



## **ADMA Biologics Submits Response and Provides Supplemental Information to FDA for BIVIGAM® Complete Response Letter**

January 7, 2019 12:08 PM EST

RAMSEY, N.J. and BOCA RATON, Fla., Jan. 07, 2019 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, announces that the Company has submitted responses to the U.S. Food and Drug Administration ("FDA") Complete Response Letter ("CRL") received on December 19, 2018 for BIVIGAM®s (Intravenous Immune Globulin [Human], 10%) ("IVIG") Prior Approval Supplement ("PAS"). The Company anticipates receiving an acknowledgement letter from the FDA within 30 days, and plans to provide appropriate updates on the progress of the BIVIGAM® PAS review.

### **About ADMA Biologics, Inc. (ADMA)**

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PIDD") and the prevention and treatment of certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886 and 9,969,793 related to certain aspects of its lead product candidate, RI-002. For more information, please visit [www.admabiologics.com](http://www.admabiologics.com).

### **About BIVIGAM®**

BIVIGAM® is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies ("PI") are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as 250,000 people in the U.S. have some form of PI. BIVIGAM® contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PIDD patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated polyclonal Immunoglobulin ("IgG") antibodies. Antibodies are proteins in the human immune system that work to defend against infections and disease. FDA's initial approval for BIVIGAM® was received by Biotest Pharmaceuticals Corporation ("BPC" or "Biotest") on December 19, 2012, and production of BIVIGAM® was halted by Biotest in December 2016. ADMA Biologics obtained ownership and all rights, title and interest in BIVIGAM® on June 6, 2017 as part of the Biotest Therapy Business Unit ("BTBU") asset acquisition and resumed the production of BIVIGAM during the fourth quarter of 2017.

### **Cautionary Note Regarding Forward-Looking Statements**

*This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics, Inc. ("we", "our" or the "Company"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "is likely," "will likely," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the "FDA") in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications, our ability to realize increased prices for plasma growth in the plasma collection industry and our expectations for future capital requirements. Actual events or results may differ materially from those described in this document due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.*

### **COMPANY CONTACT:**

Brian Lenz

Executive Vice President and Chief Financial Officer | 201-478-5552 | [www.admabiologics.com](http://www.admabiologics.com)

### **INVESTOR RELATIONS CONTACT:**

Jeremy Feffer

Managing Director, LifeSci Advisors, LLC | 212-915-2568 |



Source: ADMA Biologics, Inc.