ImmunityBio Announces Results of Phase 2 Metastatic Pancreatic Cancer Trial at ASCO GI With Median Overall Survival of 6.3 Months in Patients With Third-Line Disease, More Than Doubling Historical Survival

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- Data show that ImmunityBio's combination immunotherapy, Nant Cancer Vaccine, is potentially effective in pancreatic cancer where very few treatment options exist
- Nant Cancer Vaccine therapy more than doubles median overall survival (OS) versus historical OS in patients who had progressed after two prior lines of therapy (N=30) with median OS of 6.3 months (95% CI: 5.0, 9.8 months)
- When patients with even more advanced disease who failed four to six prior lines of therapy are added, the median OS even with such advanced disease (N=63) is 5.8 months (95% CI: 3.9, 6.9 months)
- Treatment-related serious adverse events were uncommon and no treatment-related deaths were reported
- 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)--Jan. 18, 2022-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced interim results (N=63) in its metastatic pancreatic cancer trial (QUILT 88) showing that the overall survival rate for patients doubled compared to historical survival rate of three months after two prior lines of therapy (Manax ASCO GI 2019). The data of the Phase 2 trial studying a combination immunotherapy (Nant Cancer Vaccine) also show treatment-related serious adverse events were uncommon (8%) and no treatment-related deaths were reported. Based on these findings, ImmunityBio plans to meet with the FDA in 2022 to discuss the path for the approval of combination therapies for pancreatic cancer.

The results were presented today at the American Society of Clinical Oncology Gastrointestinal conference, which is being held virtually.

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, 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.

"There are thousands of patients in advanced stages of this disease and there are few, if any, treatment options for them," said Patrick Soon-Shiong, M.D., Founder and Global Chief Scientific and Medical Officer of ImmunityBio, Inc. "Based on this encouraging data from our QUILT 88 trial, we are hopeful that our Nant Cancer Vaccine can potentially address this unmet need. What's more, we designed this therapeutic candidate to be administered in an outpatient setting making it more accessible to future patients than traditional immune checkpoint inhibitors."

To date, 27% of third-line or greater patients (17/63) remain on study. The median overall survival in this highly advanced group of patients, who failed two to six prior lines of treatment, is 5.8 months (95% CI: 3.9, 6.9 months) exceeding the approximately three-month historical median overall survival. Of the 63 patients, 30 (48%) had progressed after two prior lines of therapy. Median overall survival in this group was 6.3 months (95% CI: 5.0, 9.8 months), more than doubling the historical overall survival. On the strength of this early data and significant unmet medical need, the company has expanded enrollment in the third-line or greater cohort.

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 Nant Cancer Vaccine is randomized against standard-of-care high-dose chemotherapy for first- and second-line treatment; the third-line or greater cohort, with an original target of 50 patients, is a single arm with the primary endpoint of overall survival.

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 study is expected to enroll 328 subjects across all three cohorts giving effect to the expanded enrollment of Cohort C (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, 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 broad immunotherapy and cell therapy platforms—including Antibody cytokine fusion proteins, synthetic immunomodulators, vaccine technologies (hAd5 viral vector, mRNA, recombinant protein, and adjuvant), and genetically-modified, off-the-shelf natural killer cells (autologous and allogenic cytokine-enhanced memory NK cells)—activate both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio's clinical pipeline consists of 21 clinical trials—13 of which are in Phase II or III development—across 12 indications in solid and liquid cancers (including bladder, pancreatic, and lung cancers) and infectious diseases (including SARS-CoV-2 and HIV). 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 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 potential meetings with the FDA, the timing of enrollment of additional patients in the Quilt-88 trial, the design and structure of the Quilt-88 trial, the efficacy of ImmunityBio's product candidates as compared to existing treatment options and ability to address an unmet medical need, 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) ImmunityBio's ability 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) risks and uncertainties regarding the regulatory review and approval process, (vii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (viii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, (ix) ImmunityBio's ability to successfully commercialize its product candidates and (x) 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 November 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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