Samus Therapeutics Receives IND Clearance from FDA for PU-AD for the Treatment of Recurrent Malignant Glioma

Boston, MA, May 11, 2021 -- Samus Therapeutics, Inc. ("Samus Therapeutics" or the "Company"), a privately held, Boston-based biopharmaceutical company developing epichaperome inhibitors to treat CNS diseases and hematologic malignancies, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to develop PU-AD for the treatment of recurrent malignant glioma. Under this IND, Samus will proceed with its Phase 1b study addressing the safety, tolerability and pharmacokinetics of PU-AD (icapamespib) in patients with recurrent malignant glioma. Icapamespib is an orally administered small molecule that is a specific inhibitor of epichaperomes.

Under the leadership of Dr. John de Groot, at the University of Texas M.D. Anderson Cancer Center and Dr. Howard Colman at the Huntsman Cancer Institute at the University of Utah, the multicenter Phase 1b study will be conducted in two stages at multiple sites across the U.S. The dose escalation will address daily administration of icapamespib in patients with a first, second or third recurrence of isocitrate dehydrogenase (IDH) wild type glioblastoma, or grade 3 or 4 IDH mutant astrocytoma.

"The expansion stage of this trial will not only confirm safety of the Phase 2 dose, but also investigate the biology of recurrent disease through biomarker analysis and evidence of target engagement," said Dick Bagley, President and CEO of Samus Therapeutics.

Malignant glioma is a characterization of Stage 3 and 4 glioblastoma/astrocytoma diagnoses. Standard of care at outset is varied but predominantly includes surgery, chemotherapy, and radiation therapy. According to the American Cancer Society glioblastoma is the most common and most aggressive form of the primary brain tumors in adults, accounting for half of all primary brain cancers. Despite extensive research, available treatments have not improved the median survival of 14-16 months.

"Through the work of our scientific founder Gabriela Chiosis, PhD and her collaborators, we have established that glioblastomas express high levels of epichaperomes as evidenced in explants, primary and secondary neurospheres, and glial stem cells. Epichaperome driven glioblastoma cells respond well to icapamespib treatment in xenograft mouse models and *ex vivo* studies even when resistant to Temodar® (temozolomide) and Avastin® (bevacizumab), giving us a signal that icapamespib could have a clinical impact on this devastating disease," commented Barbara Wallner, PhD, Chief Scientific Officer.

About Samus Therapeutics
Samus Therapeutics is a privately held Boston-based biopharmaceutical company developing orally administered PU-AD (icapamespib) and PU-H71 (zelavespib) that target the epichaperome, also termed the stress chaperome, to address the breakdown of regulatory pathways that normally prevent aggregation and accumulation of disease associated aberrant proteins in CNS diseases and oncogenic protein signaling pathways in cancer.

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, 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 Therapeutics 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.

Investor Inquiries:
David Pitts
Argot Partners
212-600-1902
david@argotpartners.com

Media Inquiries:
Leo Vartorella
Argot Partners
212-600-1902
leo@argotpartners.com