ImmunityBio Announces QUILT Trial Results for BCG-Unresponsive Bladder Cancer and Advanced Metastatic Pancreatic Cancer at the 2022 American Society of Clinical Oncology Annual Meeting

June 6, 2022

- Data from trials underscore ImmunityBio's vision of activating NK cells and T cells to advance care in difficult-to-treat cancers
- **Bladder Cancer:** 71% of BCG-unresponsive NMIBC patients who had failed on previous therapies showed a complete response with a median duration of 26.6 months; cystectomy avoidance rate of 91% and 100% bladder cancer overall survival at 24 months with 0% immune-related serious adverse events (SAE)
- **Advanced Metastatic Pancreatic Cancer:** Nant Vaccine more than doubled median overall survival for patients versus historical overall survival with median overall survival in patients with third- to sixth-line pancreatic cancer at 6.2 months and treatment-related SAEs uncommon (6%)
- ImmunityBio is exhibiting at booth number 26135

CULVER CITY, Calif.--(BUSINESS WIRE)--Jun. 6, 2022-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading clinical-stage immunotherapy company, today announced new positive data from the company's pivotal Phase 2/3 trial for BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (QUILT 3032) and Phase 2 trial in advanced pancreatic cancer (QUILT 88). The results, which were presented during the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrate the strong and diverse growth of ImmunityBio's immunotherapy platform that includes an IL-15 superagonist (N-803), adenovirus vaccine platform, and engineered off-the-shelf natural killer (NK) cell therapy. Together with the company's self-amplifying RNA and yeast platforms, and Toll receptor activators, along with clinical progress across a range of highly challenging cancer types and commercial-scale manufacturing capabilities, ImmunityBio believes that it is well positioned to change the paradigm of care in cancer and infectious disease.

"The theme at this year's ASCO conference finally is about combination therapy and immunotherapy. We have been focused on this approach for the past decade and the trial results we presented at this year's ASCO conference are validation that the approach of harnessing the patient's immune system with a combination of NK and T-cell activation has clinical benefit," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "We have, at risk, made the investments to build GMP commercial-scale manufacturing for our platforms and are now positioned to launch QUILT trials in earlier first-line, neoadjuvant and even preventative settings."

The data demonstrate a potential new option for BCG-unresponsive non-muscle invasive bladder cancer patients who were treated with Bacillus Calmette-Guérin (BCG) plus N-803 (Anktiva™) and the doubling of historic overall survival rates in patients with advanced pancreatic cancer who were treated with the Nant Cancer Vaccine, N-803 (Anktiva, IL-15 cytokine fusion protein), and off-the-shelf PDL1-targeted high-affinity NK cell (PDL1 t-haNK) infusion.

"Collectively, bladder cancer and pancreatic cancer claim more than half a million lives globally each year, with many patients failing to respond to the current standards of care," said Sandeep Bobby Reddy, M.D., Chief Medical Officer at ImmunityBio. "In dozens of studies, we have shown that N-803 proliferates NK and T cells and thus serves as an enhancing *secondary boost,* augmenting the immunological response when given in combination with BCG or a checkpoint inhibitor. This mechanism of action of inducing *trained innate immune memory*, through the combination of N-803 and a prime, contributes we believe to the compelling results we're seeing in these important trials."

The study results presented at ASCO are summarized below:

QUILT 3032 BCG-unresponsive NMIBC CIS (Cohort A)
In an oral presentation on June 3, 2022, Principal Investigator Karim Chamie, M.D., Associate Professor of Urology at UCLA, presented the final clinical results of pivotal trial of IL-15RαFc superagonist N-803 with BCG in BCG-unresponsive CIS and papillary non-muscle-invasive bladder cancer (Abstract #4508).

Link to video presentation on ecancer.org:

http://ecancer.org/en/video/10353-n-803-bcg-combination-shows-promising-results-in-bcg-unresponsive-nmibc

Excellent safety and tolerability profile of N-803 + BCG for CIS

- 1% treatment-related SAEs
- 0% immune-related AEs
- 0% grade 4 and 5 AE
- 71% Complete remission (CR) rate at anytime
- 26.6 months median durable complete remission
- 96% Avoidance of bladder cancer progression at 24 months in responders
- 91% Avoidance of cystectomy at 24 months in responders

- 100% Bladder cancer-specific overall survival at 24 months
- Favorable & familiar dosing schedule with activity localized to the bladder

QUILT 3.032 is an open-label, three cohort, multicenter Phase 2/3 study of intravesical BCG plus N-803 in patients with BCG-unresponsive high-grade NMIBC (NCT03022825) and was opened in 2017. The primary endpoint for Cohort A of this Phase 2/3 study is incidence of complete response (CR) of CIS at any time. The U.S. Food and Drug Administration (FDA) previously granted N-803 *Breakthrough Therapy* and *Fast Track* designations when used in combination with Bacillus Calmette-Guerin (BCG) for the treatment of BCG-unresponsive NMIBC CIS. On May 23, 2022, ImmunityBio announced that it had submitted a Biologics License Application (BLA) to the FDA for N-803 plus BCG for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS) with or without Ta or T1 disease.

QUILT 88 Pancreatic Cancer
The study results were presented on June 4, 2022 by the Principal Investigator Dr. Tara Seery of Hoag Cancer Center in a poster session titled Phase 2 clinical trial of DAMP inducers combined with IL15 superagonist, N-803, and anti–PD-L1 NK cell therapy more than doubles historical overall survival in patients with third- to sixth-line advanced pancreatic cancer (Abstract #4147, Poster #132).

- Nant Cancer Vaccine (NCV) more than doubled median OS versus historical OS (Manax ASCO GI 2019) of 3 months after >2L
- Median overall survival in 3rd line subjects (n=34) was 6.2 months (95% CI: 4.9, 9.8)
- Overall survival for ITT population (N=78) of 3rd, 4th and 5th line is 5.8 months (95% CI: 4.0, 6.9)
- Treatment-related (TR) SAEs were uncommon (6%), no TR deaths were reported
- All treatments were performed as outpatient
- Treatment ongoing for 25 patients

“For the first time, we are seeing clinical efficacy of immunotherapy in pancreatic cancer. Lung, Kidney, Head and Neck cancer, melanoma and many other cancers have been successfully treated with immunotherapy, but pancreatic cancer has been left behind in the revolution. Now, with ImmunityBio’s combination immunotherapy there is renewed hope for patients with this dreaded disease,” said Dr. Seery. “We are hopeful to be able to present similar results at future ASCO conferences in the other cohorts of this trial in which we continue to enroll patients.”

QUILT 88 is a Phase 2, randomized, three-cohort, open-label study evaluating the comparative efficacy and overall safety of standard-of-care chemotherapy versus low-dose chemotherapy in combination with PD-L1 t-haNK, 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 study is expected to enroll 328 subjects across all three cohorts (63 of 80 participants are currently enrolled in Cohort C, third-line or greater). 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).

Currently, four trial sites have been activated: Hoag Memorial Hospital Presbyterian in Orange County, Calif., The Chan Soon-Shiong Institute for Medicine in Los Angeles County, Calif., 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); and Astera Cancer Care, East Brunswick, N.J.

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 27 clinical trials—18 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 data from the clinical trials for certain of ImmunityBio’s product candidates, regulatory review process and timing thereof, potential implications to be drawn from the QUILT 3.032 and QUILT 88 studies, whether the described mechanism of action contributes to response rate and duration, potential commercialization of ImmunityBio’s product candidates, 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,” “indicate,” “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) whether the FDA will fileand/or approve ImmunityBio’s recently submitted BLA and the risks and uncertainties associated with the regulatory 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 May 10, 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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