Oncotelic Announces Peer-Reviewed Validation of Deciparticle™ Platform Supporting Clinical Development of Sapu003

Publication Highlights Novel Intravenous Everolimus Formulation and Demonstrates Broad Potential of Deciparticle™ Technology for Hydrophobic Therapeutics

SAN DIEGO, Calif., June 29, 2026 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc. ("Oncotelic" or the "Company") (OTCQB: OTLC) and Sapu Nano today announced today announced the publication of a peer-reviewed scientific manuscript validating its proprietary **Deciparticle™** nanoparticle platform through the successful development of **Sapu003**, the Company's investigational intravenous everolimus formulation currently being evaluated in an ongoing Phase 1b clinical trial.

The publication, **"Intravenous Everolimus Formulation (Sapu003) for Clinical Trials,"** has been published in the **International Journal of Molecular Sciences** and provides the first comprehensive description of the Deciparticle™ platform, including formulation design, scalable cGMP manufacturing, product characterization, stability, and preclinical evaluation.

Publication Citation

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.

Everolimus is a well-established inhibitor of the mammalian target of rapamycin (mTOR) approved for the treatment of multiple cancers. However, because of its poor aqueous solubility and limited oral bioavailability, clinical use has historically been restricted to oral administration. Sapu003 was developed using the Deciparticle™ platform to enable intravenous delivery through a stable nanoparticle formulation.

The publication reports several significant achievements, including:

- Development of a stable intravenous everolimus formulation with mean particle sizes below 20 nanometers.
- A robust, scalable cGMP manufacturing process capable of producing clinical-grade material with high batch-to-batch reproducibility.
- Favorable product stability following lyophilization and refrigerated storage.
- Successful formulation of multiple hydrophobic therapeutic compounds, demonstrating the broader applicability of the Deciparticle™ platform beyond everolimus.
- Potent preclinical antitumor activity supporting continued clinical development of Sapu003.

"The publication of this work represents an important milestone for Sapu Bioscience," said Vuong Trieu, Ph.D., CEO and Chairman of Oncotelic. "Independent peer review validates not only the scientific foundation supporting Sapu003, but also the broader Deciparticle™ platform. We believe this technology has the potential to address one of the longstanding challenges in drug development-enabling intravenous delivery of poorly water-soluble therapeutic compounds through a scalable and reproducible manufacturing process."

Unlike many formulation technologies developed for a single product, the published research demonstrates that the Deciparticle™ platform is compatible with wide range of hydrophobic molecules, including rapalogs, macrocyclic compounds, immunosuppressants, and selected peptide therapeutics. The Company believes this broad formulation capability may support future pipeline expansion and collaborative development opportunities.

Sapu003 is currently being evaluated in an ongoing Phase 1b open-label dose-escalation study in patients with advanced mTOR-sensitive solid tumors. The study is assessing the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of weekly intravenous Sapu003 administered in combination with exemestane.

"The publication marks the successful translation of the Deciparticle™ platform from laboratory research to clinical-stage manufacturing," added Dr. Trieu. "As our Phase 1b clinical study progresses, we look forward to further evaluating the potential of Sapu003 while continuing to expand the application of the Deciparticle™ platform to additional therapeutic programs."

About Sapu003

Sapu003 is an investigational intravenous formulation of everolimus developed using Sapu Bioscience's proprietary Deciparticle™ nanoparticle platform. The program is designed to overcome the formulation limitations associated with oral everolimus while enabling predictable intravenous administration for the treatment of patients with advanced cancers.

About Deciparticle™

Deciparticle™ is Sapu Bioscience's proprietary nanoparticle formulation platform designed to enable intravenous delivery of poorly water-soluble therapeutic compounds. The technology combines amphiphilic polymer design with scalable cGMP manufacturing to generate stable nanoparticle formulations suitable for clinical development. The platform has demonstrated compatibility across multiple classes of hydrophobic therapeutic agents and is being evaluated for broader pharmaceutical applications.

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 (intravenous everolimus), is currently in Phase 1b clinical

development for advanced mTOR-sensitive solid tumors. In addition to Sapu003, the Deciparticle™ platform is being developed to enable next-generation nanomedicine products across oncology and other serious diseases. For more information, please 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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