ImmunityBio Expands Vaccine Program to Accelerate Use of “Mix-and-Match” Technologies in Developing and Manufacturing Next-Generation COVID-19 Vaccines

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- Second-generation vaccines that combine different advanced DNA, RNA, Protein, and Adjuvant components are critical to providing accessible, broad, and durable protection against current and future likely SARS-CoV-2 variants
- By adding self-amplifying self-adjuvating RNA (SASA-RNA), next-generation nano-lipid carriers, recombinant protein, and adjuvant vaccine technologies to ImmunityBio’s current adenovirus vector vaccine, the company offers one of the most comprehensive vaccine technology platforms
- Such combination approaches are already being studied in trials in South Africa, including the fully enrolled Phase 2 SISONKE Boost trial, which is studying ImmunityBio’s hAd 5 as a boost to the Janssen COVID-19 prime
- This vaccine consortium is designed to create a comprehensive technology platform to serve as a foundation for the large-scale manufacture of multiple vaccine vectors for pandemic preparedness and for the treatment of cancer

CULVER CITY, Calif.--(BUSINESS WIRE)--Nov. 18, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced the expansion of the company’s cancer and infectious disease vaccine programs to include self-amplifying self-adjuvating RNA (SASA-RNA), recombinant protein vaccine candidates, and potent adjuvant formulations that enhance the quality, durability and breadth of immune responses to infectious diseases and cancer. When combined with the company’s hAd5 T-cell-based vaccine candidate, the company believes this “mix-and-match” approach will enable a new generation of COVID-19 vaccines that could potentially confer long-term immune memory to overcome the threat of current and future variants of the SARS-CoV-2 virus.

ImmunityBio has established partnerships with Amyris, Inc., Infectious Disease Research Institute (IDRI), and a collaboration with Baylor College of Medicine to bring these technologies together to establish a vaccine consortium and develop multiple vaccine candidates, conduct comprehensive clinical testing, and to immediately further scale ImmunityBio’s manufacturing capabilities for global capacity for each of these vaccine candidates. The creation of this novel “mix-and-match” platform, which is also rapidly amenable to incorporation of variant constructs as they emerge, is aimed at establishing widespread availability of cost-effective, broad-spectrum vaccines to meet the enormous remaining global need for COVID-19 vaccines and boosts, especially in low- and middle-income countries.

“Even though the first COVID-19 vaccines were approved almost a year ago, and billions have been invested to develop those first-generation shots, just 40% of the global population is fully vaccinated today,” said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. “What’s more, most of the people who have not yet received a vaccination are in low- and middle-income countries where cost and access are huge factors, and where the virus has ideal conditions for developing potent new variants. Not only do we believe our expanded platform approach will create powerful new vaccines, but we also believe that we already have the large-scale infrastructure in place to quickly and cost-effectively scale up production immediately. In addition, our vaccine candidates do not require the difficult storage conditions of several current vaccines, which we believe makes them more practical to make, store, and distribute to remote areas.”

Self-Amplifying, Self-Adjuvanted RNA vaccines are rapidly scalable and show enhanced antigen expression at lower doses than conventional mRNA vaccines

In preclinical and clinical studies, next generation self-amplifying, self-adjuvanted RNA (SASA-RNA) COVID-19 vaccine, developed by IDRI, have shown enhanced antigen expression at lower doses than conventional RNA vaccines. Thus, more doses can be created per manufacturing run and the nano-lipid carrier can be manufactured independently of the SASA-RNA. Through a joint-venture agreement with Amyris, ImmunityBio will accelerate the commercialization and large-scale manufacture of this next-generation RNA COVID-19 vaccine. The vaccine candidate is currently part of a heterologous prime and boost Phase 1 / 2 trial design submitted to the South African Health Products Regulatory Authority (SAHPRA) for approval.

Next-generation adjuvant-based, nano-lipid carriers for SASA-RNA vaccines are manufactured at scale with long-term storage capabilities for global preparedness

Currently authorized mRNA vaccines are delivered by a lipid nanoparticle (LNP) to both protect the RNA from degradation and allow for more efficient transport of the RNA to the inside of a cell. In contrast, this next-generation SASA-RNA is combined with a nanostructured lipid carrier (NLC) to protect and deliver RNA vaccines that we believe has several important advantages over current technologies.

“IDRI’s NLC technology allows RNA vaccines to be stable under simple refrigeration for nearly a year and several months at room temperature. Perhaps even more exciting, the technology can be manufactured in bulk and stockpiled, then combined with SASA-RNA that can be rapidly made to address a newly emergent viral strain,” said Corey Casper, M.D., MPH, CEO of IDRI. “This technology, therefore, is ideal for both providing a stable vaccine that does not require cold chains for low-resource environments and also addressing the current and future pandemics.”

Recombinant Protein Subunit vaccines use proven yeast fermentation technology to address COVID-19

ImmunityBio has licensed a recombinant protein COVID-19 vaccine candidate from Baylor College of Medicine, which was developed at the Texas Children’s Hospital Center for Vaccine Development. Protein-based vaccines have long been used to confer immunity against hepatitis B and human

papillomavirus (HPV), as immune responses often target proteins that are part of viruses and bacteria. This recombinant protein vaccine technology is proven and well-established. Production of these vaccines can be easily scaled up in low-resource countries. Paired with powerful adjuvant formulations, protein-based vaccines can provide broad protection against multiple coronavirus variants and are stable at room temperatures. ImmunityBio will lead development, manufacture scale up and commercialization of the recombinant protein vaccine candidate in South Africa. Combination trials to include this and the above ImmunityBio technologies are currently being designed.

"We're excited about this partnership to advance heterologous boosting opportunities globally, especially for the world's low- and middle-income countries. Our recombinant protein vaccine technology is well positioned for this purpose," said Dr. Peter Hotez, Dean of the National School of Tropical Medicine at Baylor College of Medicine and Co-director of the Texas Children's Hospital Center for Vaccine Development.

"Our recombinant protein vaccine technology is well positioned to provide a path to success for the mix-and-match" approach, said Dr. Maria Elena Bottazzi, associate dean of the National School of Tropical Medicine at Baylor and co-director of the Texas Children's Hospital Center for Vaccine Development. "We are delighted to be part of this co-development program and join forces with ImmunityBio and with our long-lasting collaborators at IDRI."

ImmunityBio's hAd5 S+N Adenovirus Vector vaccine stimulates T-cell response designed to provide enhanced protection against current and future SARS-CoV-2 variants

ImmunityBio's second-generation hAd5 viral-vector vaccine is unique in targeting both S and N SARS-Cov-2 proteins to generate B and T cell memory to these antigens and, potentially, long-term immunity to the virus. In addition, the platform was developed to elicit anti-SARS-CoV-2 immune responses even in Ad-immune individuals, meaning subjects can receive the vaccine multiple times, if necessary. Finally, the hAd5 vaccine candidate has been developed for different routes of administration: subcutaneous (SC) injection, sublingual (SL) drops, and intranasal (IN) spray. The vaccine candidate is currently being studied in Phase 1 and 2 trials in the U.S. and South Africa.

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's clinical pipeline consists of 20 actively recruiting clinical trials in Phase I, II, or III development. There are 13 active clinical trials 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). 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. 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 development of therapeutics for cancer and infectious diseases, ImmunityBio's expectation that is joint venture with Amyris will accelerate commercialization of a next generation COVID-19 vaccine, the efficacy of the combination approach in conferring long-term immunity against COVID-19 and its variants, potential advantages of ImmunityBio's vaccine candidates as compared to existing COVID-19 vaccines, ImmunityBio's ability to scale its vaccine candidates for further clinical and commercial use and related cost-effectiveness, and the anticipated storage, transportation and distribution benefits of ImmunityBio's vaccine candidates. 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 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) risks related to ImmunityBio's reliance on third parties including its partners and licensors, (iii) inability to retain and hire key personnel, (iv) 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, (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, (vii) ImmunityBio's ability to successfully commercialize its product candidates and (viii) 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 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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