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iBio Announces Progression of Vaccine Program for Multi-Variant COVID-19 Disease

- IBIO-202 Designed to Address Unmet Needs for Durability, Access, and Variant-inclusion -

BRYAN, Texas, Jan. 26, 2022 (GLOBE NEWSWIRE) -- iBio, Inc. (NYSEA:IBIO) ("iBio" or the "Company"), a developer of next-generation biopharmaceuticals and pioneer of the sustainable ***FastPharming*** Manufacturing System®, today shared an update on its lead COVID-19 vaccine program, IBIO-202.

iBio recently received the U.S. Food and Drug Administration's ("FDA") response to its pre-investigational new drug ("IND") package for IBIO-202. In light of the feedback received, the Company is moving forward with IND-enabling challenge studies for its second-generation vaccine candidate targeting the nucleocapsid ("N") protein and plans to file an IND application before the end of calendar 2022.

Commercially available first-generation vaccines target the frequently mutating spike ("S") protein, resulting in waning periods of immunity and the spread of new variants.[1] These developments have prompted the World Health Organization to state that, "a vaccination strategy based on repeated booster doses of the original vaccine composition is unlikely to be appropriate or sustainable."[2] Meanwhile, evidence continues to emerge that "N-, not S-, reactive T cells appear to play a protective role" for SARS-CoV-2 and potentially other betacoronaviruses as well.[3]

"Science is showing us that real-world vaccine effectiveness has diminishing returns with an overreliance on S-based vaccines," said Tom Isett, Chairman & Chief Executive Officer of iBio. "Several studies have demonstrated that the N protein appears to be more effective than the S protein towards stimulating a durable immune response. Obviously, the emergence of variants like Omicron underscores how mutations to the S protein can enable the virus to spread and sicken millions of people, despite steadily increasing immunization rates. So, we intend to move forward quickly with our IND-enabling studies and be in position to file an IND application for IBIO-202 as soon as possible."

The Company previously reported that it had completed extensive preclinical studies and identified an antigen-adjuvant pairing with a favorable Th1 skew. The cytokine response observed with this pairing indicated activation of a primary immune response, differentiation of mature T cells, and reactivation of memory T-cells.

“We selected a highly conserved region of the N protein and used advanced epitope design techniques to create IBIO-202,” said Martin Brenner, DVM. Ph.D., iBio’s Chief Scientific Officer. “We believe the data suggests this candidate has the potential to address many of the unmet needs that remain in the fight against COVID, a pandemic which may very well continue to wreak havoc if we continue to focus only on S-based vaccines. We need to work towards a ‘last dose’, not a ‘next dose’.”

About iBio’s COVID-19 Vaccine Development Program

In November 2020, iBio began exploring a second-generation COVID vaccine program based upon the nucleocapsid protein. In July 2021, iBio announced positive results from dose ranging, preclinical studies that demonstrated IBIO-202 could generate a robust, antigen-specific, memory T-cell response. In addition, T-cell priming was achieved via both intramuscular and intranasal administration, allowing for the further exploration of multiple routes of administration and their respective benefits. In September 2021, iBio submitted a pre-IND package for IBIO-202 to the FDA. In November 2021, the Company announced that it entered a collaboration agreement with a leading innovator of microarray patch systems, which are a painless alternative to intramuscular injections, to evaluate feasibility of intradermal delivery of a COVID-19 vaccine antigen. Today, iBio announced that, based on feedback it has received from the FDA, it will pursue IND-enabling studies for IBIO-202. More information on the COVID-19 vaccine program can be found on the Company’s website.

The Scientific Rationale Behind Targeting the N Protein of SARS-CoV-2

iBio believes that the N protein represents an important target for next-generation COVID-19 vaccines for several reasons. First, the N protein is abundantly expressed during infection and contains multiple immunogenic epitopes. Second, the N protein is more highly conserved than the S protein, and therefore, new variants may be less likely to escape vaccine protection. Third, research has shown that the N protein appears to be significantly more effective than the S protein in stimulating antibody-dependent natural killer cell activation, a critical element of the adaptive immune response that the SARS-CoV-2 virus attempts to evade.[4,5,6,7,8]

References

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About iBio, Inc.

iBio is a developer of next-generation biopharmaceuticals and a pioneer in sustainable, plant-based biologics manufacturing. Its ***FastPharming*** System® combines vertical farming, automated hydroponics, and novel glycosylation technologies to rapidly deliver high-quality monoclonal antibodies, vaccines, bioinks and other proteins. iBio is developing proprietary biopharmaceuticals for the treatment of cancers, as well as fibrotic and infectious diseases. The Company's wholly-owned subsidiary, iBio CDMO LLC, provides ***FastPharming*** Contract Development and Manufacturing Services along with ***Glycaneering*** Development Services™ for advanced recombinant protein design. For more information, visit www.ibioinc.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. These forward-looking statements are based upon current estimates and assumptions and include statements regarding a next-generation vaccine development strategy such as filing an IND application for IBIO-202 before the end of calendar 2022; the intent to move forward quickly with IND-enabling studies and be in position to file an IND application for IBIO-202 as soon as possible; N-, not S-, reactive T cells playing a protective role for SARS-CoV-2 and potentially other betacoronaviruses as well; IBIO-202 having the potential to address many of the unmet needs that remain in the fight against COVID, a pandemic which may very well continue to wreak havoc if we continue to focus only on S-based vaccines; and the N protein representing an important target for next-generation COVID-19 vaccines for several reasons. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the Company on the date of this release. These forward-looking statements are subject to various risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important

factors that could cause actual results to differ materially from current expectations include, among others, the Company's ability to successfully develop IBIO-202 as a vaccine that can better protection against future variants; iBio's ability to obtain regulatory approvals for commercialization of IBIO-202 and its other product candidates, or to comply with ongoing regulatory requirements; regulatory limitations relating to its ability to promote or commercialize its product candidates for specific indications; acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products; and the other factors discussed in the Company's filings with the SEC including the Company's Annual Report on Form 10-K for the year ended June 30, 2021 and the Company's subsequent filings with the SEC on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and the Company undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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