Sapu Nano Unveils First-in-Human Clinical Trial of Sapu-003 at 8th Australian Translational Breast Cancer Research Symposium

Using Sapu Nano's proprietary Deciparticle™ technology, Sapu-003 delivers everolimus intravenously

SYDNEY, Australia, Oct. 08, 2025 (GLOBE NEWSWIRE) -- via IBN - *Sapu Nano* today announced the presentation of its poster, "Sapu-003: Novel Intravenous Deciparticle™ Everolimus Entering Phase 1 Study in Australia," at the 8th Australian Translational Breast Cancer Research Symposium (ATBCR 2025). Sapu Nano is part of the Sapu family of companies, formed through GMP Biotechnology Limited, a joint venture between Oncotelic Therapeutics, Inc. (OTCQB: OTLC) and Dragon Overseas Capital Limited.

Sapu-003 is the first intravenous (IV) Deciparticle™ formulation of everolimus, an mTOR inhibitor widely used in oncology. While oral everolimus (*Afinitor*®) has demonstrated efficacy in breast cancer, renal cell carcinoma, and neuroendocrine tumors, its broader use has been constrained by low bioavailability, variable systemic exposure, and gastrointestinal toxicities.

Global Development Partnership
The trial is being conducted in collaboration with SOCRU, a leading Phase 1 clinical unit in Australia; Ingenū, a clinical research organization with deep early-phase expertise; and Medicilon, Sapu Nano's strategic partner for preclinical drug development. Together, these partnerships ensure robust clinical execution, regulatory alignment, and high-quality product supply for the study.

Call to Patients and Physicians
The trial (**ACTRN12625001083482**) is now open for enrollment at leading oncology centers across Australia. Eligible participants include adults with advanced HR+/HER2- breast cancer or other mTOR-sensitive tumors who have exhausted standard therapies. Physicians are encouraged to refer patients who may benefit from participation.

"Sapu-003 represents a significant advance in the delivery of mTOR-targeted therapies," said **Vuong Trieu, PhD**, Chief Executive Officer of Sapu Nano. "Through the combined expertise of SOCRU, Ingenū, and Medicilon, we are positioned to accelerate development and bring this next-generation treatment option to patients with advanced cancers."

About Oncotelic Therapeutics

Oncotelic Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development of oncology and immunotherapy products. The Company's mission is to address high-unmet-need cancers and rare pediatric indications with innovative, late-stage therapeutic candidates.

In addition to its directly owned and developed drug pipeline, Oncotelic benefits from the robust portfolio of inventions created by its CEO, **Dr. Vuong Trieu**, who has filed over 500 patent applications and holds 75 issued patents. Beyond its internal programs, the Company also licenses and co-develops select drug candidates through joint ventures. Currently, Oncotelic owns **45% of GMP Bio**, a joint venture under Dr. Trieu's leadership and guidance, which is advancing its own pipeline of drug candidates that further complement and strengthen Oncotelic's strategic position in oncology and rare disease therapeutics.

For more information, please visit: www.oncotelic.com

Oncotelic Cautionary Note on Forward Looking Statements

This press release contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this release other than statements of historical fact are forward looking and are based on current expectations, estimates, and projections about our business and future plans. In some cases, you can identify forward looking statements by terms such as "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "project," "forecast," "potential," "continue," and similar expressions (including the negative of such terms).

Forward looking statements in this release include, without limitation: our plans, timelines, and priorities for the OT 101 program in PDAC and other indications; potential biomarker driven development strategies; the advancement, scope, timing, and results of current or future preclinical and clinical studies; regulatory interactions and potential approvals; development or commercialization of any product candidates within the Oncotelic/GMP Bio/Sapu ecosystem; the utility of our PDAOAI platform; future financings, strategic transactions, and/or public offerings involving our joint ventures or affiliates; and other statements that are not historical facts. Actual results may differ materially from those indicated by such forward looking statements as a result of various important factors, including, but not limited to: the inherent uncertainties of drug discovery and development; our ability to enroll patients and complete studies on expected timelines; whether preclinical or early clinical findings (including biomarker associations) will be replicated in larger, controlled trials; regulatory developments in the United States and other jurisdictions; competitive developments; our ability to obtain or maintain intellectual property protection; our liquidity and access to capital; the performance of collaborators, suppliers, and manufacturers; and other risks described in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our most recent Form 10 K and subsequent periodic reports.

Forward looking statements speak only as of the date of this press release, and we undertake no obligation to update or revise such statements, whether as a result of new information, future events, or otherwise, except as required by law.

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