ImmunityBio Announces Positive Overall Survival Results of Anktiva Combined With Checkpoint Inhibitors in Non-Small Cell Lung Cancer; Meeting Scheduled with FDA to Discuss Registration Path for ANKTIVA in Lung Cancer

April 25, 2024

- QUILT 3.055 trial completed and shows median overall survival almost double that of standard of care chemotherapy in 2nd- and 3rd-line non-small cell lung cancer (NSCLC) patients whose cancer did not respond to checkpoint inhibitors with or without chemotherapy
- Positive results seen in both PD-L1 negative and PD-L1 positive participants with NSCLC
- Data reaffirms the mechanism of action of ANKTIVA as an immune cell enhancer that activates natural killer (NK) cells and memory T cells to rescue checkpoint inhibitor (pembrolizumab, nivolumab, atezolizumab) failures across multiple tumor types
- Meeting scheduled with FDA in June to discuss path to registration filing of ANKTIVA plus checkpoint inhibitors in 2nd- and 3rd-line NSCLC patients whose cancer previously did not respond to checkpoint therapy
- $100 million in non-dilutive cash infusion with ANKTIVA approval brings cash-on-hand to approximately $240 million for launch of ANKTIVA in non-muscle invasive bladder cancer (NMIBC)
- Company has scheduled a conference call to discuss registration plans for NSCLC, status of ANKTIVA launch readiness for NMIBC, and ANKTIVA as the backbone of our clinical trial pipeline for multiple tumor types

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 25, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX), an immunotherapy company, today announced positive overall survival results in the QUILT 3.055 study of 2nd- and 3rd-line NSCLC patients who progressed after checkpoint inhibitor therapy (pembrolizumab, nivolumab, or atezolizumab) and standard-of-care chemotherapy to be discussed during the upcoming conference call. The results continue to reinforce ImmunityBio's belief in the unique mechanism of action of ANKTIVA (N-803, or nogapendekin alfa inbakicept-pmln) and its potential efficacy as a next-generation immunotherapy across multiple solid and liquid tumor types.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20240424428572/en/

In NSCLC patients who relapsed or were refractory to checkpoint inhibitors, ANKTIVA was administered together with the same checkpoint inhibitor. The addition of ANKTIVA resulted in the rescue of the checkpoint therapy efficacy, with significant prolongation of overall survival. These positive results were noted regardless of the patient's PD-L1 status, consistent with the mechanism of action of ANKTIVA in activating and proliferating natural killer cells, and stimulating CD8+ Killer Memory T cells. This prolongation of survival in NSCLC following checkpoint failure is consistent with ImmunityBio's findings of durable complete responses following BCG failure in NMIBC.

A meeting with the FDA has been scheduled for June to discuss the company's overall survival results in PD-L1 negative and positive patients and registration plans for 2nd-line and 3rd-line NSCLC patients whose cancer did not respond or continue to respond to checkpoint therapy and for whom few alternative therapies are available.

The positive overall survival data of patients enrolled in QUILT 3.055, a basket trial across multiple tumor types, in which checkpoint inhibitors failed, will be discussed, along with the status of launch readiness for ANKTIVA for its recently approved indication in NMIBC on an investor conference call Friday, April 26 at 8 am PDT/11 am EDT.

"The results we noted with the completion of the QUILT 3.055 basket trial across multiple tumor types in patients with late-stage cancers for whom standard of care plus checkpoints failed, validates our hypothesis that orchestration of NK cells with killer T cells and memory T cells could result in meaningful clinical improvements to current standards of care. We hypothesized that activation and proliferation of natural killer cells through IL-15 stimulation could rescue T cells after checkpoint failure, regardless of tumor type or of tumor location. As with non-muscle invasive bladder cancer, we believe that ANKTIVA enhanced the NK and T cell activity critical for targeting and killing cancer cells which have entered the phase of tumor evasion and resistance," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "QUILT 3.055 was the initial and seminal study of our Cancer Moonshot program launched in January 2016 (see related video here). The findings of a significant extension of overall survival in 2nd- and 3rd-line lung cancer affirms that combination therapy, with the orchestration of the innate and adaptive immune system, could potentially lead to the evolution of immunotherapy beyond T cells for all cancer patients. We are excited that these results continue to demonstrate the broad potential for ANKTIVA across multiple tumor types and its role as the next-generation immunotherapy. We are committed to pursuing additional indications for ANKTIVA in our pipeline with a mission to deliver new hope to patients with serious, advanced cancers where standard therapies have failed."

The QUILT trials initiated since the launch of the Cancer Moonshot program across multiple tumor types can be found on ImmunityBio.com and are summarized in the figure accompanying this announcement. As can be seen, ANKTIVA (N-803) serves as the backbone to the immunotherapy vaccine across multiple tumor types at late-stage with exploratory evidence of complete remissions. Updates to this figure denoting the QUILT trials at the time of publication in 2021 will be forthcoming.

According to the American Cancer Society, lung cancer is the second most common cancer in the U.S. In 2023, it is estimated that 238,340 new cases

of lung cancer will be diagnosed in the U.S. and 127,070 deaths will be attributed to the disease. NSCLC accounts for about 80% to 85% of all lung cancers diagnoses and there are very few successful treatment options for these patients once the cancer spreads beyond the lungs.

The development of checkpoint inhibitors in NSCLC has been revolutionary, doubling the median overall survival in some settings; however, patient response may be short lived, due to late response and/or progression after achieving an initial response. Historical and real-world experience (RWE) data show that the median overall survival rates in these patients range from 7 to 9 months.

In addition, the company will provide information about the status of launch readiness of ANKTIVA for NMIBC. Presentations by the company on ANKTIVA data in NMIBC are scheduled at the upcoming American Urological Association (AUA) conference in San Antonio, Texas from May 3-6, 2024. It is anticipated the first vials of ANKTIVA will be available for shipment the week of May 6, 2024.

Further details regarding ANKTIVA as the backbone of ImmunityBio's late-stage clinical pipeline across multiple solid and liquid tumor types will be discussed during the conference call, along with commercial launch readiness details, and the corporate financial position to support launch of ANKTIVA for the U.S. market.

Conference call details:

Investors may access the live audio webcast of the call via this weblink. A replay of the webcast will be available at https://ir.immunitybio.com. All participants may join the call by dialing (800) 579-2543 (U.S. and Canada Toll-Free) or (785) 424-1789 and using the access code ANKTIVA.

About ImmunityBio

ImmunityBio is a vertically-integrated 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 data and results from clinical trials and potential implications therefrom, commercialization plans and timelines, including product availability and shipments, potential regulatory pathways and approval requests and submissions, FDA meetings, timelines and potential results therefrom, the regulatory review process and timing thereof, market and prevalence data, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, information regarding potential benefit to patients, information regarding ongoing pre-clinical studies and clinical trials, potential future uses and applications of ANKTIVA and use in cancer vaccines and across multiple tumor types, methods, conference call and webcast timing, and ImmunityBio's approved product and investigational agents 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 commercial launch execution, success and timing, (ii) risks and uncertainties related to the regulatory submission and review process, (iii) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development, patient enrollment and planned regulatory submissions, (iv) the timing and funding of the incremental $100 million of non-dilutive financing following ImmunityBio's receipt of FDA approval of the BLA, (v) ImmunityBio's ability to retain and hire key personnel, (vi) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vii) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (viii) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (ix) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (x) 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 19, 2024 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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