Predictive Oncology and Dr. Daniel Carter Collaborating to Develop a Potential COVID-19 Vaccine Utilizing Novel Nanoparticle Vaccine Platform, Based on NSP-10

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MINNEAPOLIS, May 06, 2020 (GLOBE NEWSWIRE) -- Predictive Oncology (NASDAQ: POAI) has, with the announced acquisition of Soluble Therapeutics, Inc. and the subsequent partnership and licensing of a novel nanoparticle vaccine platform recently developed by Dr. Daniel Carter, entered the race to develop a COVID-19 vaccine. The groundbreaking vaccine technology being developed by Dr. Carter is based on a self-assembling nanoparticle called NSP-10 (NSP is Non Specific Protein) which follows a foundational vaccine platform developed earlier by Dr. Carter and his team, using another self-assembling protein called ferritin (1), an iron storage protein found in all living things. The ferritin platform is currently exploited by NIH in its exploration of the universal flu vaccine which completed phase I clinical trials earlier this year and is currently recruiting for a second Phase 1 trial on a modified version of the ferritin self-assembly universal vaccine (2,3). POAI has entered into an agreement with Dr. Carter under which POAI is licensing this technology, subject to certain conditions including additional documentation.

NSP-10 is a newly patented self-assembling nanoparticle technology sometimes referred to as virus-like particles or VLP (4). Called a nanoparticle because of its small size, typically 10-12 nanometers in diameter and self-assembling because a single small subunit has the built-in “self-assembly” instructions to form engineered complex Virus Like Particle (“VLP”) assemblies. They can be thought of as “smart-Legos”, so that when a large number are thrown together, they automatically self-assemble into the same large complex structures – in this case the vaccine. In the case of a DNA vaccine, the DNA instructs the body’s cells to make the Legos in mass which assemble into numerous vaccine particles.

This is a brand-new technology, published on January 4th, 2020 in Journal of Nanomaterials and the associated patent has just received notice of allowance from the US Patent Office in February 2020 (4,5). In addition to its publication during the beginning of the current coronavirus epidemic, its self-assembling elements are coincidentally based on an obscure gene regulatory protein found in the original SARS-CoV-1 coronavirus.

According to Dr. Carter, principal inventor of the ferritin self-assembling nanoparticle platform (1), now widely applied by many, including NIH, to other applications and principal inventor of the new NSP10 approach, “NSP10 is a ‘game changer’ vaccine platform with significant advantages over current state-of-the-art. These game changer properties have also been validated with SARS-CoV-2 vaccine candidates – resulting in extraordinary animal titers against the coronavirus spike protein which is required for viral infectivity – all with a simple injection of small quantities of DNA.”

1. NSP-10 is especially interesting because it has structural properties permit the rapid creation of nanoparticle vaccines for a broad spectrum of viruses and microbes in a “click and play” type design process.
2. They exhibit an ability to induce exceptional vaccine titers as either a protein or DNA-based vaccines, often as much as 10 to 100 times higher titers (more antibodies against the target) than traditional vaccines; and
3. They have the potential to rapidly move an effective DNA vaccine into the field with numerous advantages in safety, production, stability, distribution and administration.

The NSP COVID-19 vaccine has produced atypically strong titers against the coronavirus spike protein in small animals using a single small dose of plasmid-based DNA. Plasmid DNA is extremely safe, non-replicating, non-viral and can be produced in large quantities by established methods.

Vaccine in support of a Phase I clinical trial is in production with expected delivery later this month.

Predictive Oncology’s next step, in support of its partnership with Dr. Carter, is seeking quotes for a Phase 1 clinical trial from one or more of the BARDA approved CROs.

There is no assurance that a vaccine will be successfully developed using this technology, or that definitive documentation of all arrangements will be completed. As previously announced, POAI has taken over the operation of Soluble Therapeutics, which is also working on applications that can aid in COVID-19 development, and POAI this acquisition to be completed in the first part of May.

References:

1. D. C. Carter and C. Li, “Genetically Engineered Ferritin as a Vehicle for Vaccine Production, Biomaterials, Oxygen Transport, and Therapeutic Delivery, issued in Germany, France, United Kingdom, China and Canada, US Patent No. 7,097,841(2006)

2. Influenza HA Ferritin Vaccine, Alone or in Prime-Boost Regimens with an Influenza DNA Vaccine in Healthy Adults: Link: https://www.clinicaltrials.gov/ct2/show/NCT03186781?term=ferritin&cond=influenza&draw=2&rank=1

3. Dose, Safety, Tolerability and Immunogenicity of an Influenza H1 Stabilized Stem Ferritin Vaccine, VRCFLUNPF099-00-VP, in Healthy Adults: Link: https://www.clinicaltrials.gov/ct2/show/NCT03814720?term=ferritin&cond=influenza&draw=2&rank=2

4. D.C. Carter, W. Gray Jerome, B. Wright, J. Rose and E. Wilson, “ A Unique Protein Self-Assembling Nanoparticle with Significant Advantages in Vaccine Development and Production, J. of Nanomaterials, Vol 2020, Article ID: 4297937 (2020).

5. D. C. Carter, “NSP10 Self-Assembling Fusion Proteins for Vaccines, Therapeutics, Diagnostics and other Nanomaterial Applications,” US Patent Appln: US2018/0326044 Issuing (2020), Canada Pending.

About Dr. Carter

Dr. Carter has over 30 years of experience in the leadership and management of science in both the government and private sectors with core science

expertise in molecular structural biology, protein engineering, protein production and microgravity science and applications. He has maintained an internationally recognized research program throughout his career, authoring over 60 peer reviewed papers which include publications in Science, Nature and PNAS and is the inventor on more than 24 patents. His publications are highly cited (~13,500) with a current h-index ranking of 40.

Creator of highly successful self-assembling nanomaterial platforms for vaccine, therapeutic and diagnostic applications Internationally recognized authority on serum albumin structure and drug transport chemistry at the atomic scale. A pioneer in microgravity crystal growth hardware development and related science support services.

Prior to his career in the commercial biotechnology sector, Dr. Carter was employed by NASA for a period of 11 years in progressively more responsible positions including Chief of the Biophysics and Advanced Materials Branch, as well as, the prestigious SST appointment as the NASA Senior Scientist for Biophysics. While at NASA and New Century Pharmaceuticals, Inc., Dr. Carter also served as the Principal Investigator on an extensive series of multi-user microgravity protein crystal growth experiment payloads carried out on board the Space Shuttle, Mir and International Space Station, which included a large international co-investigator group of scientists from academics and industry. During his tenure at NASA, Dr. Carter was the recipient of many awards including NASA Inventor of the Year Awards and the NASA Exceptional Service Medal.

About Predictive Oncology Inc.

Predictive Oncology (NASDAQ: POAI) operates through three segments (Domestic, International and other), which contain four subsidiaries; Helomics, TumorGenesis, Skyline Medical and Skyline Europe. Helomics applies artificial intelligence to its rich data gathered from patient tumors to both personalize cancer therapies for patients and drive the development of new targeted therapies in collaborations with pharmaceutical companies. Helomics' CLIA-certified lab provides clinical testing that assists oncologists in individualizing patient treatment decisions, by providing an evidence-based roadmap for therapy. In addition to its proprietary precision oncology platform, Helomics offers boutique CRO services that leverage its TruTumor(TM), patient-derived tumor models coupled to a wide range of multi-omics assays (genomics, proteomics and biochemical), and an AI-powered proprietary bioinformatics platform to provide a tailored solution to its clients' specific needs. Predictive Oncology's TumorGenesis subsidiary is developing a new rapid approach to growing tumors in the laboratory, which essentially "fools" cancer cells into thinking they are still growing inside a patient. Its proprietary Oncology Discovery Technology Platform kits will assist researchers and clinicians to identify which cancer cells bind to specific biomarkers. Once the biomarkers are identified they can be used in TumorGenesis' Oncology Capture Technology Platforms which isolate and help categorize an individual patient's heterogeneous tumor samples to enable the development of patient specific treatment options. Helomics and TumorGenesis are focused on ovarian cancer. Predictive Oncology's Skyline Medical division markets its patented and FDA cleared STREAMWAY System, which automates the collection, measurement and disposal of waste fluid, including blood, irrigation fluid and others, within a medical facility, through both domestic and international divisions. The company has achieved sales in five of the seven continents through both direct sales and distributor partners. For more information, please visit www.Predictive-Oncology.com.

Forward-Looking Statements

Certain of the matters discussed in this press release contain forward-looking statements that involve material risks to and uncertainties in the Company's business that may cause actual results to differ materially from those anticipated by the statements made herein. Such risks and uncertainties include: we may not be able to continue operating without additional financing; current negative operating cash flows; the terms of any further financing, which may be highly dilutive and may include onerous terms; no assurance that a vaccine will be successfully developed in collaboration with Dr. Daniel Carter, or that definitive documentation of all arrangements with Dr. Carter will be completed, risks related to the 2019 merger with Helomics including; 1) significant goodwill could result in further impairment; 2) possible failure to realize anticipated benefits of the merger; 3) costs associated with the merger may be higher than expected; 4) the merger may result in the disruption of our existing businesses; and 5) distraction of management and diversion of resources; risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns; risks related to the transaction with Quantitative Medicine including: 1) completion of the transaction; 2) possible failure to realize anticipated benefits of the merger; 3) costs associated with the merger may be higher than expected; 4) the merger may result in the disruption of our existing businesses; and 5) distraction of management and diversion of resources; risk that we will be unable to complete the transaction with InventaBioTech to acquire Soluble Therapeutics and BioDtech; risk that we will be unable to protect our intellectual property or claims that we are infringing on others' intellectual property; the impact of competition; acquisition and maintenance of any necessary regulatory clearances applicable to applications of our technology; inability to attract or retain qualified senior management personnel, including sales and marketing personnel; risk that we never become profitable if our product is not accepted by potential customers; possible impact of government regulation and scrutiny; unexpected costs and operating deficits, and lower than expected sales and revenues, if any; adverse results of any legal proceedings; the volatility of our operating results and financial condition; and, and management of growth and other risks and uncertainties that may be detailed from time to time in the Company's reports filed with the SEC, which are available for review at www.sec.gov.

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