Phase 1 Study Indicates Allogeneic Cytokine-Induced Memory-Like Natural Killer Cells Plus N-803 May Induce Tumor Regression in Advanced Head-and-Neck Cancer Patients

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CULVER CITY, Calif.--(BUSINESS WIRE)--Jul. 10, 2023-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced findings from a Phase 1 study showing that allogeneic cytokine-induced memory-like (CIML) natural killer (NK) cells used in combination with ImmunityBio's IL-15 superagonist N-803 may induce tumor regression associated with persistent CIML NK cell expansion in advanced head-and-neck cancer patients. The results indicate the potential for a new treatment approach for the disease in advanced cases that currently have extremely poor prognoses.

The data from the proof-of-concept study were presented by Glenn J. Hanna, M.D., Medical Oncologist with Dana-Farber Cancer Institute and Assistant Professor of Medicine at Harvard Medical School at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint conference in Montreal, July 7-8, 2023.

Patients with recurrent incurable or metastatic (R/M) head and neck cancers (HNCs) that do not respond to platinum chemotherapy and immunotherapy have poor survival rates. Cellular therapies have emerged as treatments with potential activity in solid tumors.

"It was exciting to observe some tumor regression among heavily pre-treated patients with advanced head-and-neck cancer using a live cell therapy approach," said Dr. Hanna. "I am hopeful that future studies can build on this work to further evaluate NK and other immune cell therapies for these cancers."

This study (NCT04290546) sponsored by Dana-Farber Cancer Institute investigated allogeneic CIML NK cell infusion followed by N-803 after lead-in CTLA-4 inhibition (ipilimumab) plus lymphodepleting (LD) chemotherapy in advanced HNC. The study showed that tumor regression was associated with expansion of the NK cell type with cytolytic activity, CD56dimCD16+ NK cells, that target and kill tumor cells.

This phase 1 single-center trial enrolled 10 patients with R/M HNC (n=7 HNSCC, n=3 salivary cancer) regardless of human papillomavirus (HPV) status who had prior platinum chemotherapy and immunotherapy. Patients in cohort 1 received LD fludarabine (25 mg/m2) and cyclophosphamide (60 mg/m2/kg) on days -6 to -2 prior to haploidentical CIML NK cell infusion on day 0 (5-10 x 10^6 viable cells/kg=dose level 0) followed by N-803 (15 mcg/kg subcutaneously) starting on day +1 every 21-days for 4-doses. Patients in cohort 2 received the same regimen with a dose of lead-in ipilimumab on day -7. A total of 6 patients were treated in cohort 1 and 4 patients in cohort 2.

The primary objective was safety and maximum tolerated dose of CIML NK cells. The secondary objective was objective response rate (ORR), progression-free survival (PFS), overall survival (OS), and phenotypic expansion and function of adoptively transferred NK cells.

"It is encouraging that allogeneic CIML NK cells supported by N-803 may induce tumor regression in advanced head-and-neck cancer patients," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "These results may have potential implications for many of the estimated 68,000 men and women in the United States who are diagnosed with head-and-neck cancers annually, and it is an ongoing pursuit of ImmunityBio's technology platform to orchestrate T and NK cells to fight cancer."

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. 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 conference participation and timing, the regulatory review process and timing thereof, timing of data from the clinical trials for certain of ImmunityBio's product candidates, potential implications to be drawn from clinical trials, the potential for allogeneic CIML NK cells given in combination with N-803 to induce tumor regression in advanced head and neck cancer patients, potential new treatment approaches, and future studies and trials. 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 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) the risks and uncertainties associated with the regulatory submission, review and approval process, (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, 2023 and the Company's Form 10-Q filed with the SEC on May 11, 2023, 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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