ANI Pharmaceuticals Announces Approval and Launch of Aminocaproic Acid Tablets

December 17, 2020

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced U.S. Food and Drug Administration (FDA) approval and the launch of Aminocaproic Acid Tablets USP, 500mg. The current annual U.S. market for this product is approximately $12.7 million, according to IQVIA/IMS Health.

"This is ANI’s seventh generic product launch in 2020 and reaffirms our commitment to increasing the pace of market introductions for our products. This important therapeutic is one of the pipeline generic products we acquired from Amerigen Pharmaceuticals, Ltd. earlier this year. I congratulate our team on this achievement and look forward to additional ANI product launches in the near future, as we focus on realizing the full potential of our product portfolio,” stated Nikhil Lalwani, President and CEO.

About Aminocaproic Acid Tablets USP

Aminocaproic Acid Tablets are useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, transfusion of appropriate blood products and other emergency measures may be required. For more information, including the complete list of indications and usages, please see the Full Prescribing Information.

About ANI

ANI Pharmaceuticals, Inc. 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, those relating to the development, manufacturing and commercialization of the product and any additional product launches from the generic pipeline acquired from Amerigen Pharmaceuticals, Ltd. 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; competition from other products; 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 (“SEC”), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. 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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Source: ANI Pharmaceuticals, Inc.