

Oncotelic Publishes SNO 27th Annual Meeting Presentation Materials

AGOURA HILLS, Calif., Nov. 30, 2022 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc (OTCQB:OTLC) ("Oncotelic", the "Company" or "We"), a developer of treatments for rare and orphan indications, including Parkinson's Disease, PDAC, DIPG, and COVID-19, today announced the publication of the presentation materials from the Society for Neuro-Oncology ("SNO") 27th Annual Meeting held in Tampa Bay, FL on November 16th-20th, 2022 on our website (www.oncotelic.com).

Abstract #DDEL-16: Delivery of OT-101 - TGF-β2 Antisense for the Treatment of Glioblastoma. https://www.oncotelic.com/wp-content/uploads/2022/11/Trieu-DDEL-16-Delivery-of-OT-101-TGF-2-Antisense-for-the-treatment-of-glioblastoma.pdf

Abstract #RTID-04: Clinical Potential of Targeting Transforming Growth Factor β2 with OT-101 for Post-Radiation Consolidation in Diffuse Intrinsic Pontine Glioma.

https://www.oncotelic.com/wp-content/uploads/2022/11/Uckun-RTID-04-Clinical-potential-of-targeting-transforming-growth-factor-beta-2-with-OT-101-for-post-radiation-consolidation-in-diffuse-intrinsic-pontine-glioma revised.pdf

"Pediatric DMG is a very aggressive brain tumor in children that has a dismal prognosis with a median overall survival (OS) of less than one year after standard radiation therapy. Therefore, there is an urgent need for therapeutic innovations for treatment of pediatric DMG," explained Fatih Uckun, MD PhD, the Chief Medical Officer of Oncotelic. "The primary goal of our DIPG project will be to carefully evaluate in a stepwise manner the safety and tolerability as well as efficacy of OT-101 when it is administered directly into the CSF of pediatric patients with DMG. The protocol of a new Phase 1 study was recently submitted to the FDA. The protocol for another study we recently designed was presented at the SNO meeting."

"The support and strong interest from the subject matter experts who visited our poster reaffirmed the clinical importance of our DIPG project and the urgency of the unmet medical need in this field," stated Cynthia Lee, PhD, VP of Regulatory R&D of Oncotelic.

"Oncotelic's participation during the Society of Neuro-Oncology Annual Meeting is absolutely critical in the Company's efforts to further its clinical development of OT-101 in the setting of tumors, particularly of the CNS. During the four day conference I met with many of the world's Key Opinion Leads (KOLs) who share our belief in the promise of treating patients with anti-TGF-β2 antisense oligodeoxynucleotides either as a monotherapy or in combination with various anti-tumor modalities which may include radiation, chemotherapy, checkpoint inhibitors or various immunotherapeutic agents. It was a confirmation of our confidence in the clinical promise of OT-101 in the clinic and ultimately benefit to patients." said Dr. Anthony Maida, Chief Clinical Officer - Translational Medicine, Oncotelic.

About Dr. Fatih Uckun, DIPG Lead

The Chief Medical Officer of Oncotelic, Dr. Fatih Uckun MD, PhD, is an internationally renowned KOL in pediatric cancer research and treatment. Dr. Uckun is an elected Member of the American Society for Clinical Investigation (ASCI), an honor society for physician-scientists, and an active member of several professional organizations. He received numerous awards for his work on monoclonal antibodies, recombinant cytokines and fusion proteins, radiation sensitizers, kinase inhibitors and targeted therapeutics for difficult-to-treat cancers, including the Stohlman Memorial Award of the Leukemia Society of America (now known as Leukemia and Lymphoma Society), the highest honor given to a Leukemia Society Clinical Scholar. Dr. Uckun completed his residency training in pediatrics, clinical fellowship training in Hematology/Oncology/Blood and Bone Marrow Stem Cell Transplantation as well as postdoctoral research training in immunology at the University of Minnesota. Dr. Uckun has more than 30 years of professional experience in developmental therapeutics with a special emphasis on targeted therapeutics/precision medicines and biopharmaceuticals against childhood cancer. Dr. Uckun worked as a Professor of Pediatrics, Therapeutic Radiology-Radiation Oncology, Pharmacology, as well as Director of the Biotherapy Institute at the University of Minnesota (1986-1997), where he became the first recipient of the highly prestigious Endowed Hughes Chair in Biotherapy, and as a Professor of Pediatrics and Head of Translational Research in Leukemia and Lymphoma of the Children's Center for Cancer and Blood Diseases at the University of Southern California (2009-2015). From 2012-2015, Dr. Uckun served as chair of the Biotargeting Working Group and a Member of the Coordination and Governance Committee of the NCI Alliance for Nanotechnology in Cancer. Prior to joining Oncotelic, Dr. Uckun served as Head of Immuno-Oncology at Ares Pharmaceuticals and Executive Medical Director and Strategy Lead in Global Oncology and Hematology at Syneos Health. Prior to this, he was Chief Scientific Officer of Jupiter Research Institute and, before that, held senior-level scientific and research positions at Parker Hughes Institute and its cancer center, Paradigm Pharmaceuticals, and the Children's Cancer Study Group, an NCI-funded cooperative clinical trials consortium that coordinated pediatric leukemia trials at 120 institutions in the US, Canada, Australia and Europe. As a Vice Chair of the New Agents Committee as well as Member of the Leukemia Steering Committee of the Children's Cancer Study Group, Dr. Uckun has helped design and direct several Phase I-III studies in pediatric cancer patients.

About Oncotelic

Oncotelic (f/k/a Mateon Therapeutics, Inc.), 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 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 has rare pediatric designation for Diffuse Intrinsic Pontine Glioma "DIPG" (through OT-101) through its 45% joint venture, melanoma (through CA4P), and Acute Myeloid Leukemia "AML" (through OXi 4503). Oncotelic also acquired PointR Data Inc. in November 2019.

Oncotelic acquired AL-101, during the 4th quarter of 2021, for the intranasal delivery of apomorphine. We intend to develop AL-101 for the treatment of Parkinson Disease ("PD"). Over 60,000 new patients are being diagnosed with PD in the United States and currently there are over 1 million patients in the US and expected to increase to over 1.2 million by 2030. In addition, approximately 10 million suffer from this disease globally. https://www.parkinson.org/Understanding-Parkinsons/Statistics. AL-101 is also being developed for Erectile Dysfunction ("ED"). ED is the most prevalent male sexual disorder globally. The percentages of men affected by ED are as follows: 14.3-70% of men aged 60 years, 6.7-48% of men aged 70 years, and 38% of men aged 80 years (Geerkens MJM et al. (2019). Eur Urol Focus. pii: S2405-4569(19)30079-3). However, with the increasing administration of PDE5 inhibitors in clinical practice, it was found that approximately 30-35% of ED patients are treatment failures (McMahon CN et al. (2006). BMJ, 332: 589-92). AL-101 is designed to target treatment failure ED patients who do not respond to PDE5 inhibitors. Through similar mechanism of action, AL-101 is being developed for Female Sexual Dysfunction ("FSD"). Female sexual dysfunction is a prevalent problem, afflicting approximately 40% of women and there are few treatment options. FSD is more typical as women age and is a progressive and widespread condition.

(Allahdadi, KJ et al. (2009) Cardiovascular & hematological agents in medicinal chemistry, 7(4), 260-269). There is no available drug for the treatment of FSD. In June 2019, the U.S. Food and Drug Administration approved Vyleesi (bremelanotide) to treat acquired, generalized hypoactive sexual desire disorder ("HSDD") in premenopausal women. This is the only available drug treatment. Vyleesi has essentially replaced the only other drug for HSDD - however, it has a long list of drug-drug interactions, including commonly used antidepressants, such as fluoxetine and sertraline. In addition, it has a black box warning regarding its use with alcohol, a combination that has been associated with hypotension and syncopal episodes. Therefore, there is an urgent need for effective therapy against FSD and HSDD.

About OT-101

Oncotelic jointly owns OT-101 with its joint venture partners Dragon and GMP Bio. OT-101 has completed seven clinical trials including one phase 2 trial in COVID and two phase 2 trials in brain cancer and against pancreatic cancer. It has pediatric designation for a rare form of pediatric brain cancer known as DIPG. There are about 200-300 new cases of DIPG every year in the United States. DIPG most often occurs in children aged 5-10 years old. Treatment options are limited with surgery being contraindicated. Most children do not survive more than 2 years after diagnosis. Currently, the main treatment for DIPG is radiation therapy. Although radiation temporarily improves symptoms in most patients, it is not a cure. Palliative care or quality of life services help patients and families manage pain and other symptoms, promote quality of life, and making difficult decisions including treatment choices and end of life care.

When COVID-19 emerged in China, Oncotelic and GMP entered into a research and services agreement in February 2020 to develop and test COVID-19 antisense therapeutics. In March 2020, Oncotelic reported the anti-viral activity of OT-101. The anti-viral activity of OT-101, in an in vitro antiviral testing performed by an independent laboratory, OT-101 has a 50% effective concentration (EC50) of 7.6 µg/mL and is not toxic at the highest dose of 1000 µg/mL giving a safety index (SI) value of >130, which is considered highly active and on par or superior to Remdesivir - a Gilead drug. Unlike Remdesivir, OT-101 targets not only the virus replication but also the virus induced pneumonia and fibrosis. Our Phase 2 trial was completed for OT-101 in South America. This was a randomized, double-blind, placebo-controlled Phase 2 study intended to evaluate the safety and efficacy of OT-101 in adult patients hospitalized with positive SARS-CoV-2 and pneumonia. As reported in November 2021, the top line data was positive for safety and efficacy.

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 related to the operations of the JV, taking the JV into an initial public offering or the success thereof, the progress, timing of 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 and upon granting of approval by the regulatory agencies, the successful marketing of the products. Each of these forwardlooking statements involves risks and uncertainties, and actual results may differ materially from these forward-looking statements or may not occur at all. 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, taking the Company or its affiliates through initial public offerings. 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, 2022 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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11/30/2022 8:00:00 AM