Oncotelic Initiates Phase 2 Trial Evaluating OT-101 in Combination with KEYTRUDA® for Mesothelioma

AGOURA HILLS, Calif., Dec. 01, 2021 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc. ("Oncotelic" or the "Company") (OTCQB:OTLC), a leading developer of TGF-β therapeutics for oncology and virology, today announced that it has submitted clinical study protocol to the US FDA for the initiation of a Phase 2 Trial (designated "M201") for OT-101, the Company's TGF-β inhibitor, in combination with Anti-PD-1 (Pembrolizumab/Keytruda®) as a treatment for patients with Malignant Pleural Mesothelioma (MPM).

M201: Phase 2 Trial of TGF-β Inhibition (OT-101) with Anti-PD-1 (Pembrolizumab) in Patients with Malignant Pleural Mesothelioma (MPM) Failing to Achieve or Maintain Response to Checkpoint Inhibition.

OT-101 is a first-in-class anti-TGF-β ribonucleic acid ("RNA") therapeutic that has exhibited single agent activity in relapsed/refractory cancer patients in multiple clinical trials. OT-101 has also demonstrated activity against the SARS-CoV-2 virus, the virus that causes COVID-19, and is currently being evaluated in the Company's C001 clinical trial against hospitalized severe COVID-19 patients. Both tumor cells and SARS-Cov-2 induce TGF-β as part of their immune evasion mechanism. Consequently, inhibiting TGF-β by OT-101 is expected to impact both cancer and COVID.

The OT-101 oncology program ("OT-101-ONC") is designed to assess the impact of OT-101 across multiple cancer indications where local tumoral secretion of TGF-β suppressed the clinical activity of checkpoint inhibitors, CAR-T, and vaccine. The OT-101-ONC program has been moving forward steadily through strategic alliance with top pharmaceutical companies. Of note is the biomarker program spanning mesothelioma, glioblastoma, lung and colorectal cancers, where AI driven transcriptome analyses will be used to derive the predictive biomarker for TGF-β therapeutics such as OT-101.

"This is the first of a series of planned clinical trials in patients with various solid tumors evaluating clinical benefit while also assessing a host of parameters associated with changes in the tumor microenvironment, including but not limited to T-cell infiltration, expression of various cytokines, and phenotypic and functionality changes pre-therapy versus post-therapy," noted Dr. Anthony Maida, Chief Clinical Office - Translational Medicine.

"The groundwork laid down by OT-101/IL-2 and OT-101/PD-1 will serve as the foundation for future strategic alliances for OT-101/CAR-T and OT-101/Vaccines." said Dr. Vuong Trieu, CEO and Chairman of Oncotelic. "CAR T-cell therapy, in which a patient's immune T cells are modified so they will bind to cancer cells and kill them, has been shown to benefit greatly from TGF-β inhibition in early clinical testing."

About Oncotelic Therapeutics
Oncotelic Therapeutics, Inc. (f/k/a Mateon Therapeutics, Inc.) ("Oncotelic"), was formed in the State of New York in 1988 as OXiGENE, Inc., was reincorporated in the State of Delaware in 1992, and changed its name to Mateon Therapeutics, Inc. in 2016, and Oncotelic Therapeutics, Inc. in November 2020.

Oncotelic is an artificial intelligence driven immuno-oncology company with a robust pipeline of first in class TGF-β immunotherapies for late stage cancers such as gliomas, pancreatic cancer and melanoma. OT-101, the lead immuno-oncology drug candidate of Oncotelic, is a first-in-class anti-TGF-β RNA therapeutic that exhibited single agent activity in relapsed/refractory cancer patients. OT-101 also has shown activity against SARS-CoV-2 and has completed a phase 2 trial against COVID-19 with data cleaning and datalock ongoing. Oncotelic is seeking to leverage its deep expertise in oncology drug development to improve treatment outcomes and survival of cancer patients with a special emphasis on rare pediatric cancers. Oncotelic also has rare pediatric designation for DIPG (OT-101), melanoma (CA4P), and AML (OXi 4503). The Company also acquired PointR Data Inc. ("PointR") in November 2019.

For more information, please visit www.oncotelic.com.

Oncotelic’s 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, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Words such as "may," "expect," "anticipate" "hope", "vision", "optimism", "design," "exciting," "promising", "will," "conviction", "estimate," "intend," "believe", "quest for a cure of cancer", "innovation-driven", "paradigm-shift", "high scientific merit", "impact potential" and similar expressions are intended to identify forward-looking statements. Forward looking statements contained in this press release include, but are not limited to, statements about future plans, the progress, timing, clinical development, scope and success of future clinical trials, the reporting of clinical data for the company's product candidates and the potential use of the company's product candidates to treat various cancer indications as well as obtaining required regulatory approval to conduct clinical trials. Each of these forward-looking statements involves risks and uncertainties, and actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. These risks are not exhaustive, the company faces known and unknown risks, including the risk factors described in the Company's annual report on Form 10-K filed with the SEC on April 15, 2021 and in the company's other periodic filings. Forward-looking statements are based on expectations and assumptions as of the date of this press release. Except as required by law, the company does not assume any obligation to update forward-looking statements contained herein to reflect any change in expectations, whether as a result of new information future events, or otherwise.

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