



Oncotelic Presenting Data for OT101 Against Pancreatic Cancer (PDAC) at the SITC 37th Annual Meeting

AGOURA HILLS, Calif., Sept. 28, 2022 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc. ("Oncotelic" or the "Company") (OTCQB:OILC), developer of treatments for rare and orphan indications, including Parkinson Disease, Pancreatic Cancer, and DIPG, today announced that the Company will be presenting at the upcoming SITC 37th Annual Meeting, held November 10-12, 2022, in Boston, MA.

Abstract Number: 599

- Title: Mechanism of Action for OT-101 TGF- β immunotherapy
- Session Date: 11/10/2022 - 11/11/2022,
- Presentation time: 9:00 am - 9:00 pm

"Pancreatic cancer is the fourth leading cause of cancer-related mortality with a 5-year survival rate of approximately 10%. Incidence of pancreatic cancer has been steadily increasing despite advances in immunotherapy," said Dr. Vuong Trieu, CEO Oncotelic. "Using deep learning we demonstrated a combinatory approach for treatment of pancreatic cancer leveraging on OT-101 as suppressor of TGF- β . We are initiating late-stage clinical trials around this program and are excited to work with leading thought leaders to bring OT-101 to patients".

About OT-101 Pancreatic Cancer Program

Pancreatic cancer is associated with the poorest prognosis of gastrointestinal cancers and is expected to become the second leading cause of cancer-related mortality in the USA by 2030. Globally, over 400,000 people die of pancreatic cancer each year. Pancreatic cancer is traditionally considered to be an immune-resistant disease. There is a lack of effector T cells, an abundance of myeloid-derived suppressor T cells, and a dearth of key immune effector and regulatory cells. This may be part of the reason why single-agent checkpoint inhibitors are not as effective in comparison to other diseases. Here is where breaking immune tolerance by inhibiting TGF- β with OT-101 will have a significant impact.

The P001 trial was an open-label, multicenter dose-escalation study to evaluate the safety and tolerability of OT-101 (TGF- β 2-specific Phosphorothioate Antisense Oligodeoxynucleotide) in adult patients with advanced tumors known to overproduce TGF- β 2, which are not or no longer amenable to established therapies. Of the 61 patients treated, 37 had advanced treatment failure pancreas cancer, a very difficult-to-treat cancer with an overall survival rate that is measured in months even with the best available chemotherapy regimens. Disease control (complete response (CR)), partial response (PR) or stable disease (SD) was achieved in 19 of 35 evaluable pancreas cancer patients (54%). Among liver mets only patients, there are exceptional single-agent activity and survival. Patient 1006 was pushed to complete response (CR) and survived as far out as 77 mos. This patient failed multiple lines of therapies: (1) surgery: Whipple's procedure, (2) 1st line: 5-FU/LV, Dose 425 mg/m², (3) 2nd line: 5-FU/LV, Dose 2600 mg/m²/24hr, (4) 3rd line: Gemcitabine, Dose 1000 mg/m²/week, and (5) went on to OT-101 with liver mets and complete response. Patient 1022 was pushed to stable disease ("SD") with overall survival of 40 months. This patient had also failed multiple lines of therapies: (1) surgery: Whipple's procedure, (2) 1st line: radiation therapy (50 Gy), (3) 2nd line: 5FU, and (4) went on to OT-101 with liver mets and SD.

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 DIPG (OT-101) through its 45% joint venture, melanoma (CA4P), and AML (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 forward-looking 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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