SA53 MDM2 Inhibitor: Lamassu Biotech Reports Significant Progress, Favorable Safety Profile in Phase 1/2a Clinical Trial

Novel SA53 MDM2 Inhibitor Therapy Has Potential to be a Breakthrough in Genetically-Targeted Cancer Treatment

CLEVELAND, OHIO, UNITED STATES, November 3, 2025 /EINPresswire.com/ -- Lamassu Biotech, a clinical-stage pharmaceutical company, today announced a significant clinical milestone in its Phase 1/2a trial investigating SA53, a first-in-class, small-molecule MDM2 inhibitor. According to data reviewed to date, there have been no serious or dose limiting adverse events, and SA53 has thus far demonstrated a favorable safety and tolerability profile. The therapy is currently advancing into higher-dose cohorts for the treatment of adult patients with solid tumors.

SA53 could potentially provide better targeted treatment for many types of cancer, transforming precision oncology practices.

The ongoing Phase 1/2a trial, conducted in collaboration with the National Institutes of Health (NIH) and Cleveland Clinic, is designed to determine the safety, tolerability, pharmacokinetics, and preliminary efficacy of SA53. The therapy is being investigated in adult patients with sarcoma and other solid tumors who possess the p53 wild-type gene and who currently have limited therapeutic options.

The dose-escalation portion of the trial is successfully advancing and has reached the third cohort. SA53 has met all defined safety parameters to date, without the occurrence of dose-limiting toxicities (DLTs) or any clinically significantly adverse events that would prevent the continuation of treatment as planned in the current protocol.

Having substantially de-risked the program from a safety standpoint, the trial is progressing toward determining the Maximum Tolerated Dose (MTD) and assessing the efficacy of the drug.

The trial is overseen by Principal Investigator Peter Anderson, MD, PhD, and Joseph Wooley, MD, at the Cleveland Clinic. Link for the trial.

SA53 is a genetically targeted therapeutic designed to reactivate the tumor suppressor protein p53 commonly referred to as the “Guardian of the Genome by inhibiting the MDM2 protein, which typically prevents p53 from functioning, the objective is to induce highly targeted tumor cell death and inhibit growth without the systemic toxicity often associated with traditional chemotherapy agents. Since the p53 pathway is functional (p53 wild-type) in approximately half of all human cancers, the therapeutic potential for SA53 is very broad.
"The safety evaluation of SA53 has been highly encouraging, which is the paramount goal of any Phase 1 study," said Greg Palmer, PhD, Co-founder and Chief Scientific Officer for Lamassu Biotech. "The strong tolerability demonstrated thus far is a credit to the targeted mechanism of action, and it enables us to move rapidly through dose escalation to define the optimal therapeutic dose for the Phase 2 efficacy assessment."

Gabi Hanna, MD, Lamassu Biotech CEO and Co-founder, added: "Advancing a novel, targeted therapy past the initial safety milestones is a critical inflection point, especially for one of the major cancer pathways, p53. The favorable safety data, coupled with the FDA's decision to grant an accelerated study protocol design, validates our preclinical assessment of the significant unmet medical need, particularly in diseases like liposarcoma where MDM2 amplification is common. This design is effectively accelerating our development timeline, which is a key benefit to our program."

New patients continue to be screened and will be added to the trial on an ongoing basis. Complete details about the trial design, locations, and participation criteria can be found HERE.

ABOUT LAMASSU BIOTECH
Lamassu Biotech is a private pioneering clinical stage pharmaceutical company focused on developing innovative treatments for severe and unmet medical needs in oncology and inflation disease. With decades of experience, Lamassu specializes in advancing transformational treatments from concept to bedside with efficiency and precision. At Lamassu, we believe in the transformative power of science and the hope it brings to patients and families. Learn more at LamassuBiotech.com.

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