Predictive Oncology (NASDAQ Symbol POAI) is licensing and partnering this groundbreaking NSP10 technology in the race to develop a vaccine for development

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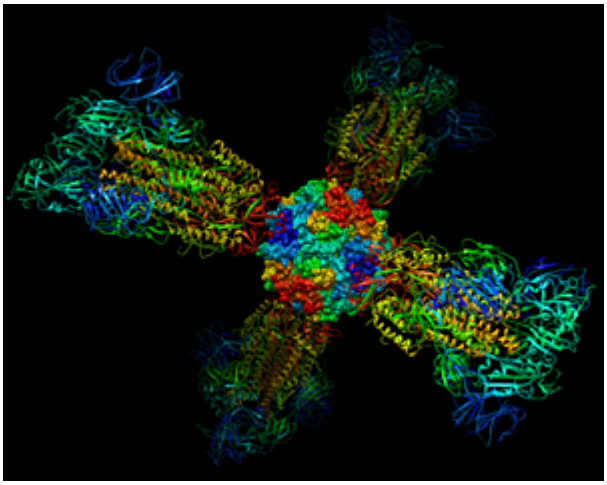
MINNEAPOLIS, May 14, 2020 (GLOBE NEWSWIRE) -- Predictive Oncology (NASDAQ: POAI) has, with the announced acquisition of Soluble Therapeutics and the subsequent partnership and licensing of a novel nanoparticle vaccine technology platform recently developed by Dr. Daniel Carter, entered the race to develop a COVID19 vaccine. The ground-breaking vaccine technology is based on a self-assembling nanoparticle called *NSP10* which follows a foundational vaccine platform developed earlier by Dr. Carter and his team, using another self-assembling protein called ferritin (1).



An atomic model of one of the NSP COVID19 Nanoparticle vaccine candidates displaying the SARS CoV-2 spike protein. The unique trimeric fusion points on NSP10 stabilize the proper native stem folding and present SARS spike protein to the immune system in exactly the same way as it occurs on the COVID19 virus, which in turn is expected to produce the desired results: immunity to COVID19.

NSP10 Vaccine Technology: How Does it work and Why is it a "Game Changer"?

NSP10 Nanoparticle has special surface properties that allow for the rapid design and display of viral receptor stems for virtually any virus, making it extremely versatile. "Couple these properties with the extraordinary immunogenic properties and you have a potentially "game changing" technology," according to Dr. Joel Dobbs, a retired pharmaceutical industry executive, who is now Executive-in-Residence at UAB's Collat School of Business, "this is a truly transitional technology that could change the way vaccines are made in the future."

Previous vaccine studies of *NSP10-based Nanoparticles* in rabbits produced exceptionally high titers against a herpes viral protein called glycoprotein D, normally non-highly antigenic (Titer refers to the number of times the blood serum can be diluted and still react with the virus antigen). Titers in this case ranged from 1:1,000 with a simple injection of 500 micrograms of plasmid DNA, to as much as 1:25,000 after a second booster (third injection) - all without the use of adjuvants or transfection agents (2). To our knowledge, this is unprecedented and revolutionary for a DNA vaccine. The exact reasons why the *NSP10-based Nanoparticles* exhibit these properties is still a subject of study, but scientists know that nanoparticles are processed differently by the immune system (3) and smaller nanoparticles can often produce higher titers – *NSP* is one of the smallest currently evaluated.

The level of titer is important for many reasons, for example, earlier animal experiments with vaccines focused on severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) found that low antibody levels could potentially lead to dysfunctional immune responses, increasing infection and damaging the lungs (4). In addition to enhanced protective immunity, stronger titers mean that it takes less vaccine per dose which has added advantages in safety and production scale. In the special case of *NSP10-based* vaccines, as it translates to humans, this could mean that a single gram of plasmid DNA can potentially immunize as many as 2,000 people, perhaps more. According to Dr. Daniel Carter, the inventor of this technology (5), "this suggests that if we see similar titers in humans, no atypical resources or capabilities are required to manufacture the vaccine at a sufficient scale to impact the pandemic." For example, a single bacterial fermentation at commercial scale can in a span of 2 to 3 days, produce enough raw material to eventually immunize millions of people - "merge this with the well-established processes for purifying injectable-grade plasmid DNA (which can also be done in short order) and you have the potential for a disruptive game changing technology," said Dr. Carter.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/99c5c11c-8099-44a7-af8d-8531cc437011

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. D.C. Carter, B. Wright, W. Gray Jerome, 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).
3. Tokatlian T, Read BJ, Jones CA, Kulp DW, Menis S, Chang JYH, et al. Innate immune recognition of glycans targets HIV nanoparticle immunogens to germinal centers. Science. 363(6427):649-54 (2019).
4. J. Cohen, “COVID19 Shot Protects Monkeys,” Science, 368(6490), 456-467 (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.

Dr. Carter’s research focus areas include: (1) understanding the atomic structure and chemistry of albumin, the principal protein of the circulatory system and key pharmacokinetic effector of virtually all pharmaceuticals; (2) development and applications of self-assembling nanomaterial platforms for vaccine, therapeutic and diagnostic applications; and (3) microgravity science and applications.

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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