ImmunityBio Completes Enrollment in Phase 2 Study of Nant Cancer Vaccine for 3rd Line or Greater Metastatic Pancreatic Cancer Patients—90% of Patients Have Exceeded Historical Survival Rates to Date

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- More than 50 participants in third-line cohort of QUILT 88 trial have received the Nant Cancer Vaccine, which includes ImmunityBio's off-the-shelf, targeted natural killer cells (PD-L1 t-haNK), IL-15 receptor agonist Anktiva (N-803), and Aldoxorubicin, plus low-dose chemotherapy.
- Of the evaluable patients in the study's third cohort (third-line or greater disease state), 90% (43/48) have exceeded the historical survival rates of approximately two months with standard-of-care chemotherapy.
- Of the 48 evaluable patients, approximately half had extremely advanced disease upon enrollment (i.e. had progressed after three to six prior lines of therapy) and, of these patients, 87% (20/23) have exceeded historical survival rates.
- Mature data is expected in Q1 2022 and the company plans to meet with the FDA in 2022 to discuss the path for the approval of combination therapies for pancreatic cancer.

CULVER CITY, Calif.--(BUSINESS WIRE)--Oct. 13, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has fully accrued the initial planned number of participants in Cohort C (third-line or greater) of its Phase 2 trial studying a combination immunotherapy (Nant Cancer Vaccine) in advanced metastatic pancreatic cancer. The majority of participants in the study to date remain on therapy and 90% (43/48) of the evaluable patients have exceeded the approximately two-month historical survival rate. Of the 48 evaluable patients, 23 (48%) had extremely advanced disease upon enrollment (i.e. had progressed after three to six prior lines of therapy) and, of these patients, 20 out of 23 (87%) have exceeded historical survival rates. On the strength of this early data and significant unmet medical need, the company has submitted an amendment to increase enrollment in Cohort C.

"Patients with advanced metastatic pancreatic cancer who have failed all standards of care have very grave prognoses with few treatment options. This study was to explore if the Nant Cancer Vaccine could address this unmet need," said Patrick Soon-Shiong, M.D., Founder and Global Chief Scientific and Medical Officer of ImmunityBio, Inc. "It is gratifying to note that patients in this study, who had progressed after up to six lines of prior therapy, have exceeded historical survival rates despite having very advanced pancreatic cancer upon enrollment."

QUILT 88 is an open-label study to evaluate the safety and efficacy of the Nant Cancer Vaccine, comprising ImmunityBio's IL-15 receptor agonist Anktiva (N-803), its off-the-shelf targeted natural killer cells (PD-L1 t-haNK), and aldoxorubicin, an albumin-modulated agent, plus low-dose chemotherapy. This combination therapeutic vaccine will be randomized against standard-of-care high-dose chemotherapy for first- and second-line treatment; the third-line cohort, with a target of 50 patients, is a single arm with the primary endpoint of overall survival.

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. Surgery and subsequent adjuvant chemotherapy are the preferred treatment options for pancreatic cancer today and 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.

"Achieving robust enrollment in this patient group and early promising efficacy evidence are important milestones in ImmunityBio's effort to develop this therapeutic with the potential to improve survival rates and provide a replacement for toxic chemotherapy," continued Soon-Shiong. "As the historical survival rate for third- to sixth-line pancreatic cancer patients is approximately two months, we are encouraged by this early data and have decided to open this cohort to more patients with advanced metastatic disease who have no further treatment options."

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 standard-of-care 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 study will initially enroll 298 subjects across all three cohorts. 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, three 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., 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).

About ImmunityBio

ImmunityBio is a leading late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and

adaptive (T cell) immune systems to create long-term “immunological memory.”

ImmunityBio has a comprehensive immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated)—of which 25 are at Phase II and III stages of development—across 19 indications in solid and liquid cancers and infectious diseases. Currently 17 first-in-human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. Anktiva™ (ImmunityBio’s lead cytokine infusion 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’s platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform.

ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. 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 development of therapeutics for cancer and infectious diseases, the timing of availability and release of data, the timing of potential meetings with the FDA, the timing of enrollment of patients in other cohorts of the Quilt-88 trial, the design and structure of the Quilt-88 trial, and regulatory approval, commercialization and commercial success of ImmunityBio’s product candidates and related matters. 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 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 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 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, (ii) inability to retain and hire key personnel, (iii) uncertainty of the expected financial performance and successful integration of the combined company following completion of the recent merger of ImmunityBio with NantCell (the “Merger”), including the possibility that the expected synergies and value creation from the Merger will not be realized or will not be realized within the expected time period, (iv) whether interim, initial, “top-line” and preliminary data from ImmunityBio’s 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, (v) the ability of clinical trial sites to initiate and complete ImmunityBio’s clinical trials on time, or at all, and the cost associated with such clinical trials, (vi) ImmunityBio’s ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vii) ImmunityBio’s ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, (viii) ImmunityBio’s ability to successfully commercialize its product candidates and (ix) 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 10, 2021, Form 10-Q filed with the SEC on August 12, 2021 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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