



ImmunityBio and NantOmics Announce Clinical Validation of a Proprietary Method to Identify Unique Targets for Immunotherapy in Individual Breast Cancer Patients

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- The “neopeptide” identification pipeline facilitates discovery of immunotherapy targets unique to individual cancer patients as a personalized and precision medicine approach to treatment
- The neopeptides identified can be leveraged to improve outcomes with adoptive cell transfer therapy and personalized vaccines
- Adenovirus and Yeast vaccine platforms in Phase 1/2 clinical trials to drive immunity to tumor-associated antigens and neoantigens across multiple solid tumor types

CULVER CITY, Calif.--(BUSINESS WIRE)--Jun. 28, 2021-- ImmunityBio, Inc. (NASDAQ: [IBRX](#)), a publicly traded immunotherapy company, and privately-held NantOmics today announced publication of a stepwise approach or “pipeline” for identification and validation of neopeptide and neopeptide-reactive T cells from individual patients. The identification of neopeptides—short peptide sequences that are mutated in tumors and are capable of generating an immune response—provides critical support in the successful development of next-generation immunotherapies delivered by ImmunityBio’s Adeno- and yeast-based platforms. The pipeline is described in [“Identification and validation of expressed HLA-binding breast cancer neopeptides for potential use in individualized cancer therapy.”](#) which recently published in the *Journal for Immunotherapy of Cancer*.

The pipeline leverages the bioinformatics capabilities of NantOmics and ImmunityBio to predict neopeptides based on genomic and expression analyses that have a high likelihood of generating a tumor-fighting immune response and the generation of neopeptide-specific CD4+ and CD8+ T cells when delivered using the Adeno and yeast vaccine platforms. These predicted neopeptides once identified are synthesized as short peptides, and run through a series of studies to confirm their potential utility in the cancer vaccine platforms. The pipeline was developed in conjunction with physicians and scientists at Friedrich Alexander University in Germany and the National Cancer Institute (NCI) in the U.S.

In clinical use, this neopeptide discovery system supports the targeted delivery of antigens with ImmunityBio’s second-generation Adeno platform. This platform, which [has shown promising results in Phase 1 and 2 trials](#), activates CD4+ and CD8+ T cells after delivery of tumor-associated antigens in patients with advanced solid tumors and colon cancer. In preclinical studies conducted in collaboration with the NCI, accurate prediction of neopeptides, delivered via the adenovirus platform, resulted in complete response in colon cancer when combined with ImmunityBio’s IL-15 superagonist Anktiva and other immune-based therapies. [That study highlights the potential for neopeptide identification to inform highly effective anti-tumor therapy.](#)

“The future of immunotherapy is in a personalized approach,” said Dr. Patrick Soon-Shiong, Founder and Executive Chairman of ImmunityBio. “By tailoring therapies to the individual biology of each patient’s cancer, we greatly increase the likelihood of successful treatment using our ever-increasing arsenal of immune-based therapies.”

“Validation of the neopeptide identification pipeline in actual patients from the TILGen study was an important aspect of the proposed method,” said Dr. Peter Fasching, who with Dr. Anita Kremer, was senior author on the manuscript. “We were able to isolate the specific immune cells that recognized the predicted neopeptides. Those immune cells aimed at the cancer cells’ neopeptides are very important because they could potentially kill a tumor. Clinically, the predicted and confirmed neopeptides could be targeted by vaccines or adoptive cell transfer therapies and improve patient outcomes.”

Neopeptides can be unique for each patient and when the pipeline is applied, the analyses for identification of these neopeptides would be performed using tumor and other tissues collected from individual patients.

This method for identifying tumor-specific immunogenic targets for individualized treatment can be used as part of a program including other immune and cell-based therapies available through ImmunityBio, including CAR T-cell therapies and vaccines. Efficacy of these therapies could be further enhanced by combination with an immune enhancer such as ImmunityBio’s Anktiva® or Natural Killer (NK) cells.

About the Neopeptide Identification Pipeline

- The bioinformatics methodology, well-established at NantOmics, readily and accurately predicts neoantigens;
- Practical cell-based assays of synthesized neopeptide peptides refines candidates to those most likely to induce an immune response;
- and Tissues and cells routinely collected from individual cancer patients can be used to confirm and further narrow neopeptide candidates.

The neopeptide identification and validation pipeline is feasible, practical and accurate, as this first report suggests. It is anticipated that it will be applied in future clinical studies of immunotherapies to determine the merits of this personalized approach to precision medicine for cancer.

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

About NantOmics

NantOmics, a member of the NantWorks ecosystem of companies, is a leader in molecular testing and the first company to employ an integrated panomic approach to inform personalized treatment options for patients with cancer. Combining DNA sequencing, RNA sequencing, and quantitative proteomics, NantOmics offers extensive testing capabilities that provide a comprehensive molecular profile of a patient's cancer. Our proprietary analytical platform delivers molecular diagnostic capabilities that provide actionable intelligence and molecularly driven decision support for cancer patients and their providers at the point of care. For more information, please visit: www.nantomics.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 our clinical trials that we announce or publish 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) our ability to obtain additional financing to fund our operations and complete the development and commercialization of our various product candidates, and (vi) 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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Investors

Sarah Singleton
ImmunityBio, Inc.
844-696-5235, Option 5

Media

Katie Dodge
Salutem
978-360-3151
Katie.Dodge@salutemcomms.com

Source: ImmunityBio, Inc.