ImmunityBio Announces Presentation at ASCO GI 2023 of Fully Enrolled Trial in Third-Line and Greater Pancreatic Cancer and Update on FDA Type B Meetings Regarding Paths to Registration

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- Positive findings in third line and greater metastatic pancreatic cancer patients (N=83) with doubled median overall survival (OS) versus historical OS
- Median overall survival of 5.8 months and 61% of patients (51/83) exhibited disease control
- All treatments in an outpatient setting of combination immunotherapy and off-the-shelf NK cell infusion
- Productive discussions with the U.S. Food and Drug Administration (FDA) and guidance toward registration paths in pancreatic cancer and NMIBC papillary via randomized trials
- Randomized trial in second line or greater patients accruing with 25 patients enrolled to date

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 19, 2023-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced positive results in its fully-enrolled metastatic pancreatic cancer study in third-line or greater subjects (QUILT 88) showing that the overall survival rate for patients continues to be double compared to historical survival rates after two or more prior lines of therapy. The results were presented at the American Society of Clinical Oncology Gastrointestinal (ASCO GI) conference in San Francisco January 19-21. See link to poster here.

The median OS in this highly advanced group of patients, up to seven lines (N=83) of treatment, was 5.8 months (95% CI: 4.9, 6.4 months), exceeding the approximately 2- to 3-month historical median OS. In the third-line setting (N=41), the median OS in this group was 6.3 months (95% CI: 5.0, 7.2 months), more than doubling the historical OS.

The baseline median CA 19-9 level (a marker of metastatic pancreatic disease) of the enrolled subjects (N=83) was very high at 4120 IU/ml, a significant increase from normal levels of 40 IU/ml. In subjects with CA 19-9 levels less than 4120 IU/ml (N=40), the median OS was 6.9 months (95% CI: 5.7,10.9).

“We are encouraged by the positive results in these patients with 3rd, 4th, 5th and even 7th line advanced pancreatic cancer and the considered and helpful feedback from the FDA,” said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. “Treatments for pancreatic cancer in the advanced setting remain an unmet need and we are committed to confirming our hypothesis that orchestrating the innate and adaptive immune system will advance the care of these patients.”

ImmunityBio also announced that it held two productive Type B meetings with the FDA in December. The first was to present the recent data and obtain guidance toward a registration pathway in metastatic pancreatic cancer with combination immunotherapy and NK cell therapy. The second meeting concerned the papillary cohort of the company’s BCG-unresponsive non-muscle-invasive bladder cancer study (QUILT 3.032; Cohort B). Cohorts A and C from this study were submitted in the BLA application for BCG-unresponsive NMIBC CIS, which has a May 2023 PDUFA date. The Agency advised the company to conduct randomized trials in localized BCG-unresponsive NMIBC papillary disease and in late-stage metastatic pancreatic cancer.

QUILT-88 Study Details

This Phase 2, randomized, three-cohort, open-label study will evaluate the comparative efficacy and overall safety of standard-of-care chemotherapy versus low-dose chemotherapy in combination with PD-L1 t-haNK, Anktiva (N-803), and aldoxorubicin in subjects with locally advanced or metastatic pancreatic cancer (NCT04390399). Each treatment setting, as well as each first- and second-line or later maintenance treatment, will be evaluated independently as Cohorts A, B, and C, respectively, with Cohorts A and B having independent experimental and control arms. The primary objective of Cohorts A and B is progression-free survival (PFS) per RECIST V1.1, and the objective of Cohort C is overall survival (OS). Secondary objectives include initial safety and additional efficacy measures, including overall response rate (ORR), complete response (CR) rate, durability of response (DoR), disease control rate (DCR), and overall survival (OS).

Trial sites include: Hoag Memorial Hospital Presbyterian in Orange County, Calif.; The Chan Soon-Shiong Institute for Medicine in Los Angeles County, Calif.; Astera Cancer Care in East Brunswick, NJ; and Avera McKennan Hospital and University Health Center in Sioux Falls, South Dakota, which serves patients in the tri-state area (Iowa, Nebraska and South Dakota).

Pancreatic cancer is the fourth leading cause of cancer-related death in the United States and has one of the highest mortality rates of all major cancers, taking nearly 50,000 lives in the U.S. every year. Today, surgery and subsequent adjuvant chemotherapy are the preferred treatment options for pancreatic cancer, but the five-year survival rate for late-stage cases is just 3%. For the majority of patients who present with more advanced disease, treatment typically consists of chemotherapy alone or supportive care for metastatic patients, and chemotherapy with or without radiation for those with locally advanced disease, leaving patients seeking new options.

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. 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.

N-803 (Anktiva™), ImmunityBio's lead cytokine fusion protein, is a novel 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). N-803 is currently under review by the FDA for this indication with a Prescription Drug User Fee Act (PDUFA) target date of May 23, 2023.

The company has established GMP manufacturing capacity at scale with cutting-edge cell therapy 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 cancers and infectious diseases and related business strategies, potential regulatory pathway for certain of ImmunityBio's product candidates and target indications, data from the clinical trials for certain of ImmunityBio's product candidates, clinical trial enrollment and results, clinical trial design and protocols, the regulatory review process and timing thereof, timing of regulatory submissions, potential implications to be drawn from clinical trials, potential commercialization of product candidates, and ImmunityBio's product candidates 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) the risks and uncertainties associated with the regulatory submission, review and approval process, (ii) 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, (iii) ImmunityBio's ability to retain and hire key personnel, (iv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (v) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, (vii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (viii) the unknown future impact of the COVID-19 pandemic on certain clinical trials or their milestones and/or ImmunityBio's business 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 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 2022 and the Company's Form 10-Q filed with the SEC on November 9, 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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