Sapu Nano Expands International Development of Sapu003 and Appoints Global Clinical Trials (GCT) as Lead CRO for Phase 1b Program

SAN DIEGO, Calif., June 03, 2026 (GLOBE NEWSWIRE) -- Sapu Nano and Oncotelic Therapeutics (OTCQB:OTLC) today announced the expansion of its Phase 1b clinical development program for Sapu003 (Everolimus for Injection) and the appointment of Global Clinical Trials (GCT) as the lead contract research organization supporting international execution of Study SP-03-B101.

The announcement follows recent regulatory approvals supporting the study expansion and CRO transition and represents an important milestone in the evolution of the Sapu003 clinical program from its initial Australian clinical footprint toward a broader multinational clinical program.

GCT was selected following a competitive evaluation process that assessed international oncology expertise, regulatory capabilities, operational execution, clinical quality systems, and global logistics infrastructure. Following its appointment, GCT successfully completed key regulatory submissions ahead of schedule and has initiated clinical operations, regulatory coordination, site activation activities, investigational product logistics, and study management functions.

The appointment supports the expansion of the SP-03-B101 study beyond Australia into Europe and represents an important step in establishing the clinical, operational, and regulatory infrastructure necessary to support future multinational Phase 3 development. By building an international clinical network early in development, Sapu Nano aims to position Sapu003 for efficient advancement into global registrational studies following successful completion of ongoing clinical evaluation.

SP-03-B101 is an open-label Phase 1b dose-escalation study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of Sapu003 in patients with advanced mTOR-sensitive solid tumors.

"Sapu003 has progressed from concept through formulation development, manufacturing, regulatory approval, and clinical evaluation in a remarkably short period of time," said Dr. Vuong Trieu, Chief Executive Officer. "The expansion of the program beyond Australia and the appointment of GCT provide the international infrastructure necessary to support continued clinical development. We believe these milestones position Sapu003 for broader global evaluation and future registrational studies while expanding access for patients with advanced cancers."

Sapu003 is a proprietary intravenous formulation of everolimus developed using Sapu Nano's Deciparticle™ platform technology. The program is designed to address limitations associated with oral everolimus administration, including variable absorption, food effects, and first-pass metabolism, while providing more predictable systemic drug exposure through intravenous delivery.

The Company expects the expanded international footprint and integrated clinical operations platform established through GCT to support continued enrollment, future site expansion, and long-term global development objectives for the Sapu003 program.About Deciparticle™

Deciparticle™ is Oncotelic's proprietary nanomedicine platform designed to formulate highly water-insoluble therapeutics into ultra-small nanoparticles for intravenous administration. The platform utilizes amphiphilic polymer architectures intended to improve aqueous compatibility, stability, manufacturability, and translational flexibility across multiple therapeutic classes.

About Sapu Nano

Sapu Nano is a biotechnology company developing next-generation nanomedicine platforms to improve drug delivery, enhance therapeutic index, and unlock new clinical potential for established and novel therapeutics, with a primary focus in oncology. For more information, visit www.sapunano.com.

About Oncotelic Therapeutics, Inc.

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 a robust portfolio of inventions created by its CEO, Dr. Vuong Trieu, who has filed over 500 patent applications and holds 75 issued patents. The Company also leverages its proprietary AI-enabled PDAOAI platform, which supports research, biomarker discovery, and regulatory processes through advanced data analysis and knowledge integration.

Beyond its internal programs, Oncotelic licenses and co-develops select drug candidates through strategic partnerships and joint ventures. The Company currently owns a 45% interest in GMP Bio, a joint venture advancing a complementary pipeline of therapeutic candidates that further strengthens Oncotelic's 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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