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Immunome Announces Initiation of Phase 1b Study of IMM-BCP-01 for the Treatment of COVID-19

- ***First study subject has been dosed in a single dose/dose escalation study of recently diagnosed COVID-19 patients***
- ***Study will evaluate safety as the primary end point with pharmacokinetics (PK) and virology as secondary assessments***

June 09, 2022 08:00 AM Eastern Daylight Time

EXTON, Pa.--(BUSINESS WIRE)--Immunome, Inc. (Nasdaq: IMNM), a biopharmaceutical company that utilizes its human memory B cell platform to discover and develop first-in-class antibody therapeutics, today announced the first patient has been enrolled in a clinical trial of IMM-BCP-01, a three-antibody cocktail for the treatment of SARS-CoV-2 (COVID-19). Topline data is expected in the second half of this year, which is an update from our prior guidance.

The Phase 1b study of IMM-BCP-01 is a single dose, dose escalation study in recently diagnosed COVID-19 patients. The primary study endpoint is safety, with pharmacokinetics (PK) and virology as secondary assessments. IMM-BCP-01 is designed to target three distinct, non-overlapping epitopes of SARS-CoV-2, to neutralize the virus and initiate multiple viral clearance mechanisms simultaneously, including complement fixation and phagocytosis.

Previously announced data has shown that IMM-BCP-01 is effective *in vitro* against live virus versions of the SARS-CoV-2 Omicron variant (BA.1 and BA.2).

“We are pleased that we have begun studying IMM-BCP-01 in patients with COVID-19,” said Purnanand Sarma, PhD, President & CEO of Immunome. “Based on the encouraging preclinical research, including data showing that our antibody cocktail demonstrated effectiveness against the Omicron variants BA.1 and BA.2 in live virus testing and Omicron BA.1 *in-vivo* in hamsters, we believe that IMM-BCP-01 can play an important role in addressing COVID-19.”

The investigational work for IMM-BCP-01 was funded by the U.S. Department of Defense’s (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) in collaboration with the Defense Health Agency (DHA) (Contract number: W911QY-20-9-0019).

About IMM-BCP-01

IMM-BCP-01 is a three-antibody cocktail targeting non-overlapping regions of the Spike protein of SARS-CoV-2, including highly conserved, subdominant epitopes, which elicits both ACE2 and non-ACE2 dependent neutralization, and induces natural viral clearance mechanisms, such as antibody dependent cellular cytotoxicity, complement activation and phagocytosis. When tested *in vivo*, these mechanisms combine to significantly reduce viral load in lungs of the hamsters infected with SARS-CoV-2. IMM-BCP-01 neutralizes all variants of SARS-CoV-2 tested to date *in vitro*. This investigational work was funded by the U.S. Department of Defense’s (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) in collaboration with the Defense Health Agency (DHA). (Contract number: W911QY-20-9-0019).

About Immunome

Immunome is a biopharmaceutical company that utilizes its proprietary human memory B cell platform to discover and develop first-in-class antibody therapeutics that are designed to change the way diseases are treated. The company's initial focus is developing therapeutics to treat oncology and infectious diseases, including COVID-19. Immunome's proprietary discovery engine identifies novel therapeutic antibodies and their targets by leveraging the highly educated components of the immune system, memory B cells, from patients whose bodies have learned to fight off their disease. For more information, please visit www.immunome.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements" intended to qualify for the "safe harbor" from liability established by the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding Immunome's beliefs and expectations regarding the advancement of its COVID-19 therapeutic antibody program, execution of its regulatory, clinical and strategic plans and anticipated upcoming milestones for IMM-BCP-01, including expectations regarding, among other things, the timing, progress and results of our preclinical studies and clinical trials of IMM-BCP-01, clinical plans, general regulatory actions, therapeutic potential and benefits of IMM-BCP-01 and other statements that are not historical fact. Forward-looking statements may be identified by the words "anticipate," believe," "estimate," "expect," "intend," "plan," "project," "suggest," "may," "will," "could," "can," "should," "seek," "potential" and similar expressions. Forward-looking statements are based on Immunome's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, those risks and uncertainties associated with: the impact of the COVID-19 pandemic on Immunome's business, operations, strategy, goals and anticipated milestones; the fact that research and development data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether the data will be published in a scientific journal and, if so, when and with what modifications; Immunome's ability to execute on its strategy, including with respect to its R&D efforts, regulatory filings, timing of these filings and the timing and nature of governmental authority feedback regarding the same, initiation and completion of any clinical studies, confirmatory testing and other anticipated milestones as and when anticipated; the effectiveness of Immunome's product candidates, including the possibility that further preclinical data and any clinical trial data may be inconsistent with the data used for advancing the product candidates and that further variants of concern could emerge; Immunome's ability to fund operations; Immunome's reliance on vendors; the competitive landscape; and the additional risks and uncertainties set forth more fully under the caption "Risk Factors" in Immunome's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (SEC) on March 25, 2021, and elsewhere in Immunome's 10-Q filings and other filings and reports with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Immunome undertakes no duty to publicly update or revise any forward looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable law. In this press release, we may discuss our current and potential future product candidates that have not yet undergone clinical trials or been approved for marketing by the U.S. Food and Drug Administration or other governmental authority, including expectations about their therapeutic potential and benefits thereof. No representation is made as to the safety or effectiveness of these current or potential future product candidates for the use for which such product candidates are being studied.

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