Oncotelic Successfully Completes Initial Safety Cohort of Phase 1b SP-03-B101 Trial; Independent Safety Review Committee Recommends Dose Escalation and European Expansion Underway

Clinical Program Advances Following Favorable Safety Review; Peer-Reviewed Publication Further Validates Deciparticle™ Platform

SAN DIEGO, Calif., July 07, 2026 (GLOBE NEWSWIRE) -- Oncotelic (OTCQB:OTLC), an AI/Robotic native biotechnology company, and its 45% owned subsidiary- Sapu Nano (US) LLC, a clinical-stage biotechnology company developing the proprietary Deciparticle™ nanomedicine platform, and today announced that the independent Safety Review Committee (SRC) has completed its review of the initial safety cohort in the Company's ongoing SP-03-B101 Phase 1b clinical trial evaluating Sapu003, an investigational intravenous formulation of everolimus.

Following completion of the protocol-defined 28-day dose-limiting toxicity (DLT) evaluation period for the initial three-patient cohort, the SRC concluded that no dose-limiting toxicities (DLTs) were observed and recommended advancing the study to the next planned dose level in accordance with the study protocol.

Sapu003 is currently being evaluated in the SP-03-B101 Phase 1b clinical trial, an open-label, multicenter, Bayesian Optimal Interval (BOIN) dose-escalation study evaluating the safety, tolerability, pharmacokinetics (PK), and preliminary antitumor activity of weekly intravenous Sapu003 in patients with advanced mTOR-sensitive solid tumors. The study is registered on ClinicalTrials.gov (Identifier: NCT07369505).

Following successful completion of the initial safety cohort, the Company has initiated expansion of the **SP-03-B101** clinical program into Europe. Additional European clinical sites are expected to participate in the study, broadening patient access, accelerating enrollment, and supporting the global clinical development strategy for Sapu003.

"Successful completion of the initial safety cohort represents an important milestone for the Sapu003 development program," said Dr. Vuong Trieu, CEO of Sapu Nano. *"The independent Safety Review Committee's recommendation to advance to the next dose level provides important clinical validation of the program's progress. Combined with the expansion of SP-03-B101 into Europe, we believe these milestones position Sapu003 for accelerated clinical development while broadening access for patients with advanced mTOR-sensitive solid tumors."*

Peer-Reviewed Publication Supports Clinical Development

The clinical milestone follows the Company's recent peer-reviewed publication describing the scientific foundation of Sapu003 and the proprietary Deciparticle™ nanoparticle platform.

Min SH, Forero K, Putnam W, Anderson J, Hoff R, Lopp J, Trieu V, Ho K, Lee C. *Intravenous Everolimus Formulation (Sapu003) for Clinical Trials.* **International Journal of Molecular Sciences.** 2026;27(13):5775. doi: **10.3390/ijms27135775**.

The publication provides the first comprehensive description of the Deciparticle™ platform, including formulation discovery, scalable cGMP manufacturing, physicochemical characterization, stability, and preclinical evaluation supporting the ongoing clinical development of Sapu003.

The published work demonstrated:

- Development of a stable intravenous everolimus nanoparticle formulation with a mean particle size below 20 nanometers.
- Development of a robust, scalable cGMP manufacturing process suitable for clinical production.
- Excellent product reproducibility and stability following lyophilization and refrigerated storage.
- Broad compatibility of the Deciparticle™ platform with multiple hydrophobic therapeutic compounds, supporting potential future pipeline expansion.
- Potent preclinical antitumor activity supporting advancement into clinical development.

"The progression from peer-reviewed publication to successful completion of our first clinical safety cohort highlights the maturity of both the Sapu003 program and the Deciparticle™ platform," added Dr. Trieu. *"We believe Deciparticle™ represents a differentiated nanomedicine platform capable of enabling intravenous delivery of numerous poorly water-soluble therapeutic compounds while supporting scalable commercial manufacturing."*

Clinical Trial Information

Study Title: SP-03-B101: A Phase 1b Study of Sapu003 (Intravenous Everolimus) in Patients with Advanced mTOR-Sensitive Solid Tumors

ClinicalTrials.gov Identifier: NCT07369505

About Sapu003

Sapu003 is an investigational intravenous formulation of everolimus developed using Sapu Nano's proprietary Deciparticle™ nanoparticle platform. Sapu003 is designed to overcome the formulation limitations associated with oral everolimus by enabling intravenous administration with a scalable cGMP manufacturing process. The program is currently being evaluated in the Phase 1b SP-03-B101 clinical trial in patients with advanced mTOR-sensitive solid tumors.

About Deciparticle™

Deciparticle™ is Sapu Nano's proprietary nanomedicine platform designed to formulate poorly water-soluble therapeutic compounds into stable intravenous formulations. The platform combines amphiphilic polymer technology with scalable cGMP manufacturing to enable the clinical development of challenging hydrophobic therapeutics. In addition to Sapu003, the platform has demonstrated compatibility with multiple classes of hydrophobic molecules, supporting future pipeline expansion and potential strategic collaborations.

About Sapu Nano

Sapu Nano (US) LLC is a clinical-stage biotechnology company developing the proprietary **Deciparticle™** nanomedicine platform for intravenous delivery of poorly water-soluble therapeutics. The Company's lead product candidate, **Sapu003**, an investigational intravenous formulation of everolimus, is currently in Phase 1b clinical development for patients with advanced mTOR-sensitive solid tumors. The Company is leveraging its Deciparticle™ platform to develop next-generation nanomedicine products for oncology and other serious diseases.

For more information, visit **www.sapunano.com**.

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 U.S. 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.

Oncotelic also develops PDAOAI, its proprietary artificial intelligence platform for drug discovery, cleanroom automation, and AI-assisted GMP manufacturing. Through Oncotelic's relationship with SAPU Bio - an OEB-5 sterile injectable cGMP manufacturing facility - PDAOAI underpins the Company's joint development work with TechForce Robotics on intelligent automation for high-containment GMP biomanufacturing.

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: the completion, scope, timing, capabilities, and commercialization of Phase 2 objectives under our joint manufacturing automation initiative with TechForce Robotics; the operational utility, performance, and customer adoption of the AI-Powered GMP Manufacturing Services Platform; the application of PDAOAI to sterile manufacturing operations, electronic batch records, GMP workflow execution, cleanroom monitoring, and autonomous materials movement; the potential for future software licensing, automation deployment, manufacturing partnerships, and technology-enabled contract development and manufacturing services; the size, growth, and addressability of the pharmaceutical manufacturing software and automation market; the demonstration of PDAOAI and the integrated robotics platform at BIO International Convention 2026; the role of SAPU Bio as commercial deployment site and proving ground; regulatory interactions and potential approvals; development or commercialization of any product candidates within the Oncotelic / GMP Bio / Sapu ecosystem; 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 competitive market of AI-enabled GMP manufacturing software and AI-enabled robotics; the performance and continued cooperation of our robotics and automation partners, including TechForce Robotics; 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.

Investor & Media Contact

Oncotelic Therapeutics, Inc.
Investor Relations
ir@oncotelic.com

Corporate Communications

IBN | Austin, Texas
www.InvestorBrandNetwork.com
Editor@InvestorBrandNetwork.com
512.354.7000

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