ANI Pharmaceuticals Signs Definitive Agreements to Acquire Generic Products and Assets from Amneal/Impax

April 27, 2018

BAUDETTE, Minnesota (April 27, 2018) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it has signed definitive agreements to acquire a portfolio of generic products and other assets from Amneal Pharmaceuticals, LLC and Impax Laboratories, Inc. (NASDAQ:IPXL) for undisclosed cash consideration. The transaction is the result of a divestiture process mandated by the Federal Trade Commission (“FTC”) in connection with Amneal Pharmaceutical’s proposed business combination with Impax Laboratories. The parties expect to close the transaction in early May.

Upon closing the transaction, ANI will acquire a product portfolio consisting of five approved generic ANDAs and one pipeline product, Erythromycin IR tablets; ANI will also acquire a license, supply and distribution agreement for a second pipeline product, Diclofenac-Misoprostol DR tablets, with a pending ANDA. The combined current annual U.S. market for these seven products is approximately $1.7 billion, according to Iqvia/IMS Health.

Currently three of the five approved products are commercialized: Ezetimibe-Simvastatin Tablets (ANDA 201890), Felbamate Tablets (ANDA 202284) and Desipramine Tablets (ANDA 205153). Following the close of the transaction, ANI will begin shipping these products to customers immediately. Two generic products are approved but not yet commercialized: Aspirin/Dipyridamole ER Capsules (ANDA 206964) and Methylphenidate HCl ER Tablets (ANDA 208607). These products will be manufactured and supplied to ANI under multi-year supply agreements with Amneal, Impax, or pre-existing third-party contract manufacturers under agreements that will be assigned to ANI. ANI intends to immediately commence efforts to tech transfer the manufacturing of the acquired ANDA for Aspirin/Dipyridamole ER Capsules to the company’s Baudette manufacturing facility.

As part of the transaction, ANI will secure a supply agreement with the option to receive generic Aspirin/Dipyridamole ER Capsules from Amneal Pharmaceuticals beginning in late 2019 with a right to distribute the product in the U.S. market through early 2021. If ANI exercises this option it may be obligated to make a milestone payment upon launch depending on the number of generic products in the market at the time of launch.

In addition, ANI will acquire certain manufacturing equipment currently installed at a third-party contract manufacturing site for the manufacture of Methylphenidate HCl ER Tablets.

Arthur S. Przybyl, ANI’s President and CEO stated, “We are pleased to announce the agreement to acquire these exciting generic products and assets. The acquisition will align strongly with ANI’s strategic focus to grow our generic pipeline, expand our commercial portfolio, and leverage our U.S. based manufacturing plants. Importantly, the acquisition includes several products that compete in exciting markets including Aspirin/Dipyridamole ER Capsules and Methylphenidate ER Tablets. Following the close of the transaction, ANI will immediately begin the work necessary to pursue the launch of these approved ANDAs, which represent considerable commercial opportunities. Finally, we are pleased to have successfully participated in this FTC-related acquisition and hope to leverage this experience to pursue similar opportunities in the future.”

About Ezetimibe-Simvastatin Tablets

Ezetimibe and simvastatin tablets, which contains a cholesterol absorption inhibitor and an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet to:

- reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia.
- reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments.

About Desipramine HCl Tablets

Desipramine HCl tablets are indicated for the treatment of depression.

About Felbamate Tablets

Felbamate tablets are not indicated as a first line antiepileptic treatment. Felbamate tablets are recommended for use only in those patients who respond inadequately to alternative treatments and whose epilepsy is so severe that a substantial risk of aplastic anemia and/or liver failure is deemed acceptable in light of the benefits conferred by its use.

If these criteria are met and the patient has been fully advised of the risk, and has provided written acknowledgement, felbamate tablets can be considered for either monotherapy or adjunctive therapy in the treatment of partial seizures, with and without generalization, in adults with epilepsy and as adjunctive therapy in the treatment of partial and generalized seizures associated with Lennox-Gastaut syndrome in children.

About Aspirin/Dipyridamole ER Capsules

Aspirin/Dipyridamole ER Capsules are indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis.

About Methylphenidate HCl ER Tablets

Methylphenidate HCl ER Tablets are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

About ANI

ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company’s future operations, products financial position, operating results and prospects , the Company’s pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company’s actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company’s actual results are described in the Company’s filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company’s current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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