PULMOHEAL™/ ARTIVEDA™ IS CLINICALLY ACTIVE AGAINST MILD AND MODERATE COVID-19.

AGOURA HILLS, Calif., Aug. 24, 2021 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc. ("Oncotelic" or the "Company") (OTCQB:OTLC), a leading developer of TGF-β therapeutics for oncology and COVID-19, reported today that PulmoHeal™/ ArtiVeda™ has proven active against mild and moderate COVID-19 following the preplanned prospective analysis of ARTI-19 clinical trial (NCT05004753- A Prospective, Randomized, Multi-center, Open label, Interventional Study to Evaluate the Safety and Efficacy of Artemisinin 500 mg capsule in Treatment of Adult Subjects with COVID-19). The study report will serve as the basis for Oncotelic's regulatory submission for marketing approval of PulmoHeal™/ ArtiVeda™.

"The positive outcome of this well conducted clinical trial has validated our TGF-β platform against COVID-19. Targeting the immutable host protein, PulmoHeal™/ ArtiVeda™ is effective against COVID-19 variants. We look forward to continuing expansion of our marketing of PulmoHeal™/ ArtiVeda™ as phytomedicine and further clinical development of Artemisinin as a pharmaceutical." said Dr. Vuong Trieu, CEO and Chairman of Oncotelic.

In summary, based on the study results, it was shown that Artemisinin 500 mg capsule administered once daily for 5 days:

- was effective in treating subjects with mild and moderate COVID-19,
- artemisinin+SOC group showed significant improvement over SOC in WHO severity scale on Day 4 and Day 5 with p=0.0045 and p=0.0370, respectively.
- decline in body temperature was faster and higher in Artemisnin+SOC group by day 2 in comparison to SOC arm,
- improvement in respiratory rate was faster and higher in Artemisnin+SOC group by day 5 in comparison to SOC arm,
- improvement in mean SpO2 level was significantly higher in Artemisnin+SOC group by day 28 (end of study) in comparison to SOC arm (p=0.029),
- no clinically significant changes in biochemistry or hematology parameters,
- was safe and well-tolerated by the study subjects.

About ARTI-19

NCT05004753- A Prospective, Randomized, Multi-center, Open label, Interventional Study to Evaluate the Safety and Efficacy of Artemisinin 500 mg capsule in Treatment of Adult Subjects with COVID-19. This was an open label, prospective, multicenter study. Subjects with a clinical diagnosis of mild to moderate COVID-19, subject to fulfilling other inclusion and exclusion criteria, were randomized to receive either SOC or test drug Artemisinin 500 mg capsule/day for 5 days + standard of care (SOC) per cycle with the option to repeat as needed until symptoms of the disease are resolved, up to a total of 3 cycles ("5 days treatment, 5 days off" comprise a cycle) or standard of care (SOC).

The subjects were randomly assigned and received treatment with either the test plus SOC (n=80) or the SOC (n=41). After having obtained signed, written Informed Consent, these subjects had undergone a screening examination. Provided all inclusion/exclusion criteria were fulfilled, the subjects were enrolled and randomized by block randomization to one of the two treatment arms on Day 1. All the subjects had received the usual treatment according to ICMR (Indian Council of Medical Research) and other Indian ministry of healthcare guidelines.

Assessments of safety and efficacy variables were performed as per the study protocol. The final visit end of study (EOS) was on Day 28. Serious AEs were followed-up until they resolve or get stabilized or until 30 days from the subject's involvement in the study had ended, whichever occurred first, and it was documented according to ICH-GCP and Indian GCP guidelines

Over all 122 patients were screened. The subjects were randomly assigned to one of the two groups: Artemisinin 500 mg (BD) with SOC or SOC in a ratio of 2:1.

Subjects were initially hospitalized for 5 days of study treatment in both treatment arms. When necessary, subjects were permitted to remain for a few more additional days in the hospital for the second cycle or third cycle of treatment.

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 was created by the 2019 merger with Oncotelic Inc., which became a wholly owned subsidiary of Mateon, thereby creating an immuno-oncology company dedicated to the development of first in class RNA therapeutics, as well as small molecule drugs against cancer and infectious diseases. 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 some relapsed/refractory cancer patients in clinical trial settings. OT-101 also has shown activity against SARS-CoV-2. 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 acquired PointR Data Inc. ("PointR") in November 2019. The PointR Acquisition was intended to create a publicly traded 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.

For more information, please visit www.oncotelic.com and www.mateon.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. 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 May 20, 2020 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.

Contact Information:
For Oncotelic Therapeutics, Inc.:
Amit Shah
ashah@oncotelic.com

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