



ANI Announces Positive Clinical Results from Cortrophin® Gel Cortisol Response Study

October 3, 2019

BAUDETTE, Minnesota (October 3, 2019) - ANI Pharmaceuticals, Inc. ("ANI") (Nasdaq: ANIP) today announced the receipt of clinical data on Cortrophin® Gel (80 units/mL) from a study that evaluated the blood-level cortisol response in a 20-person healthy volunteer population.

Key results:

- The results indicate that ANI's Cortrophin® Gel (80 units/mL) is effective for its intended use.
- In addition, the clinical data demonstrate that ANI's modernized Cortrophin® Gel (80 units/mL) drug product has a cortisol response profile consistent with that observed in historical scientific literature that evaluated Cortrophin® Gel (44 units/mL) drug product manufactured in the 1960s (Brombacher et. al, 1969).
- No adverse safety events to be reported and minor events were as expected.

The final data set from this study will be locked on October 25, 2019.

Arthur S. Przybyl, ANI's President and CEO commented, "These results represent a significant milestone for ANI in our re-commercialization effort for Cortrophin® Gel. In conjunction with our positive results in process and product characterization at commercial scale, method development and validation, release of clinical material and viral clearance, I believe this study demonstrates that we have successfully reproduced the Cortrophin® Gel drug previously manufactured in the 1990s. As such, I believe we will have an approvable drug product. We are excited to submit the Cortrophin® Gel comprehensive supplemental NDA filing currently planned for March 2020."

About Purified Cortrophin® Gel

Cortrophin® Gel is purified corticotropin (ATCH) manufactured in sterile gelatin to allow prolonged activity. The product stimulates the functioning adrenal cortex to produce and secrete adrenocortical hormones. 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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