# FDA Accepts ImmunityBio's BLA Resubmission as Complete and Sets New PDUFA Date

October 26, 2023

- BLA for N-803 plus BCG in high-risk non-muscle-invasive bladder cancer (NMIBC) was resubmitted to the Agency on October 23, 2023
- A new PDUFA date of April 23, 2024 has been communicated by the Agency

CULVER CITY, Calif.--(BUSINESS WIRE)--Oct. 26, 2023-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review ImmunityBio's resubmission of its Biologics License Application (BLA) for N-803, a first-in-class IL-15 superagonist, plus Bacillus Calmette-Guérin (BCG) for the treatment of BCG-unresponsive non-muscle-invasive bladder cancer carcinoma in situ (CIS) with or without Ta or T1 disease, and considered it as a complete response to the FDA's May 9, 2023 complete response letter. The FDA has set a user fee goal date (PDUFA date) of April 23, 2024.

"We are pleased that the FDA has accepted ImmunityBio's resubmission of the BLA as a complete response, following our productive interactions leading up to the resubmission. We look forward to working closely with the Agency to finalize the review and to bringing this important immune-enhancing therapeutic to patients suffering from bladder cancer," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio.

**ImmunityBio's IL-15 superagonist N-803 (also called Anktiva® and nogapendekin alfa inbakicept)**

The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of the natural killer (NK) and T cells. N-803 is a novel investigational IL-15 superagonist complex consisting of an IL-15 mutant (IL-15N72D) bound to an IL-15 receptor α/IgG1 Fc fusion protein. Its proposed mechanism of action is direct specific stimulation of CD8+ T cells and NK cells through beta gamma T-cell receptor binding with generation of memory T-cells while avoiding T-reg stimulation. N-803 is designed to have improved pharmacokinetic properties, longer persistence in lymphoid tissues and enhanced anti-tumor activity compared to native, non-complexed IL-15 in vivo.

N-803 is currently being evaluated in adult patients in two clinical NMIBC trials. QUILT-2.005 is investigating use of N-803 in combination with BCG for patients with BCG-naïve NMIBC; QUILT-3.032 is studying N-803 in combination with BCG in patients with BCG-unresponsive NMIBC CIS and Papillary Disease.

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. We are applying our 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 ImmunityBio's resubmission of its BLA and review thereof, ImmunityBio's belief that the BLA resubmission addresses the issues in the Complete Response Letter, the timing of the regulatory review process for the BLA resubmission, the development or commercialization of N-803 plus BCG or other therapeutics for cancer indications and related business strategies, potential regulatory pathway for certain of ImmunityBio's product candidates and target indications, and ImmunityBio's investigational agents as compared to existing treatment options, among others. While ImmunityBio believes the BLA resubmission addresses the issues identified in the CRL, 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 is complete, (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-inspection that may be required regarding ImmunityBio's third party contract manufacturing organizations or otherwise, (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 execute a partnering relationship with a large biopharmaceutical company for commercialization of N-803 plus BCG for intravesical administration on acceptable terms, if at all, (ix) 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, (x) ImmunityBio's ability to retain and hire key personnel, (xi) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xii) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (xiii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (xiv) 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 August 8, 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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