ImmunityBio's Novel Immunotherapy NANT Cancer Vaccine Currently Being Studied in Multiple Clinical Trials Is Awarded a U.S. Patent

July 27, 2021

- The novel immunotherapy NANT Cancer Vaccine (NCV) developed at ImmunityBio based on the concept of founder Patrick Soon-Shiong, M.D. has been studied in both Phase 1 and 2 trials in tumor types including pancreatic, breast, colorectal, and head and neck cancers.
- The NCV is an innovative approach combining delivery of low-dose chemotherapy with ImmunityBio's adenoviral and yeast-based cancer antigen vaccines, proprietary natural killer cell platform and the IL-15 superagonist N-803 (Anktiva™).
- In clinical trials, the NCV approach has been shown to induce complete remission across multiple tumor types in patients who previously progressed on standard-of care therapy, with an adverse effect profile that is favorable compared to high-dose chemotherapy.
- With this issued patent, ImmunityBio's intellectual property portfolio includes more than 1,100 issued and pending patents worldwide for its immunotherapy technologies, with patent life extending to 2035 and beyond.

CULVER CITY, Calif.--(BUSINESS WIRE)--Jul. 27, 2021-- ImmunityBio, Inc., a publicly traded immunotherapy company, announced today that it has been granted a patent by the U.S. Patent and Trademark Office for its proprietary NANT Cancer Vaccine (U.S. Patent 11,071,774). This novel investigational treatment for cancer is designed to bolster a patient's own immune response to cancerous cells, augment that response with additional natural killer and T-cell therapies to overcome the cancer's resistance, and induce long-term T-cell memory to induce remission across multiple tumor types.

The NCV has been in clinical testing since 2017 and has its foundation in earlier work that led to the development of Abraxane®, an albumin nanoparticle that enables the delivery of paclitaxel to the tumor microenvironment. The basis of the orchestrated, multi-modal NCV approach is delivery of chemotherapy agents in a 'metronomic' fashion—low doses spread over time—to expose the tumor to immune system recognition by release of tumor-specific antigens. The tumor antigens are then targeted by antigen-specific T-cells activated via ImmunityBio's adenoviral- and yeast-based vaccine vectors. T cell activation can then be enhanced further by infusion of the company's proprietary, off-the-shelf, natural killer cell platform and its IL-15 superagonist N-803 (Anktiva).

To study the safety and early efficacy signals across multiple tumor types, the company has launched a series of Quantitative Lifelong Trials (QUILT). To date, the NANT Cancer Vaccine has been studied in more than 100 patients across multiple tumor types, including pancreatic, breast, colorectal, and head and neck cancers. Among these studies is QUILT 88, a Phase 2 trial studying the NCV in metastatic pancreatic cancer patients. Enrollment of Cohort C, patients who have previously failed two lines of standard-of-care therapy, is expected to be completed in the third quarter of 2021 and an early readout of survival data is expected in the first quarter of 2022.

"We are excited to be developing this orchestrated approach to activate as many elements of the immune system that we can and overcome cancer's ability to evade the immune system. Our hypothesis is that by revealing tumor antigens to the immune system, we activate tumor-specific T cells and targeted natural killer cells to eradicate tumors by what is known as immunogenic cell death," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "The issuance of the NANT Cancer Vaccine patent is recognition of this innovative approach to therapy that not only potentially provides long-term immune system protection from cancer, it does so with a reduced risk of the toxicity risk that comes with using high-dose chemotherapy and radiation. This closely aligns with the FDA's recent 'Project Optimist' guidelines for exploring lower doses of therapeutic agents."

ImmunityBio's intellectual property portfolio includes more than 1,100 issued and pending patents worldwide across multiple categories including biologics, vaccine vectors, natural killer cells, and GMP devices. Patents for key areas such as N-803 (Anktiva), adenovirus vaccine vectors, yeast vaccine vectors, NK-92 cells and therapies extend to 2035 and beyond.

About ImmunityBio

ImmunityBio is a leading late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio has a comprehensive immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated)—of which 25 are at Phase II and III stage of development—across 19 indications in solid and liquid cancers and infectious diseases. Currently 17 first-in-human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. Anktiva™ (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC).

The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform.

ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams. For more information, please visit: www.immunitybio.com

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding patent protection, the potential of the NCV and the timing of availability and release of data from the Company's clinical trials. Statements in this press release that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as "anticipates," "believes," "continues", "could", "estimates," "expects," "intends," "may," "plans," "potential", "predicts", "projects," "seeks," "should," "will," and variations of such words or similar expressions. Statements of past performance, efforts, or results of our clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about ImmunityBio, including, without limitation, (i) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (ii) inability to retain and hire key personnel, (iii) uncertainty of the expected financial performance and successful integration of the combined company following completion of the recent merger of ImmunityBio with NantCell (the "Merger"), including the possibility that the expected synergies and value creation from the Merger will not be realized or will not be realized within the expected time period, (iv) whether interim, initial, "top-line" and preliminary data from ImmunityBio's clinical trials that it announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, (v) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vi) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies and (vii) the unknown future impact of the COVID-19 pandemic delay on certain clinical trials or their milestones and/or ImmunityBio's operations or operating expenses. More details about these and other risks that may impact ImmunityBio's business are described under the heading "Risk Factors" in the Company's Form 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 10, 2021, Form 10-Q filed with the SEC on May 14, 2021 and in subsequent filings made by ImmunityBio with the SEC, which are available on the SEC's website at www.sec.gov. ImmunityBio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. ImmunityBio does not undertake any duty to update any forward-looking statement or other information in this press release, except to the extent required by law.

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