ImmunityBio Provides Updated Status of Biologics License Application (BLA) for VesAnktiva Plus BCG for Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer Carcinoma in Situ

April 1, 2022

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 1, 2022-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced that it has achieved a major milestone with over 80 subjects in the QUILT-3.032 study completing at least 12 months of follow-up as of January 14, 2022. All data for QUILT-3.032, which is studying VesAnktiva™ plus BCG in subjects with BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ (NMIBC CIS), have been locked and analyzed. The results continue to demonstrate a clinically meaningful benefit that is sustained. The BLA has been compiled and, following final quality review, is expected to be submitted to the U.S. Food and Drug Administration (FDA) this month. The FDA granted Fast Track Designation to the pivotal trial based on Phase I data. In December 2019, the FDA granted ImmunityBio Breakthrough Therapy Designation (BTD) based on interim Phase 2 data indicating the primary endpoint of the trial was already met.

"We are excited to announce that the comprehensive compilation of our BLA is essentially written," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "With 71% of the participants in this study having a complete response and a median duration of response of 26.6 months, we believe we have a clinically meaningful therapeutic alternative for patients suffering from NMIBC in which the only option remaining is total cystectomy."

About ImmunityBio

ImmunityBio is a clinical-stage 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. 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.

ImmunityBio's clinical pipeline consists of 26 actively recruiting clinical trials—17 of which are in Phase 2 or 3 development—across 13 indications in liquid and solid tumors (including bladder, pancreatic, and lung cancers) and infectious diseases (including SARS-CoV-2 and HIV). Anktiva™, ImmunityBio's lead cytokine fusion 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 anticipated timing of the filing of ImmunityBio's Biologics License Application (BLA) for bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS), potential regulatory approval and commercialization of ImmunityBio's product candidates, the efficacy of ImmunityBio's product candidates as compared to existing treatment options, and clinical trial enrollment, advancements and data, 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 prepare, finalize and submit the BLA filing, (ii) whether the FDA will accept, review and/or approve the BLA and the risks and uncertainties associated with the regulatory submission and approval process, (iii) 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, (iv) risks related to ImmunityBio's reliance on third parties including its partners, licensors and strategic collaborators, (v) inability to retain and hire key personnel, (vi) 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, (vii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (viii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, (ix) ImmunityBio's ability to successfully commercialize its product candidates and (x) 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 1, 2022 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
Sarah.Singleton@immunitybio.com

Media
Greg Tenor
Salutem
+1 717-919-6794
Gregory.Tenor@salutemcomms.com

Source: ImmunityBio, Inc.