ANI Pharmaceuticals Announces FDA Approval of Potassium Citrate Extended-Release Tablets USP

January 16, 2020

BAUDETTE, Minnesota (January 16, 2020) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced it has received approval of the Company’s abbreviated new drug application (ANDA) from the U.S. Food and Drug Administration (FDA) for Potassium Citrate Extended-Release Tablets USP, 10 mEq and 15 mEq. The current annual U.S. market for this product is approximately $75 million, according to IQVIA.

Arthur S. Przybyl, ANI’s President and CEO stated, "We are excited to receive FDA approval for this extended release drug that was successfully developed by ANI’s internal formulation group. We plan to launch the drug, which will be manufactured at our Baudette, Minnesota plant, in the first quarter of this year.”

About Potassium Citrate Extended-Release Tablets USP

Potassium Citrate Extended-Release Tablets USP are indicated for the management of renal tubular acidosis with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stones. For more information, including the complete list of indications and usages, please see the Full Prescribing Information.

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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