ANI Announces FDA Acceptance of Supplemental Filing for Cortrophin® Gel 80 U/mL FDA Sets Prescription Drug User Fee Act (PDUFA) Goal Date of July 23, 2020

April 13, 2020

BAUDETTE, Minnesota (April 13, 2020) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that the U.S. Food & Drug Administration (“FDA”) has accepted its supplemental new drug application (“sNDA”) for Purified Cortrophin® Gel (Repository Corticotropin Injection USP) (80 U/mL). The FDA set a PDUFA goal date of July 23, 2020.

Arthur Przybyl, ANI’s President and CEO commented, “The acceptance of our filing with a confirmed four-month goal date is an important milestone in our re-commercialization effort for this drug. Notably, in the letter, FDA acknowledged our stated objective of lowering the cost of this drug. We are prepared to immediately launch Cortrophin® Gel in July if FDA approves our filing at that time. We look forward to introducing a new treatment option for patients and physicians and much needed competition into the market.” The current annual market for repository corticotropin injection 80 U/ml is $950 million and has only one competitor.

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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