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Immunome Announces Submission of an Investigational New Drug (IND) Application for IMM-BCP-01 for the Treatment of COVID-19

- IMM-BCP-01 targets three non-overlapping regions on the Spike protein to provide broad coverage across CDC current and former variants of concern
- IMM-BCP-01 elicits multi-modal activity in pre-clinical testing including ACE2 and non-ACE2 dependent neutralization, as well as natural viral clearance mechanisms

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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, announced today that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for IMM-BCP-01, a three-antibody cocktail, for the treatment of SARS-CoV-2 (COVID-19).

“I am thrilled that Immunome has submitted its first IND, which is another milestone towards advancing IMM-BCP-01 into the clinic. We look forward to a close collaboration with clinical investigators to study this important and novel candidate for the treatment of COVID-19, especially as the pandemic continues to be a major public health issue,” said Purnanand Sarma, PhD, President & CEO of Immunome. “With the continued emergence of new variants, such as Omicron, and resurgence in SARS-CoV-2 cases despite high vaccination rates, we believe therapeutic treatment options for COVID-19 are essential. We further believe that a carefully designed cocktail, based on direct human immune response against SARS-CoV-2, could provide a novel and powerful approach to combat this virus.”

IMM-BCP-01 is a three-antibody cocktail targeting non-overlapping regions of the Spike protein and elicits multi-modal activity in pre-clinical testing, including both ACE2 and non-ACE2 dependent neutralization, as well as inducing natural viral clearance mechanisms, such as complement activation and phagocytosis. The cocktail significantly reduces viral load in lungs of the hamsters infected with SARS-CoV-2, and broadly neutralizes CDC current and former variants of concern, including the Delta variant, in *in vitro* testing. Immunome’s preclinical work includes investigational product safety testing. Immunome plans to initiate a placebo-controlled dose escalation study of IMM-BCP-01 in patients infected with SARS-CoV-2, pending FDA’s acceptance of Immunome’s IND submission.

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 regulatory actions, clinical plans and therapeutic potential and benefits thereof. Forward-looking statements may be identified by the words “anticipate,” believe,” “estimate,” “expect,” “intend,” “plan,” “project,” “suggest,” “may,” “will,” “could,” “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, IND submissions and other 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 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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