# ANI Pharmaceuticals Announces FDA Approval of Memantine Hydrochloride Extended-Release Capsules

March 17, 2020

**BAUDETTE, Minnesota (March 2, 2020)** - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it has received approval of the Company’s abbreviated new drug application (ANDA) from the U.S. Food and Drug Administration (FDA) for Memantine Hydrochloride Extended-Release Capsules 7 mg, 14 mg, 21 mg and 28 mg. The current annual U.S. market for this product is approximately $127 million, according to IQVIA.

Arthur S. Przybyl, ANI’s President and CEO commented, “This ANDA approval comes from the recently announced acquisition of 23 commercial and pipeline drugs and will be the third launch from the acquired pipeline. We plan to launch the drug in the near term.”

**About Memantine Hydrochloride Extended-Release Capsules**

Memantine Hydrochloride Extended-Release Capsules are indicated for the treatment of moderate and severe dementia of the Alzheimer’s type. 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.

For more information about ANI, please contact:
Investor Relations
IR@anipharmaceuticals.com