Oncotelic Announces Peer-Reviewed Publication Validating Deciparticle™ Technology Supporting the Ongoing Clinical Development of Sapu003 (IV everolimus)

AGOURA HILLS, Calif., July 22, 2026 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc. (OTCQB: OTLC) and Sapu Nano today announced the publication of a comprehensive peer-reviewed study in *Biomedicines* describing the preclinical translational package supporting **Sapu003**, the Company's intravenous Deciparticle™ formulation of everolimus. The publication provides a complete evaluation of the formulation's absorption, distribution, metabolism, excretion (ADME), pharmacokinetics (PK), tissue distribution, GLP toxicology, and cGMP manufacturing, representing one of the most comprehensive nonclinical evaluations reported for an intravenous formulation of everolimus.

The study demonstrates that Deciparticle™ technology successfully transforms everolimus from an oral therapy with well-recognized pharmacokinetic limitations into a clinically manufacturable intravenous formulation while preserving the drug's intrinsic metabolic characteristics. The findings support the ongoing Phase 1 clinical evaluation of Sapu003 in patients with advanced solid tumors.

The publication integrates multiple components required for clinical translation, including:

- Complete ADME characterization
- Pharmacokinetic and tissue-distribution studies
- Metabolic pathway analysis
- Excretion studies
- GLP repeat-dose toxicology
- cGMP manufacturing and release testing
- Product stability and quality characterization

Reduced Gastrointestinal Drug Exposure

Compared with oral everolimus, intravenous Sapu003 produced broad systemic distribution without the marked gastrointestinal accumulation characteristic of oral administration. Repeat-dose GLP toxicology studies demonstrated no treatment-related gastric pathology following intravenous dosing, supporting the potential for improved tolerability.

Clinical-Grade Manufacturing Successfully Demonstrated

The publication also describes the successful development of a reproducible cGMP manufacturing process for Sapu003. These manufacturing studies establish that Deciparticle™ technology is suitable for clinical production under current Good Manufacturing Practice (cGMP) conditions.

"This publication represents a significant milestone in the clinical translation of the Deciparticle™ platform," said Vuong Trieu, Ph.D., Chief Executive Officer of Oncotelic Therapeutics. "Rather than describing only a formulation or a pharmacokinetic study, this work brings together the complete scientific package-from cGMP manufacturing and quality control to ADME, pharmacokinetics, tissue distribution, metabolism, and GLP toxicology-that supports the ongoing clinical development of Sapu003."

"Our objective has always been to build a platform capable of transforming challenging hydrophobic therapeutics into clinically practical intravenous medicines. The successful demonstration of reproducible manufacturing together with favorable pharmacokinetic and safety characteristics provides strong validation of the Deciparticle™ technology."

About the Publication

The manuscript, titled **"IV-EVE: EVE for Injection-ADME, Pharmacokinetic and Toxicological Evaluation for Novel Deciparticle EVE Formulation,"** was published in *Biomedicines* on July 14, 2026. https://www.mdpi.com/2227-9059/14/7/1573

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.

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