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ADMA Biologics Receives FDA Approval for VanRx Aseptic Fill-Finish Machine and Related Operations

Expected to Provide Improved Gross Margins, Enhanced Patient Supply Consistency, Accelerated Inventory Production Cycle Time and Increased Control and Visibility of Commercial Product Lot Releases

Additional Opportunity for Contract Manufacturing Filling Services and Capabilities to Third Parties

RAMSEY, N.J. and BOCA RATON, Fla., Sept. 08, 2021 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, announced that the U.S. Food and Drug Administration ("FDA") has granted approval for the Company's in-house aseptic fill-finish machine, the VanRx SA25 ("VanRx").

"The FDA approval of the VanRx marks the successful completion of ADMA's multi-year supply chain enhancement initiative, firmly establishing ADMA as the only American domiciled end-to-end producer of specialty plasma-derived biologic drugs. Today's announcement is expected to have transformative financial and strategic implications for ADMA as the Company now joins an elite group of U.S.-based drug manufacturers with comprehensive in-house control of its critical manufacturing functions," said Adam Grossman, President and Chief Executive Officer of ADMA. "The VanRx approval provides ADMA with internal fill-finish operations, capable of sufficiently addressing all forecasted production requirements for our commercial products. With the VanRx operational, we are anticipating meaningfully improved gross margins, enhanced patient supply consistency, accelerated inventory production cycle times, and increased control and visibility of commercial product lot releases, creating more predictable near-term revenue results.

"The approval of the VanRx will also provide ADMA with the opportunity to onboard new fill-finish contract manufacturing opportunities with third parties. This additional revenue stream can provide the Company with the ability to potentially exceed previous financial targets, which we will update as progress unfolds. With extensive vertical integration successfully established and the Company's more meaningful capital investment initiatives having now concluded, ADMA is entering the next phase of its profit-focused growth strategy. We look forward to sustaining quarter-over-quarter revenue growth for the foreseeable future as well as meaningfully improving profitability metrics in the periods ahead," concluded Mr. Grossman.

The VanRx fill-finish machine utilizes a state-of-the-art closed isolator design, allowing for

the removal of human interventions and providing safe drug products for patients. The VanRx machine has the capability of rapidly switching between different container and closure formats, enabling aseptic filling in a variety of different fill volumes and presentation sizes. The combination of the FDA-approved increased BIVIGAM® manufacturing production scale earlier this year as well as the enhanced vertical integration resulting from this approval of the VanRx machine is expected to allow ADMA to bring its products to market faster, improve gross margins and substantially increase ADMA's end-to-end control over its critical manufacturing process. ADMA will continue to work with its third-party contract manufacturing organization (CMO) fill-finish partner who will continue to fill a portion of ADMA's production at their site. The CMO's site will remain in ADMA's FDA-approved product Biologics License Applications to provide the Company with alternatives on a go-forward basis to ensure continued supply-chain robustness.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end American 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 FDA-approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) 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 BioCenters 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.

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," "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, including our production capacity; and the expected financial, strategic and commercial benefits of the VanRx approval. Actual events or results may differ materially from those described in this press release 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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