July 29, 2016

ADMA Biologics Receives Complete Response Letter from FDA for Pending Biologics License Application

RAMSEY, N.J., July 29, 2016 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ:ADMA), a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the proposed treatment of immune deficiencies and prevention of certain infectious diseases, announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) to the Company's Biologics License Application (BLA) for RI-002, an Intravenous Immune Globulin (IVIG), for the treatment of patients with Primary Humoral Immunodeficiency Disease (PIDD).

The CRL did not cite any concerns with the clinical safety and efficacy data for RI-002 submitted by ADMA in the BLA, nor has the FDA requested any additional clinical studies be conducted prior to FDA approval of RI-002 for PIDD.

The FDA identified in the CRL certain outstanding inspection issues and deficiencies at ADMA's third-party contract manufacturers, including its contract drug substance and product manufacturer, its contract fill and finisher and compliance issues with a third-party contract testing laboratory, and requested documentation of corrections for a number of those issues.

ADMA has been informed by its third party drug substance and product manufacturer that it is working to resolve the outstanding inspection issues. ADMA will work diligently with the Company's third party drug substance and product manufacturer, its contract fill and finish provider and a third-party contract testing laboratory to monitor their efforts in addressing and resolving outstanding issues relating to the observations. The Company will work with the agency to reach an agreement on acceptable language for the package insert and container and vial labeling, if and when approval is granted.

"ADMA is highly committed to bring RI-002 to market, offering another IVIG treatment option for the heterogeneous population of immune deficient patients," stated Adam Grossman, President and CEO of ADMA Biologics, Inc. "We will continue to collaborate as effectively and expeditiously as possible with our third-party contract manufacturers and testing laboratory to resolve the outstanding deficiencies. We continue to build our commercial organization and infrastructure in preparation for the earliest possible launch of our product."

About ADMA Biologics, Inc. (ADMA)
ADMA is a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease (PIDD) and the prevention and treatment of certain infectious diseases.

ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for medical reasons. The company has received U.S. Patent 9,107,906 relating to certain aspects of its product candidate. 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. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "intend," "target," "will," "is likely," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements concerning our ability to pursue an indication for the use of RI-002 specialty IVIG product for treatment of patients diagnosed with PIDD, the ability of each of our third party contract manufacturer, contract fill and finish provider and the contract testing laboratory to resolve deficiencies identified in the CRL to the satisfaction of the FDA, our ability to work with our third-party contract manufacturers and testing laboratories to resolve the outstanding deficiencies, compliance issues and inspection issues identified by the FDA in the CRL, our ability to successfully negotiate labeling for RI-002, plans and timing to develop, market and commercialize RI-002 and the success of such efforts, our ability to obtain and maintain regulatory approvals for RI-002 or any other product candidates, the timeframe within which we may receive approval from the FDA, if at all, of concurrence by FDA with our conclusions and the satisfaction by us of its guidance, and the potential of RI-002 to provide meaningful clinical improvement for patients living with PIDD. Forward-looking statements are subject to many risks and uncertainties 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 those risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Therefore, 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. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. 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.

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Source: ADMA Biologics, Inc.