ImmunityBio Quality-of-Life Study in BCG-Unresponsive Bladder Cancer Trial Indicates Improved Physical Function in the 71% Complete Responders Suggesting a Favorable Risk-Benefit Ratio for N-803 Plus BCG

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- Patient Reported Outcomes (PROs) based on a May 16, 2022 data cutoff in the QUILT 3.032 trial indicate stability of physical function and global health in patients who completed PRO questionnaires and reached month 24 on-study
- Overall, participants with complete responses (CRs) to combination therapy with the novel interleukin-15 (IL-15) superagonist N-803 and bacillus Calmette-Guerin (BCG) reported better physical function than those who did not achieve a CR at month 6
- Stability of these PROs supports the safety and tolerability of the potential new treatment combination
- Taken together with the positive durable 71% response and 89.2% cystectomy avoidance rates in cohort A and a favorable safety profile at the May 16, 2022 data cutoff, along with the available PROs, support a favorable risk-benefit ratio for N-803 plus BCG in this patient population
- The Food and Drug Administration (FDA) is currently reviewing the Biologics License Application (BLA) for N-803 plus BCG for the treatment of NMIBC CIS with a Prescription Drug User Fee Act (PDUFA) date of April 23, 2024

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 5, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced that findings from Patient-Reported Outcomes (PROs) of participants in the phase 2/3 QUILT 3.032 study of N-803 plus BCG in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) were published by the peer-reviewed journal *Urology Practice*. These PROs support the positive interim results from the study published in *NEJM Evidence*, wherein 71% of patients in cohort A with CIS with or without Ta/T1 disease achieved a complete response.

The published PROs based on a May 16, 2022 data cutoff indicate that both physical function and global health as self-reported by QUILT 3.032 participants with BCG-unresponsive NMIBC CIS (cohort A) or papillary disease (cohort B), remained stable over the 2-year course of the study for patients who completed the PRO questionnaires and reached 24 months on-study. In addition, overall both cohort A and B participants who reached month 24 on-study and also completed an NMIBC-specific questionnaire focusing on the challenges of bladder cancer, also reported no decline of their health or urinary tract-related symptoms while in the study. Overall, participants who achieved a complete response with the novel combination therapy reported better physical function by month six of the study than those who did not achieve a complete response.

“The self-reported stability of health and physical function over the course of the study by the participants reflect another aspect of safety and tolerability of this new combination therapy,” said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. “Taken together with the positive response rate in cohort A of over 70%, the persistence of responses and cystectomy avoidance, these QoL findings suggest a favorable risk-benefit ratio for this potential new therapeutic option for patients with BCG-unresponsive bladder cancer.”

The finding of relative stability of global health and physical function during the course of the study is similar to that reported by others for BCG monotherapy, suggesting the novel combination is as tolerable as treatment with BCG alone.

“Many current therapies for bladder cancer slow disease progression but can cause debilitating side effects,” said Principal Investigator Karim Chamie, M.D., Associate Professor of Urology at UCLA. “The data from the QUILT 3.032 Quality of Life study suggest that many patients not only have a durable response but also report no decline in physical function, which is very important for these patients.”

QUILT 3.032 Study Details

The ongoing phase 2/3 open-label multicenter registrational study QUILT 3.032 (NCT03022825) is evaluating the safety and efficacy of the investigational interleukin-15 superagonist N-803 (also known as Anktiva® and nogapendekin alfa inbakicept, NAI) in combination with a standard therapy for NMIBC, bacillus Calmette-Guerin (BCG), in patients who failed or in whom cancer returned after BCG monotherapy, and thus were diagnosed as BCG-unresponsive. The study comprises three cohorts, with cohort A enrolling patients with carcinoma in situ (CIS) with or without Ta/T1 disease and cohort B enrolling patients with high grade Ta/T1 papillary disease. Both cohorts A and B received combination N-803 plus BCG therapy. Cohort C patients, with CIS +/- Ta/T1 disease received N-803 monotherapy.

- The primary end point is the incidence of CR at the 3- or 6-month assessment visit for cohorts A and C, and the disease-free survival (DFS) rate at 12 months for cohort B.
- Durability, cystectomy avoidance, progression-free survival, disease-specific survival (DSS), and overall survival are secondary end points for cohort A.
- Cohort C was discontinued due to a low response rate with N-803 monotherapy, per study design.
- The FDA has accepted for review ImmunityBio’s resubmission of its biologics license application (BLA) for N-803 plus BCG for the treatment of BCG-unresponsive NMIBC CIS with or without Ta or T1 disease, and has set a user fee goal date (PDUFA date) of April 23, 2024.

Bladder cancer is the 10th most-commonly diagnosed cancer, with approximately 80% of newly diagnosed cases being NMIBC. Intravesical (directly to the bladder) instillation of BCG after removal of cancer tissue from the lining of the bladder (transurethral resection of the bladder tumor; TURBT) is Standard-of-Care (SoC) for intermediate and high-risk NMIBC patients, but up to 40% of patients will fail BCG therapy and ~50% will relapse after an initial response and given a diagnosis of being BCG-unresponsive. Therapies approved by the FDA for this indication include pembrolizumab, nadofaragene, combined gemcitabine and docetaxel, and valrubicin. Radical cystectomy – surgical removal of the bladder - is also an option for these patients. QUILT 3.032 is being conducted to address the need for a safe, effective therapeutic option for BCG-unresponsive NMIBC patients that provides an opportunity for avoidance of radical cystectomy.

N-803 is investigational. Safety and efficacy have not been established by any Health Authority or Agency, including the FDA.

About ImmunityBio

ImmunityBio is a vertically-integrated, 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. ImmunityBio 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 ImmunityBio believes sharply reduce or eliminates 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 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 data and results from ongoing clinical trials and potential implications therefrom, potential benefits to patients, potential treatment outcomes for patients, the regulatory review process and timing thereof, market and prevalence data, and ImmunityBio's investigational agents as compared to other existing and potential treatment options, among others. While ImmunityBio believes the BLA resubmission addresses the issues identified in the FDA's complete response letter, there is no guarantee that the FDA will ultimately agree that such issues have been successfully addressed and resolved. 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) the risks and uncertainties associated with the regulatory review process, (ii) whether or not the FDA will ultimately determine that the BLA resubmission and related actions successfully addresses and resolves the issues identified in the FDA's complete response letter, (iii) uncertainties regarding the timeline of FDA review of the resubmitted BLA, (iv) any inability to successfully work with the FDA to find a satisfactory solution to address any concerns in a timely manner or at all during the review process for the BLA, including any inability to provide the FDA with data, analysis or other information sufficient to support an approval of the BLA, (v) the ability of ImmunityBio and its third party contract manufacturing organizations to adequately address the issues raised in the CRL, (vi) any potential facility re-inspections that may be required regarding ImmunityBio's third party contract manufacturing organizations or otherwise and results therefrom, (vii) whether the FDA accepts the data and results as included in the BLA resubmission at levels consistent with the published results, or at all, (viii) 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 and planned regulatory submissions, (xi) ImmunityBio's ability to retain and hire key personnel, (ix) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (x) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (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 1, 2023 and the Company's Form 10-Q filed with the SEC on November 9, 2023, 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
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1 858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

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

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