



ImmunityBio Awarded Seminal Patent on Natural Killer Cells

January 4, 2022

- NK cells engineered with a high-affinity CD16 receptor have the potential to enhance monoclonal antibody therapeutic effects against cancer cells
- Combination monoclonal antibody therapy and CD16 NK-92 cell therapy patent term to 2036

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 4, 2022-- ImmunityBio, Inc. ([NASDAQ: IBRX](#)), a clinical-stage immunotherapy company, has been granted a U.S. patent ([11,207,350 B2](#)) for a novel natural killer (NK) cell therapy composition and method for treating cancer that combines the company's genetically modified NK-92 cells with CD16 receptors to enhance binding and activity of monoclonal antibodies. The combination of these engineered NK-92 cells with current monoclonal antibody therapies has the potential to augment the overall cytotoxic effects of monoclonal antibody treatment alone and help to address relapse by bolstering the patient's own natural immune system response.

ImmunityBio's NK-92 cells are specifically modified versions of the NK cells that are a core element of the human immune system. First discovered in the blood of a non-Hodgkins lymphoma patient, these cells retain most of the activating receptors of NK cells but lack the major inhibitory receptors, giving them higher baseline cytotoxicity against tumor cells. The cells have been included in more than 450 published papers covering a wide range of research and they are currently being studied in clinical trials for pancreatic cancer, triple-negative breast cancer, and non-Hodgkin lymphoma.

The off-the-shelf NK cell platform can be easily expanded, genetically modified and cryopreserved. By inserting chimeric antigen receptors (CARs) in the NK-92 cells, they have the potential for multi-specific killing including direct NK cell killing via stress ligands, CD16-mediated killing via tumor-targeted antibodies, and [CAR-mediated killing](#).

The patent, which protects this therapeutic approach for 20 years from its original filing, covers the use of these NK-92 cells in conjunction with the mAbs that are a standard of care in many cancer cases.

"While monoclonal antibodies have significantly improved the clinical outcomes in patients with cancer, many of these patients ultimately relapse," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "A growing body of research suggests that clinically meaningful responses to these antibody therapies is dependent upon the overall health of the patient's own natural killer cells and whether the cells express the high-affinity variant of the CD16 receptors, which are found on the surface of natural killer cells. [Only about 10% of NK cells](#) in the blood of healthy people have the high-affinity CD16 receptors for monoclonal antibody binding—the majority of NK cells have the intermediate- and low-affinity receptor—therefore an infusion of these NK-92 cells engineered with a high-affinity CD16 receptor supercharges the monoclonal antibodies, potentially enabling the antibodies to be therapeutically more effective in combination with the killing activity of these engineered NK-92 cells."

The new patent adds another asset to ImmunityBio's strong intellectual property portfolio, which 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 2036 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 broad immunotherapy and cell therapy platforms—including Antibody cytokine fusion proteins, synthetic immunomodulators, vaccine technologies (hAd5 viral vector, mRNA, recombinant protein, and adjuvant), and genetically-modified, off-the-shelf natural killer cells (autologous and allogenic cytokine-enhanced memory NK cells)—activate both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio's clinical pipeline consists of 21 clinical trials—13 of which are in Phase II or III development—across 12 indications in solid and liquid cancers (including bladder, pancreatic, and lung cancers) and infectious diseases (including SARS-CoV-2 and HIV). 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 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 the potential effects and efficacy of ImmunityBio's therapeutic product candidates and treatments, including ImmunityBio's NK cell platform, and the length and scope of protection of the patent described herein, among others. 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 preclinical and 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 information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. 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) whether interim, initial, "top-line" and preliminary data from ImmunityBio's preclinical and 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, (iv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (v) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (vi) competition in the biotechnology industry and ImmunityBio's beliefs regarding the benefits and perceived limitations of competing approaches and the future of competing technologies in the industry. 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 November 12, 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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