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ADMA Biologics Provides Corporate Update on Supply Chain Robustness and Recent Accomplishments

RAMSEY, N.J. and BOCA RATON, Fla., May 07, 2020 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immuno-deficient patients at risk for infection and others at risk for certain infectious diseases, today announced several recent corporate achievements pertaining to its supply chain robustness objectives as established at the beginning of 2020.

"We have been very active during these challenging times in executing upon what we believe to be high value-added improvements to our supply chain to enhance robustness, increase capacity and heighten control over the production of our products. These achievements include the successful manufacturing of three BIVIGAM® conformance batches at an increased scale of plasma volume, purchase of a new aseptic filling machine and installation, along with our plasma collection center expansion initiatives, all of which are on schedule with our budgeted expectations. These important accomplishments are in-line with our 2020 corporate goals and are designed to enhance shareholder valued by reducing operating costs, improve margins and provide for faster turnaround time in the production cycle of our commercial immunoglobulin products," stated Adam Grossman, President and Chief Executive Officer. "We believe these additional capabilities will also allow us to provide a broader range of high-quality services, both to our existing customers, as well as potential new clients and ultimately provide increased control and independence from vendors and contractors as we grow our Company."

The conformance batch production for BIVIGAM is at double the plasma volume of the currently U.S. Food and Drug Administration ("FDA") approved process for the manufacture of immune globulin ("IG"). There have been no significant changes to the manufacturing process, in-process controls or final release testing other than validating the effectiveness of the ADMA manufacturing process at the larger scale. At the newly increased scale, we observed the same potency and purity of the IG production process as our FDA-approved production process. Upon approval of this manufacturing change, ADMA anticipates it will be in a position to produce double the peak forecasted quantity of BIVIGAM using the same equipment, single-use disposables and same labor force.

Mr. Grossman continued, "Additionally, we completed the installation and site acceptance testing of our new in-house aseptic filling machine, a Vanrx SA25 Workcell, which utilizes a state-of-the-art closed isolator design allowing for the removal of human interventions and provides safe drug products for patients. The combination of increased production capacity for BIVIGAM and the enhanced vertical integration of in-house filling and packaging will allow ADMA to bring our products to market faster, and substantially increase ADMA's end-

to-end control over our complete manufacturing process."

The Vanrx SA25 Workcell has been installed by many leading biologics and vaccine producers in the U.S. and has been FDA approved numerous times. Once installed, the SA25 Workcell will have the capability of rapidly switching between different container and closure formats enabling aseptic filling in a variety of different fill volumes and presentation sizes.

Before the BIVIGAM production scale increase and filling machine can be fully implemented for commercial manufacturing, ADMA must submit an amendment(s) to its Biologics License Application to the FDA. ADMA anticipates submitting applications to the FDA for the increased production scale conformance batches of BIVIGAM and the Vanrx filling machine during the second half of 2020. Both the increased production scale and filling machine initiatives and investments are anticipated to be fully operational and contribute to product supply during 2021.

"Lastly, we have executed on our plasma collection center buildout expansion initiatives, which are on schedule. We have secured additional locations and have commenced construction of two facilities in Tennessee. All of these important plasma collection site expansion activities will continue for the duration of 2020 and into 2021 and we believe we should be able to submit for FDA approvals toward the end of the second half of this year. We look forward to keeping our investors apprised of meaningful developments as we continue to execute on our 2020 stated goals and objectives." concluded Mr. Grossman.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. 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 the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA Bio Centers subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides a portion of its blood plasma for the manufacture of its products. 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, 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 about ADMA’s future results of operations; being well-positioned to weather current macroeconomic challenges while continuing to execute on future growth plans; continuing progress regarding the commercial launches for BIVIGAM and ASCENIV; ramping production throughput for commercial products and building inventory; continued sales growth and market penetration; potential plasma product supply constraints and the timing thereof; increasing ADMA’s production throughput; expansion of manufacturing capacity; reducing our operating costs, improving margins and providing for faster turnaround time in the production cycle of our commercial products; and expected annual revenues from ADMA’s manufacturing and supply agreement to produce and sell plasma-derived intermediate fractions. 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.

COMPANY CONTACT:

Brian Lenz

Executive Vice President and Chief Financial Officer | 201-478-5552 | www.admabiologics.com

INVESTOR RELATIONS CONTACT:

Sam Martin

Managing Director, Argot Partners | 212-600-1902 |sam@argotpartners.com

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