Oncotelic Therapeutics Highlights 2 Years of Clinical and Regulatory Advancements Across Late-Stage Pipeline

AGOURA HILLS, Calif., Sept. 12, 2025 (GLOBE NEWSWIRE) -- via IBN -- Oncotelic Therapeutics, Inc. (OTCQB: OTLC) ("OTLC" or the "Company"), a clinical-stage biopharmaceutical company developing transformative oncology and immunotherapy treatments, today announces a summary of its major accomplishments over the past two years. These milestones underscore meaningful clinical progress and regulatory validation across the Company's lead drug candidates.

Oncotelic's pipeline includes multiple late-stage programs targeting oncology and rare diseases, with several drug candidates achieving significant clinical milestones

Two-Year Clinical Progress Snapshot

- OT-101 (TGF-β inhibitor): Phase 3 for pancreatic cancer, with additional applications in ARDS/COVID-19
- OXi4503 (vascular disrupting agent): Phase 2 in AML/MDS; advancing toward pivotal phase 3 design
- CA4P / Fosbretabulin: Late-stage oncology asset currently under repositioning
- AL-101 (intranasal apomorphine): Phase 2 for Parkinson's disease and sexual dysfunctions
- AL-102 (oligonucleotide antisense via intrathecal injection): Discovery stage for Alzheimer's disease
- Pediatric Rare Disease Programs: Targeting orphan indications with the potential to generate Priority Review Vouchers (PRVs)
- Nanomedicine Pipeline**:** Advancing multiple 505(b)(2) drug candidates into clinical testing, leveraging the 505(b)(2) pathway-a faster and more cost-efficient route to market approval compared to a full New Drug Application (NDA).

"OTLC has achieved steady progress across multiple programs, strengthening our position as a late-stage biotech with broad value creation potential. Our pipeline addresses multi-billion-dollar markets with high unmet medical need," said Dr. Vuong Trieu, Chairman and CEO of Oncotelic.

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 150 patent applications and holds 39 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.

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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