ImmunityBio, Serum Institute of India Agree on an Exclusive Arrangement for Global Supply of Bacillus Calmette-Guerin (BCG) Across All Cancer Types

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- Collaboration will result in BCG manufacture at large scale for use in combination with ANKTIVA®, ImmunityBio's recently approved treatment for non-muscle invasive bladder cancer (NMIBC)
- Serum Institute of India (SII) will manufacture both standard BCG ("sBCG") and next-generation recombinant BCG ("iBCG"), creating a long-term solution to chronic BCG supply shortage issues
- Standard BCG (sBCG) from the Serum Institute is currently administered in number of countries worldwide for treatment of NMIBC
- Recombinant BCG (iBCG) has demonstrated potent immunogenicity with CD8+ and CD4+ stimulation and improved safety compared to standard BCG in clinical trials across Europe.
- Collaboration will help to ensure availability of BCG for all approved indications that benefit from ANKTIVA's triangle offense of natural killer cells, T cells, and memory T cells
- Global clinical trials planned to study standard of care ANKTIVA plus BCG with globally available sBCG and iBCG from Serum Institute, the QUILT BCG randomized clinical trial

CULVER CITY, Calif.--(BUSINESS WIRE)--May 2, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX), has signed an exclusive global arrangement with the Serum Institute of India, the world's largest manufacturer of vaccines by number of doses produced, to supply ImmunityBio with Bacillus Calmette-Guerin (BCG). The agreement covers the manufacturing of standard BCG (sBCG) that is currently approved for use outside the U.S., as well as a next-generation recombinant BCG (iBCG) undergoing testing, intended for use in combination with ImmunityBio's ANKTIVA (nogapendekin alfa inbakicept-pmln) for currently approved and potential future indications, subject to regulatory approvals.

"We are pleased to partner with the Serum Institute of India so that the power of its large-scale, world-class, GMP manufacturing capacity can be used to address the issue of BCG shortage, which affects thousands of bladder cancer patients annually," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "We are especially proud to be partnering with Dr. Cyrus Poonawalla, the Institute's Chairman and founder and someone who has made such a positive impact on global health."

The arrangement will result in additional supplies of the current standard sBCG immediately for trials. At the same time, the two companies will work to accelerate the ongoing Phase 2 clinical trials of iBCG currently being conducted in Europe which has so far demonstrated safety advantageous over standard BCG as well as enhanced immunogenicity in driving both CD8+ and CD4 T cells.

The collaboration between SII and ImmunityBio comes on the heels of the FDA's approval of ANKTIVA for the treatment of non-muscle invasive bladder cancer with carcinoma in situ (CIS). Increasing the available supply of BCG is intended to address shortages for the combination therapy with ANKTIVA.

"The collaboration between Serum Institute of India and ImmunityBio will undoubtedly transform the way we approach cancer treatment. It will improve global access to BCG and at the same time—the unique therapy is the key to achieve a complete solution for bladder cancer. We are truly excited to witness the incredible impact this collaboration will have on improving patient outcomes and saving countless lives," said Mr. Adar C. Poonawalla, CEO, Serum Institute of India.

Originally used as a tuberculosis vaccine, BCG administered via intravesical instillation (delivery to the bladder via a catheter) has been the standard of care for patients with non-muscle invasive bladder cancer since 1977. BCG is a benign bacterium that induces an immune response in the bladder in proximity to the cancer cells, leading to clearance of the cancer in many patients.

BCG is one of the most widely used vaccines worldwide and has been given to more than 4 billion individuals with astonishing safety records. However, because BCG is a biologic drug that uses benign bacteria it is more complicated to make than many other types of drugs. SII is the largest manufacturer of BCG vaccine across the world, while Merck & Co. based in New Jersey currently is the only manufacturer of BCG (TICE® BCG) in the U.S.

"The scale and quality of vaccines that the Serum Institute manufacturers is unparalleled and we are honored to partner with Dr. Poonawalla and his leadership team on this important initiative," said Richard Adcock, President and CEO of ImmunityBio. "By providing another option for BCG, we believe more NMIBC patients will be able to benefit from this proven treatment as both a monotherapy and a combination therapy with ANKTIVA."

ImmunityBio plans to conduct clinical trials to study recombinant BCG (iBCG) and sBCG manufactured by Serum Institute in combination with ANKTIVA for the treatment of different types of bladder and other cancers. Supply of BCG is expected to be available once the protocol for the trial has been authorized by the FDA. ImmunityBio plans to submit the protocol to the FDA and to global regulatory bodies in the next 30 days.

"The opportunity to initiate a trial of an immunogenic recombinant BCG, which has already demonstrated enhanced safety compared to standard BCG in Phase 1/2 studies, is exciting. We look forward to exploring ANKTIVA in combination with BCG in non-muscle invasive bladder cancer (NMIBC) and across other tumor types. With our ability to overcome immune evasion of the tumor to BCG when BCG is given alone, and by converting a MHC-negative cold tumor to a MHC+ positive hot tumor with the combination of ANKTIVA with BCG, we will now further expand the development of our

therapeutic cancer vaccine with BCG," said Dr. Soon-Shiong.

For investigators interested in participating in clinical trials or to learn more information, please email QuiltBCG@ImmunityBio.com

About the Serum Institute of India Pvt Ltd (SII)

Serum Institute of India Pvt. Ltd, is a global leader in vaccine manufacturing, dedicated to providing affordable vaccines worldwide. Present across 170+ countries, including the US, UK, and Europe, SII holds the distinction of being the world's largest vaccine manufacturer. SII's multifunctional production and one-of-the-largest facility in Manjri, Pune, with an annual capacity of 4 billion doses, has saved over 30 million lives over the years.

Founded in 1966, SII's primary mission is to produce life-saving immunobiological drugs, with a particular emphasis on affordability and accessibility. Guided by a strong commitment to improving global health, the company has played a pivotal role in reducing the prices of essential vaccines, such as Diphtheria, Tetanus, Pertussis, HIB, BCG, r-Hepatitis B, Measles, Mumps, and Rubella. Notably, they are the manufacturers of 'Pneumosil,' the world's most affordable PCV, and 'Cervavac' the first indigenous qHPV vaccine in India. Moreover, SII has been at the forefront of the global fight against COVID-19, delivering over 2 billion doses of the COVID-19 vaccine worldwide.

To further expand its global presence and ensure widespread vaccine availability, SII has established Serum Life Sciences Ltd, a subsidiary in the UK. Through relentless pursuit of innovation, SII continues to champion the cause of affordable vaccines, making a positive impact on the lives of millions worldwide. www.seruminstitute.com

About Recombinant BCG (iBCG)

Standard BCG has originally been developed as a live vaccine against tuberculosis (TB). It is based on the well-known Mycobacterium bovis (M. bovis) Bacille Calmette-Guérin (BCG) strain which has been used since 1921 and has been administered approximately 4 billion times worldwide.

Two gene modifications have been implemented in BCG to improve its immunogenicity and safety leading to iBCG. This recombinant iBCG has completed Phase1/2 human clinical studies in Europe as immunotherapy in NMIBC patients. The findings from those studies demonstrate that iBCG is well tolerated when administered intravesically with a safety profile which appears to be enhanced as compared to the known adverse events of standard BCG. BCG is well-established as immunotherapy for the indication of NMIBC since the 1970s. Due to the similarity of both products, the safety profile of BCG serves as basis for a conservative assumption of iBCG effects in humans.

Supportive clinical data of iBCG as a TB vaccine are available from four clinical trials. Two studies in healthy adult volunteers and one Phase IIa study in healthy newborn infants were performed with iBCG. Additionally, a Phase II clinical trial was conducted with iBCG in HIV-unexposed and HIV-exposed, BCG-naïve newborn infants for clinical bridging. Clinical trials have also been conducted to assess the effect of iBCG vaccination on TB recurrence and on the susceptibility or severity of respiratory diseases during the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) pandemic.

About ImmunityBio

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. Designated an FDA Breakthrough Therapy, ANKTIVA® is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer that activates natural killer cells, T cells, and memory T cells for a long duration response. The company is applying its science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

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 collaboration between ImmunityBio and the Serum Institute of India and expected results therefrom, data and results from clinical trials and potential implications therefrom, commercialization plans and timelines, including product availability and shipments, global expansion efforts, potential regulatory pathways and approval requests and submissions, clinical trial plans and submissions, the regulatory review process and timing thereof, market and prevalence data, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, information regarding potential benefit to patients, information regarding ongoing clinical trials, potential future uses and applications of ANKTIVA and/or BCG and use in cancer vaccines and across multiple tumor types, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, 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," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "seeks," "should," "will," "strategy," 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) potential delays in product availability and regulatory approvals, (ii) whether the clinical trials described herein will receive regulatory approval and be initiated on a timely basis, or at all, (iii) whether the BCG manufactured by Serum will receive regulatory approval in the U.S. and/or other regions, (iv) the risks and uncertainties associated with commercial launch execution, success and timing, (v) additional risks and uncertainties related to the regulatory submission and review process, (vi) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development, patient enrollment and planned regulatory submissions, (vii) the risks and uncertainties associated with third party collaborations and agreements, (ix) ImmunityBio's ability to

obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (x) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (xii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies. 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 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 19, 2024 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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