profound and highly specific effects in preclinical models of cancer, neurodegenerative and other diseases," said Dr. Lewis. "These insights have translated into meaningful and durable results in early clinical

study, including responses lasting greater than 24 months in patients with myelofibrosis who stopped responding to ruxolitinib.”

Dr. Lewis added: “We are extremely excited to further elucidate these seminal insights and early results in studies conducted under the support and leadership of Drs. Larry Norton, James Armitage, and Daniel Von Hoff, who will focus on breast, hematologic, and pancreatic cancers, respectively. We also look forward to leveraging the deep experience and expertise of Dr. Geoffrey Ling in neurological disease by exploring the tremendous potential of anti-epichaperome small molecules in this challenging and vastly underserved area of medical need.”

The Company’s advisors are each a preeminent thought leader in their area of study,

- Larry Norton, MD, is Deputy Physician-in-Chief for Breast Cancer Programs, Medical Director of the Evelyn H. Lauder Breast Center and Norma S. Sarofim Chair in Clinical Oncology.
- Gabriela Chiosis, PhD, is a Member in the Chemical Biology Program of SKI and a Tri-Institutional Professor at Memorial Sloan Kettering Cancer Center, Weill Cornell Medicine and Rockefeller University.
- James Armitage, MD, is the Joe Shapiro Professor of Medicine, Division of Oncology & Hematology, at the University of Nebraska Medical Center; and former Dean, University of Nebraska Medical School.
- Daniel D. Von Hoff, MD, is the Physician in Chief, Distinguished Professor, Translational Research at the Translational Genomics Research Institute (“TGen”) Senior Consultant, Clinical Investigations for the City of Hope, and Professor of Medicine at the Mayo Clinic.
- Geoffrey Ling, MD, PhD, is Professor of Neurology at the Johns Hopkins School of Medicine, and the former Director of the DARPA Biological Technologies Office, and professor and Acting Chair of the Department of Neurology at the Uniformed Services University of the Health Sciences.

Clinical Development Programs in Cancer and Neurodegenerative Disease

PU-H71, the Company’s lead program targeting the epichaperome network, has demonstrated potent anticancer activity in preclinical *in vitro* and *in vivo* studies, including both therapeutic synergy, and reversal of resistance, in combination with multiple standard of care therapies. A Phase 1 study, conducted under an MSKCC-initiated investigational new drug application (IND), has been completed, identifying a maximum tolerated dose, establishing a well-tolerated toxicity profile, and demonstrating activity supporting further combination clinical study. The Company announces today the launch of several studies in cancer including:

- A Phase 1b/2 combination study in myelofibrosis under a second Company IND, expected to be filed in early Q2. In Phase 1, treatment with PU-H71 demonstrated durable results (>24 months) in this indication in patients who had previously failed ruxolitinib;
- A Phase 1b combination study in advanced breast cancer at MSKCC, with the first patient expected to be treated in early Q2;
- A Phase 1b combination study in chemo-naïve front-line metastatic pancreatic cancer under the Company’s first IND, recently accepted by the U.S. Food and Drug Administration (FDA), with the first patient expected to be treated early Q2.

A companion diagnostic for determining patient selection, response to treatment and dose and schedule, PU-H71-PET, is also being explored in an ongoing Phase 1 study, and the Company

is developing a companion diagnostic for *in vitro* measurement of circulating epichaperome positive cells in blood by flow cytometry ("PU-CYT"). Further, the Company is evaluating trials in other hematologic cancers, and the Chiosis lab was recently awarded a SKI "Big Bet" grant for the study of epichaperome inhibitors in combination with immunotherapy in oncology.

Samus' second anti-epichaperome small molecule, PU-AD, along with the diagnostic PU-AD-PET, are expected to move into neurodegenerative disease-directed clinical studies, including Alzheimer's disease and chronic traumatic encephalopathy ("CTE"). A Phase 1 positron emission tomography ("PET") diagnostic study is currently active and recruiting Alzheimer's patients at MSKCC, which the Company expects to expand to include patients with CTE. The Company expects to file an IND for the PU-AD therapeutic and diagnostic in neurodegenerative disease, and an exploratory Phase 1 clinical study for CTE with outside collaborators is currently in the planning stage.

The development of Samus' candidates will be led by a deeply experienced management and advisory team, including Dr. Lewis, who brings more than 20 years of experience in leadership roles in biotechnology and medicine, Dick Bagley, President and Chief Financial Officer, who has over 40 years of senior leadership in both pharma and biotechnology, and senior level professionals with experience in translational research, clinical trial design and execution, manufacturing, quality control, intellectual property, and global regulatory approvals.

For more information, visit www.samustherapeutics.com.

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 diseases, such as Alzheimer's, Parkinson's and chronic traumatic encephalopathy. Samus was founded 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, its Chief Executive Officer. The Company's lead oncology program, epichaperome inhibitor PU-H71, is advancing into Phase 1b or 1b/2 clinical studies in pancreatic cancer, breast cancer, myeloproliferative neoplasms and lymphoma/leukemia. The Company's lead CNS therapeutic, PU-AD, is being studied in Alzheimer's and CTE disease models. In parallel with its therapeutics program, Samus is advancing companion diagnostics PU-PET and PU-CYT.

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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