



ADMA Biologics Announces Publication of an Article Describing the Manufacturing Process Optimization for its Commercial Products BIVIGAM® and ASCENIV™ in the Peer Reviewed Journal Immunotherapy

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RAMSEY, N.J. and BOCA RATON, Fla., Oct. 17, 2019 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and the prevention of certain infectious diseases, today announced the publication of an article describing the manufacturing process optimization of ADMA's Intravenous Immunoglobulin ("IVIG") products, BIVIGAM® and ASCENIV™ in the peer reviewed journal *Immunotherapy*.

The article, as published in the October 2019 online-edition and the soon to be available November 2019 print-edition of *Immunotherapy*, describes the manufacturing process changes and improvements instituted by ADMA for both BIVIGAM® and ASCENIV™ following its acquisition of the Boca Raton, FL manufacturing facility. These improvements to ADMA's manufacturing process resulted in engineering modifications and enhancements to procedural controls, and reductions in thermal, physical and chemical product stressors. The optimized manufacturing process demonstrates increased control of unit operations, process consistency and robustness, decrease in product variability and enhanced removal of impurities all of which lead to enhanced product quality.

"We are very proud of the achievements made by the ADMA Biologics team and are pleased that BIVIGAM and ASCENIV are now commercially available. The diligent work of ADMA's in-house development teams, including process development, analytical development, manufacturing, quality assurance and quality control, is evident from all the improvements to the manufacturing process described in this peer-reviewed publication," stated Adam Grossman, President and Chief Executive Officer. "We hope that the improvements and manufacturing enhancements described in this peer-reviewed publication provide confidence to ADMA's stakeholders."

About ASCENIV™ (Formerly RI-002)

ASCENIV, immune globulin intravenous, human – slra 10% liquid, is a plasma-derived, polyclonal, intravenous immune globulin ("IVIG"). ASCENIV, which is indicated for the treatment of Primary Humoral Immunodeficiency or Primary Immune Deficiency Disease ("PI") in adults and adolescents (12 to 17 years of age), was approved by the FDA on April 1, 2019 and anticipates commencing commercial sales in October 2019. ASCENIV is manufactured using ADMA's unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using our proprietary microneutralization assay. ASCENIV contains naturally occurring polyclonal antibodies, which are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. ASCENIV prevented serious bacterial infection among 59 patients treated for twelve months during the pivotal investigation. ASCENIV is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

About BIVIGAM®

BIVIGAM® is an immune globulin intravenous, human - 10% liquid, indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs 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 Primary Humoral Immunodeficiency ("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 PI patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin ("IgG") antibodies. Antibodies are proteins in the human immune system that work to defend against infections and disease. BIVIGAM® was approved for marketing by the FDA in May 2019 and reintroduced to the U.S. market in August 2019.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a commercial biopharmaceutical company dedicated to marketing and developing plasma-derived, human immune globulin products for immunodeficient patients at risk for infection. ADMA currently manufactures and markets three United States Food and Drug Administration ("FDA") approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of primary humoral immunodeficiency (PI); BIVIGAM® (immune globulin intravenous, human) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against hepatitis B. ADMA's mission is to manufacture, market and develop specialty plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations 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, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

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 such words as "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 ability to operate in accordance with FDA quality and compliance, regulations and expectations; our ability to provide a continuous supply of BIVIGAM® to PI patients; our ability to successfully pursue commercialization and prelaunch activities for our products; and the potential of our specialty plasma-based biologics products and product candidates to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or

other indications. 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. 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.

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