

April 13, 2021



# **ADMA Biologics Announces Poster Presentation Highlighting Pharmacoeconomic Burden of HIV and HBV Infection in Sexual Assault Patients at the 2021 Academy of Managed Care Pharmacy Virtual Annual Meeting**

*Poster Presentation Highlights the Unmet Patient Need and Medical Cost Burden Associated with Hepatitis B Infection*

*Healthcare Costs Associated with HBV and HIV are Approximately at Parity; HBV Carries 50-100 Times Greater Transmission Risk Compared to HIV*

*Pharmacoeconomic Analysis and Unmet Patient Need Strongly Support Harmonization of HBV and HIV CDC Treatment Guidelines for Sexual Assault Victims*

RAMSEY, N.J. and BOCA RATON, Fla., April 13, 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, today announced a poster presentation at the 2021 Academy of Managed Care Pharmacy Virtual Annual Meeting (“AMCP”) taking place April 12-16, 2021.

“Current CDC guidelines for post-exposure prophylaxis of suspected Hepatitis B infection (“HBV”) offer no intervention for sexual assault victims with perpetrators of unknown Hepatitis B surface antigen status,” said Adam Grossman, President and Chief Executive Officer of ADMA. “HBV is significantly more infectious than is HIV, and can be transmitted by any bodily fluid, and amounts to a roughly equivalent cost burden for the US healthcare system. Our analysis suggests that amending CDC guidelines in this at-risk population for HBV to mirror those of HIV and specifically mandating a Hepatitis B Globulin intervention like ADMA’s Nabi-HB hyperimmune, will provide a cost-effective strategy for prophylactic seroprotection of these vulnerable patients. It is our hope that lobby groups advocating on behalf of at-risk patients will leverage this analysis to convey to policymakers that failing to address this patient population, and harmonizing treatment guidelines between HIV and HBV, may have considerable clinical and cost implications for the US healthcare system.”

**Details for the AMCP 2021 poster presentation are as follows:**

**Poster Title:** Pharmacoeconomic Analysis Comparing Medical Costs for Prophylaxis of HIV and HBV Infection in Sexual Assault Patients

**Author:** Gruenglas, Pantello, Mond

**Session Title:** Poster Abstract Sessions

**Session Dates:** Tuesday, April 13 – Wednesday, April 14, 2021 (2:30 pm ET)

**Session Location:** Virtual Poster Hall

**Poster No:** B3

View the presentation at the [virtual 2021 AMCP Annual Meeting](#)

### **About Nabi-HB<sup>®</sup>**

Nabi-HB<sup>®</sup> is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB<sup>®</sup> is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB<sup>®</sup> 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<sup>®</sup> has a well-documented record of long-term safety and effectiveness since its initial market introduction. Certain data and other information about Nabi-HB<sup>®</sup> or ADMA Biologics and its products can be found on the Company's website at [www.admabiologics.com](http://www.admabiologics.com).

### **Additional Important Safety Information about Nabi-HB<sup>®</sup>**

Individuals known to have had an anaphylactic or severe systemic reaction to human globulin should not receive Nabi-HB<sup>®</sup> [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)].

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.**

### **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<sup>®</sup> X-100) that is effective in inactivating known enveloped viruses such as HBV, HCV, and HIV. Nabi-HB is filtered using a Planova<sup>®</sup> 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 nerve<sup>22</sup>. 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, NabiHB 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 trials<sup>20</sup>. 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 ADMA Biologics, Inc.**

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 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<sup>®</sup> (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV<sup>™</sup> (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB<sup>®</sup> (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](http://www.admabiologics.com).

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Source: ADMA Biologics, Inc.