ANI Pharmaceuticals Announces Launch of Prazosin Hydrochloride (“HCl”) Capsules

February 1, 2021

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced the launch of Prazosin HCl Capsules USP, 1mg and 2mg, following the U.S. Food and Drug Administration’s (“FDA”) approval of the Company’s prior approval supplement application (“PAS”).

The current annual U.S. market for Prazosin 1mg and 2mg strengths is approximately $46.2 million, according to IQVIA/IMS Health.

"Launch of Prazosin HCl is ANI’s fourteenth re-commercialization of a previously discontinued abbreviated new drug application (“ANDA”) product. The launch underscores our capabilities and commitment to capture the full value of our product portfolio and manufacturing capabilities,” stated Nikhil Lalwani, President and CEO.

About Prazosin HCl Capsules USP

Prazosin HCl Capsules are indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes, including this drug. 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 Company’s generic pipeline, 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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