Statera Biopharma and Immune Therapeutics Inc. Announce Strategic Agreement for Rights to Low Dose Naltrexone

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FORT COLLINS, Colo., April 27, 2022 (GLOBE NEWSWIRE) -- Statera Biopharma (Nasdaq: STAB) (the "Company"), a leading biopharmaceutical company creating next-generation immune therapies that focus on immune restoration and homeostasis, announced today that the Company entered into a non-binding term sheet with respect to a strategic agreement with Immune Therapeutics, Inc. (OTC-PINK: IMUN), a drug development and commercialization company, to sell Statera's rights to naltrexone and met-enkephalin. The transaction is contingent upon negotiation of a definitive agreement and satisfaction of a number of closing conditions, including a contingency on Immune Therapeutics financing.

"The agreement with Immune will enable us to strengthen our financial position with a transaction that has the potential to produce significant non-dilutive cashflow to fund our other programs. For instance, Statera is beginning to chart a new course in the immunotherapy field by pursuing molecules that act on Toll-like Receptor pathways similar to Naltrexone," said Michael K. Handley, President and Chief Executive Officer of Statera Biopharma. "It also will help advance our new product candidates for treatment of a variety of immune-related diseases that have no cure."

Under the anticipated terms of the agreement, Statera will receive an initial $2 million upfront payment and 5% of the issued and outstanding stock of Immune Therapeutics. Additionally, Statera will receive payments for achievement of revenue-based milestones, new indications and royalties, Crohn's disease and COVID-19 indications and regulatory approvals, as well as any other payments from Immune Therapeutics in exchange for Statera's rights to any product containing low-dose naltrexone as an active ingredient. Potential indication payments will include asthma, multiple sclerosis, HIV and chemotherapy. In aggregate, this transaction has the ability to generate over $400 million in non-dilutive payments to Statera.

"Statera's naltrexone assets will be a great addition to our immune-modulation products and immunotherapy technologies," said Kevin Phelps, CEO, Immune Therapeutics. "We believe that they can significantly enhance our ability to combat chronic, life-threatening diseases and bring hope to millions of patients and their families."

About Statera Biopharma

Statera Biopharma (formerly Cytocom, Inc.) is a clinical-stage biopharmaceutical company developing novel immunotherapies targeting autoimmune, neutropenia/anemia, emerging viruses and cancers based on a proprietary platform designed to rebalance the body's immune system and restore homeostasis. Statera has one of the largest platforms of toll-like receptor (TLR) agonists in the biopharmaceutical industry with TLR4 and TLR9 antagonists, and the TLR5 agonists, Entolimod and GP532. TLRs are a class of protein that plays a key role in the innate immune system. Statera is developing therapies designed to directly elicit within patients a robust and durable response of antigen-specific killer T-cells and antibodies, thereby activating essential immune defenses against autoimmune, inflammatory, infectious diseases, and cancers. Statera has clinical programs for Crohn's disease (STAT-201), hematology (Entolimod), pancreatic cancer (STAT-401) and COVID-19 (STAT-205) in addition to potential expansion into fibromyalgia and multiple sclerosis. To learn more about Statera Biopharma, please visit www.staterabiopharma.com.

About Immune Therapeutics

Immune Therapeutics is a specialty pharmaceutical company involved in the manufacturing, distribution and marketing of novel patented therapies to combat chronic, life-threatening diseases through the activation and modulation of the body's immune system. The company's technology platform is built on two different immunotherapies, Low Dose Naltrexone (LDN) and Methionine-Enkephalin (MENK). Both therapies have been decades in the making at institutions such as the Pennsylvania State University Medical School at Hershey, University of Chicago, State University of New York, and Multiple Sclerosis Center at UCSF. To learn more about Immune Therapeutics, please visit https://www.immunetherapeutics.com.

Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. All statements other than statements of current or historical fact contained in this press release, including statements regarding the Company's expected clinical development timeline for the Company's product candidates, future financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals, the impact of any laws or regulations applicable to the company, and plans and objectives of management for future operations, are forward-looking statements. The words "anticipate," "believe," "continue," "should," "estimate," "expect," "intend," "may," "plan," "project," "will," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements on the current expectations about future events held by management. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond the Company's control. The company's actual future results may differ materially from those discussed here for various reasons. The Company discusses many of these risks under the heading "Risk Factors" in the proxy statement/prospectus filed with the SEC on June 10, 2021, as updated by the company's other filings with the SEC. Factors that may cause such differences include, but are not limited to, the outcome of any legal proceedings that have been or may be instituted against the company related to the merger between Cleveland BioLabs and Cytocom; unexpected costs, charges or expenses resulting from the merger; the Company's need for additional financing to meet the Company's business objectives; the Company's history of operating losses; the Company's ability to successfully develop, obtain regulatory approval for, and commercialize the Company's products in a timely manner; the Company's plans to research, develop and commercialize the Company's product candidates; the Company's ability to attract collaborators with development, regulatory and commercialization expertise; the Company's plans and expectations with respect to future clinical trials and commercial scale-up activities; the Company's reliance on third-party manufacturers of the Company's product candidates; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to serve those markets; the rate and degree of market acceptance of the Company's product candidates; regulatory requirements and developments in the United States, the European Union and foreign countries; the performance of the Company's third-party suppliers and manufacturers; the success of competing therapies that are or may become available; the Company's ability to attract and retain key scientific or management personnel; the Company's historical reliance on government funding for a significant portion of the

Company's operating costs and expenses; government contracting processes and requirements; the exercise of significant influence over the Company's company by the Company's largest individual stockholder; the impact of the novel coronavirus ("COVID-19") pandemic on the Company's business, operations and clinical development; the geopolitical relationship between the United States and the Russian Federation as well as general business, legal, financial and other conditions within the Russian Federation; the Company's ability to obtain and maintain intellectual property protection for the Company's product candidates; the Company's potential vulnerability to cybersecurity breaches; and other factors discussed in the Company's SEC filings, including the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and the risk factors discussed under the heading "Risk Factors" in the proxy statement/prospectus the company filed in connection with the merger on June 10, 2021.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. The forward-looking statements included in this press release are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.

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