ImmunityBio Completes GMP Drug Substance Manufacturing Sufficient for 170,000 Doses of ANKTIVA®

May 7, 2024

- ANKTIVA® Drug Substance completed and released with two-year storage stability data sufficient for 170,000 doses of ANKTIVA product
- ImmunityBio's 400,000 square foot GMP fill-finish facility in Dunkirk, New York on track to be completed in 12-18 months with capacity to produce a million vials annually
- Coupled with a recent announcement of BCG availability in partnership with the Serum Institute of India (SII), ImmunityBio has large-scale inventory and capacity for BCG

CULVER CITY, Calif.--(BUSINESS WIRE)--May 7, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX) announced today that the drug substance (DS) has been completed and successfully qualified for "fill finish" (filling vials and finishing packaging), sufficient for 170,000 doses of 400mcg ANKTIVA (nogapendekin alfa inbakicept-pmln). Coupled with the recent announcement of a partnership with the Serum Institute of India (SII) for BCG availability, this provides the Company with a significant initial supply of ANKTIVA for commercial and clinical trial use in advance of the full operation of the Company's own drug substance and fill-finish manufacturing plants in California and New York.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20240507050323/en/



ImmunityBio's state-of-the-art GMP biological manufacturing facility in Dunkirk, New York (Photo: Business Wire)

Since the Company's merger with NantKwest in 2021, ImmunityBio has made significant capital investments in personnel, plants, and equipment to ensure global capacity of ANKTIVA drug product for both the commercial launch, as well as clinical trials in bladder cancer and other tumor types in its pipeline. Both drug substance (DS) and drug product (DP) facilities are nearing completion to ensure sufficient capacity and multiple GMP manufacturing sites for ANKTIVA in its approved indication, as well as for clinical trials and future indications.

"When we began the development of ANKTIVA and enlisted our contract manufacturer, we believed that the manufacture of a biologic as complicated as ANKTIVA was best served by having multiple sites of manufacturing, including in-house capacity and external partners," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "Our investment since 2021 in our facilities, together with the agreement entered into with the Serum Institute of India (SII) ensures that both ANKTIVA and BCG could be available at scale on a global basis."

In 2020, the company began construction of a state-of-the-art biological manufacturing plant in California with large-scale bioreactors for ANKTIVA drug substance and it is anticipated to be completed in the next 12-18 months. The large-scale equipment needed for GMP biological manufacture, with long-lead times, are on site and will be installed in the next 12 months. Upon completion, this 100,000 square foot manufacturing site will have the capacity to manufacture drug substance sufficient for a million doses of ANKTIVA a year.

The drug product will be filled at the Dunkirk, New York facility, a 400,000 square foot state-of-the-art GMP facility in which the fill-finish equipment has been purchased and is in the process of being installed.

These infrastructure capacity plans were initiated in anticipation of the approval of ANKTIVA in combination with BCG for non-muscle invasive bladder cancer, carcinoma in situ (CIS), to ensure that ImmunityBio has sufficient drug product supply, not only for the first commercial launch of ANKTIVA but for other clinical trials and indications.

"Our belief in the importance of this molecule and its potential to evolve immunotherapy to the next level, guided our strategic plan to invest for the future with anticipation of ANKTIVA's approval," said Rich Adcock, CEO & President ImmunityBio. "I'm grateful for our employees and our investors who have supported and believed in our commitment to invest for our long-term vision and future."

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. Designated an FDA Breakthrough Therapy, ANKTIVA® is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer that activates natural killer cells, T cells, and memory T cells for a long duration response. The company is applying its 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 the scale of production capacity for the manufacturing facilities referenced herein, the anticipated uses of such facilities, anticipated timelines for completion of such facilities and operational status of such facilities, the collaboration between ImmunityBio and the Serum Institute of India and expected results therefrom, clinical trials and potential implications therefrom, commercialization plans and timelines, the regulatory review process and timing thereof, potential future uses and applications of ANKTIVA in additional indications, 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) potential delays in product availability and regulatory approvals, (ii) whether the BCG manufactured by Serum will receive regulatory approval in the U.S. and/or other regions, (iii) the risks and uncertainties associated with commercial launch execution, success and timing, (v) additional risks and uncertainties related to the regulatory submission and review process, (vi) 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, (vii) the ability of ImmunityBio and/or its contractors to complete the construction or address construction needs at ImmunityBio's manufacturing facilities on the anticipated timelines, or at all, (viii) ImmunityBio's ability to comply with the covenants and obligations under the Dunkirk facility lease agreement and related agreements and potential implications thereof, (ix) the risks and uncertainties associated with third party collaborations and agreements, (x) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xi) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (xiii) 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240507050323/en/

Investors
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1 858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Greg Tenor
Salutem
+1 717-919-6794
Gregory.Tenor@Salutemcomms.com

Source: ImmunityBio, Inc.