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ADMA Biologics Announces FDA Approval of Extended Shelf Life for ASCENIV™ & BIVIGAM® from 24 to 36 Months

Approval of 36-month shelf life encompasses all ASCENIV & BIVIGAM vial sizes, production scales, as well as internal and external fill-finishing

Extended shelf life ASCENIV & BIVIGAM now commercially available to U.S. healthcare providers

RAMSEY, N.J. and BOCA RATON, Fla., March 25, 2022 (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, announced the United States Food and Drug Administration's ("FDA") approval to extend the expiration dating from 24 to 36 months for both its ASCENIV and BIVIGAM immune globulin ("IG") drug product stored at 2-8°C. The expiration date extension applies to all existing ASCENIV and BIVIGAM lots currently in the commercial supply chain as well as to future production of ASCENIV and BIVIGAM in all vial sizes, production scales as well as internal and external fill-finished drug product.

"The extension of ASCENIV's and BIVIGAM's shelf life to 36 months dating is a meaningful enhancement of each product's go-to market offering as it should provide for a more efficient net working capital cycle for the Company as well as allow for more versatile utilization and inventory management by providers," said Adam Grossman, President and Chief Executive Officer of ADMA. "The approval represents an important milestone as it pertains to the culmination of remediation initiatives enacted since ADMA acquired the Boca Raton, FL manufacturing facility in 2017. We believe this FDA approval of shelf-life extension clearly demonstrates ADMA's IG portfolio and production processes are of a high-quality and meet all requirements for stability in the eyes of regulators."

Mr. Grossman continued, "The milestone approval validates the optimization of ADMA's manufacturing processes and ongoing regulatory compliance, which has been spearheaded by the Company's industry-leading regulatory, compliance, quality, production and supply chain teams. In an IG market faced with volatile supply and demand dynamics, we believe this approval will lend confidence to our distribution partners and caregivers in their procurement decision making. The new 36-month dating for ASCENIV and BIVIGAM now puts ADMA's IG portfolio on a level playing field with competitor product offerings. We look forward to increasing market penetration with our complete portfolio of IG products to better serve the growing needs of U.S. patients and physicians in the periods ahead."

The newly approved 36-month dating for ASCENIV and BIVIGAM is immediately effective and product is available to U.S. healthcare providers and patients. At the present time,

ADMA expects continuous and increasing supply across its IG product suite going forward.

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: 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-licensed 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 and European Patent No. 3375789 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About ASCENIV™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous IVIG. ASCENIV was approved by the United States Food and Drug Administration (FDA) in April 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), in adults and adolescents (12 to 17 years of age). ASCENIV is manufactured using ADMA's unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and respiratory syncytial virus (RSV) plasma obtained from donors tested using the Company's 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 is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. Certain data and other information about ASCENIV can be found by visiting www.asceniv.com. Information about ADMA and its products can be found on the Company's website at www.admabiologics.com.

About BIVIGAM®

BIVIGAM (immune globulin intravenous, human – 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). BIVIGAM was approved by the FDA in May 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), including, but not limited to, the following group of genetic disorders: X-linked and congenital

agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. 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 antibodies. Certain data and other information about BIVIGAM or ADMA and its products can be found on the Company's website at 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. and its subsidiaries (collectively, "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 "anticipate," "intend," "target," "plan," "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; the anticipated benefits and significance of the shelf life extension of ASCENIV and BIVIGAM lots from 24 months to 36 months; and supply of the Company's IG products. 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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