# Sapu Nano's Sapu003 Advances to Human Clinical Testing - Transforming Everolimus Delivery with Full Bioavailability for Breast Cancer Patients

Sapu003 Designed to Overcome Limitations of Afinitor®, FDA-Approved Oral Everolimus, by Delivering Full Strength of the Drug via Intravenous Injection

SAN DIEGO, Sept. 24, 2025 (GLOBE NEWSWIRE) -- via IBN -- Sapu Nano, developer of Deciparticle™, today announced that it has received approval from Australia's Human Research Ethics Committee (HREC) to begin enrolling patients in a Phase 1 human clinical trial of Sapu003-an injectable form of Everolimus-for the treatment of breast cancer. 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.

Everolimus is already an FDA-approved drug (sold under the brand name Afinitor®) for various cancers, including advanced breast cancer, kidney cancer, and certain rare tumors. However, in oral pill form, only about 10% of the drug is absorbed by the body, which limits how effective it can be. Using Sapu Nano's proprietary Deciparticle™ technology, Sapu003 is delivered intravenously (by injection), which allows 100% of the drug to reach the bloodstream. Preclinical studies suggest this approach could be more effective than the current oral version.

"We are extremely pleased to receive approval from the HREC to proceed with human clinical trials," said Sapu Nano Chief Executive Officer Dr. Vuong Trieu. "Despite advances in treatment, there remains a critical unmet need for next generation mTOR inhibitors. Current therapies often extend progression-free survival for less than one year and rarely deliver long-term disease control. This Phase 1 trial will allow us to determine the best dose for future studies, including a Phase 3 trial."

Dr. Sud Agarwal, Chief Executive Officer of Ingenu, added: "The approval of Sapu003 to enter human trials is a landmark moment. By enabling full drug absorption through intravenous delivery, this program has the potential to achieve meaningful tumor shrinkage where oral formulations have been limited. We are proud to support Sapu Nano in advancing this therapy, which may ultimately give breast cancer patients better outcomes and improved quality of life."

**What This Means for Patients**
Put simply, Sapu003 is a new way of giving an existing cancer drug so it works better. The pill form doesn't get fully absorbed, only about 10% makes it into the body. By delivering it as an injection, researchers can deliver the medicine at full strength, which could make it more effective at shrinking tumors. This first trial is the starting point to see if this improved version can give breast cancer patients longer-lasting benefits and new hope.

**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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