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ADMA Biologics Announces Commercial Availability of Expanded Vial Size Offerings for BIVIGAM® and NABI-HB®

ADMA Expands Commercial IG Product Offering with Additional BIVIGAM and NABI-HB Vial Sizes

BIVIGAM 100 mL Vial and NABI-HB 1 mL Vial Now Commercially Available to U.S. Healthcare Providers

RAMSEY, N.J. and BOCA RATON, Fla., Aug. 09, 2021 (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 commercial availability of additional vial sizes of BIVIGAM and NABI-HB, which are currently in stock and commercially available to U.S healthcare providers and patients.

"The availability of these additional NABI-HB and BIVIGAM vial sizes meaningfully enhances ADMA's go-to-market offering for its commercial Immune Globulin ("IG") product portfolio and allows for more versatile utilization by providers and patients," said Adam Grossman, President and Chief Executive Officer of ADMA. "We anticipate the broader suite of BIVIGAM and NABI-HB vial configurations will help in providing more targeted dosing levels, minimize drug wastage and allow ADMA's IG products to have vial presentations in line with competitor offerings. These new vial sizes, which further advance the Company's mission to differentiate through its hands-on approach to manufacturing and developing plasma-derived therapeutics, represent yet another important milestone achieved by ADMA's regulatory, commercial and supply chain teams. We look forward to increasing market penetration with our complete portfolio of IG and hyperimmune globulin products to better serve the growing needs of U.S. patients and physicians in the periods ahead."

NABI-HB 1 mL and 5 mL vial sizes are available to U.S. healthcare providers and patients and, at the present time, ADMA expects continuous supply availability of both vial sizes going forward.

Earlier this year, ADMA received United States Food and Drug Administration ("FDA") approval for the production of a 100 mL vial presentation of BIVIGAM which, with today's announcement, is now commercially available in limited quantities. The new vial size will supplement ADMA's currently marketed BIVIGAM 50 mL vial offering, for which the Company expects uninterrupted supply availability. The wider range of vial sizes now offered for NABI-HB and BIVIGAM is anticipated to aid physicians and providers with targeted dosing and avoiding unnecessary drug wastage while providing for an easier, more convenient way to prepare and administer the products according to the respective labeled

use for both NABI-HB and BIVIGAM.

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 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About Nabi-HB®

Nabi-HB® is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB® is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB® is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (HBsAg), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem and can cause chronic infection and put people at high risk of death from cirrhosis and liver cancer. Nabi-HB® has a well-documented record of long-term safety and effectiveness since its initial market introduction. Certain data and other information about Nabi-HB® or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

Additional Important Safety Information about Nabi-HB®

Individuals known to have had an anaphylactic or severe systemic reaction to human globulin should not receive Nabi-HB® [Hepatitis B Immune Globulin (Human)] or any other human immune globulin. Individuals who are deficient in IgA have the potential to develop antibodies against IgA and anaphylactic reactions. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Nabi-HB should be given only if the expected benefits outweigh the potential risks. Nabi-HB is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents (e.g., viruses) and, theoretically, the Creutzfeldt-Jakob

disease (CJD) agent. Nabi-HB [Hepatitis B Immune Globulin (Human)], must be administered only intramuscularly for post-exposure prophylaxis. Vaccination with live virus vaccines (e.g., MMR) should be deferred until approximately three months after administration of Nabi-HB. The most common adverse reactions associated with Nabi-HB in clinical trials were erythema and ache at the injection site as well as systemic reactions such as headache, myalgia, malaise, nausea and vomiting. No anaphylactic reactions with Nabi-HB have been reported. Please see the full Prescribing Information for Nabi-HB [Hepatitis B Immune Globulin (Human)].

Warnings and Precautions:
In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Nabi-HB, Hepatitis B Immune Globulin (Human), should be given only if the expected benefits outweigh the potential risks. Nabi-HB is made from human plasma. Products made from human plasma may contain infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. The risk that such products can transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current viral infections, and by inactivating and/or reducing certain viruses. The Nabi-HB manufacturing process includes a solvent/detergent treatment step (using tri-n-butyl phosphate and Triton® X-100) that is effective in inactivating known enveloped viruses such as HBV, HCV, and HIV. Nabi-HB is filtered using a Planova® 35 nm Virus Filter that is effective in reducing the levels of some enveloped and non enveloped viruses. These two processes are designed to increase product safety. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other health care provider to Biotest Pharmaceuticals at 1-800-458-4244. The physician should discuss the risks and benefits of this product with the patient.

Nabi-HB, Hepatitis B Immune Globulin (Human), must be administered only intramuscularly for post-exposure prophylaxis. The preferred sites for intramuscular injections are the anterolateral aspect of the upper thigh and the deltoid muscle. If the buttock is used due to the volume to be injected, the central region should be avoided; only the upper, outer quadrant should be used, and the needle should be directed anterior (i.e., not inferior or perpendicular to the skin) to minimize the possibility of involvement with the sciatic nerve22. The 50 healthy volunteers who received Nabi-HB in pharmacokinetic studies were followed for 84 days for possible development of anti-HCV antibodies. No subject seroconverted.

Drug Interactions
Vaccination with live virus vaccines should be deferred until approximately three months after administration of Nabi-HB, Hepatitis B Immune Globulin (Human). It may be necessary to revaccinate persons who received Nabi-HB shortly after live virus vaccination. There are no available data on concomitant use of Nabi-HB and other drugs; therefore, Nabi-HB should not be mixed with other drugs.

Pregnancy Category C
Animal reproduction studies have not been conducted with Nabi-HB. It is also not known whether Nabi-HB can cause fetal harm when administered to a pregnant woman or can affect a woman’s ability to conceive. Nabi-HB should be given to a pregnant woman only if

clearly indicated.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nabi-HB is administered to a nursing mother.

Pediatric Use
Safety and effectiveness in the pediatric population have not been established for Nabi-HB. However, the safety and effectiveness of similar hepatitis B immune globulins have been demonstrated in infants and children.

Geriatric Use
Clinical studies of Nabi-HB did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Adverse Reactions:
Fifty male and female volunteers received Nabi-HB, Hepatitis B Immune Globulin (Human), intramuscularly in pharmacokinetics trials20. The number of patients with reactions related to the administration of Nabi-HB included local reactions such as erythema 6 (12%) and ache 2 (4%) at the injection site, as well as systemic reactions such as headache 7 (14%), myalgia 5 (10%), malaise 3 (6%), nausea 2 (4%), and vomiting 1 (2%). The majority (92%) of reactions were reported as mild. The following adverse events were reported in the pharmacokinetics trials and were considered probably related to Nabi-HB: elevated alkaline phosphatase 2 (4%), ecchymosis 1 (2%), joint stiffness 1 (2%), elevated AST 1 (2%), decreased WBC 1 (2%), and elevated creatinine 1 (2%). All adverse events were mild in intensity. There were no serious adverse events. No anaphylactic reactions with Nabi-HB have been reported. However, these reactions, although rare, have been reported following the injection of human immune globulins.

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.

Additional Important Safety Information for BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid]

BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid] is indicated for the

treatment of primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

Thrombosis may occur with immune globulin intravenous (IGIV) products, including BIVIGAM. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, a history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients.

Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. BIVIGAM does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction, or renal failure, administer BIVIGAM at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

BIVIGAM is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and history of hypersensitivity.

Thrombosis may occur following treatment with IGIV products, including BIVIGAM. Thrombosis may occur in the absence of known risk factors.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/ markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients at risk of thrombosis, administer BIVIGAM at the minimum dose and infusion rate practicable.

In patients at risk of developing acute renal failure, renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output need to be monitored.

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV therapy. Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments; AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

As hemolysis can develop subsequent to treatment with IGIV products, monitor patients for hemolysis and hemolytic anemia. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). If TRALI is suspected, test the product and patient for antineutrophil antibodies.

Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Passive transfer of antibodies with IGIV treatment may yield positive serological testing results, with the potential for misleading interpretation.

Serious adverse reactions observed in clinical trial subjects receiving BIVIGAM were vomiting and dehydration in one subject. The most common adverse reactions to BIVIGAM (reported in ≥ 5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increase, diarrhea, dizziness, and lethargy.

For more information about BIVIGAM, please see full Prescribing Information.

You are encouraged to report side effects of prescription drugs to ADMA Biologics @ 1-800-458-4244 or the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

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 "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; and the anticipated benefits, and supply of, the additional BIVIGAM and NABI-HB vial sizes. 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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