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FDA Lifts Clinical Hold on Immunome's IMM-BCP-01 IND Application for the Treatment of COVID-19

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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, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on its Investigational New Drug (IND) application for its antibody cocktail (IMM-BCP-01) for the treatment of SARS-CoV-2 (COVID-19). Immunome previously announced that the FDA had placed the company's IND application on clinical hold due to a request for further information related to the preparation and administration of IMM-BCP-01 at clinical sites. In response, Immunome provided the FDA with a comprehensive report detailing the necessary information.

"We believe in the potential of IMM-BCP-01 and its ability to aid in the ongoing fight against SARS-CoV-2, especially as the new variants continue," said Purnanand Sarma, PhD, President & CEO of Immunome. "We are pleased to report the clinical hold has now been lifted. We look forward to advancing the program into the clinic."

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. Immunome has submitted an Investigational New Drug Application with the FDA and plans to initiate a placebo-controlled dose escalation study of IMM-BCP-01 in patients infected with SARS-CoV-2.

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 or follow Immunome on Twitter and LinkedIn.

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 work being done to address the clinical hold, timing to address the clinical hold, ongoing live virus testing, and general regulatory actions, clinical plans and therapeutic potential

and benefits of IMM-BCP-01. 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, 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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