ANI Announces Plans to Launch Bretylium Tosylate Injection, USP 500mg/10ml (50mg/ml) for Ventricular Arrhythmias

October 31, 2019

BAUDETTE, Minnesota (October 31, 2019) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that its partner Pharmaceutics International Inc. (Pii) has received FDA approval of a Prior Approval Supplement for Bretylium Tosylate Injection, USP 500mg/10ml (50mg/ml). ANI plans to launch this currently unavailable drug in December, introducing this critical drug for the treatment of ventricular fibrillation and life-threatening ventricular arrhythmias, such as ventricular tachycardia.

First introduced in the 1986, Bretylium Tosylate Injection was added to the Advanced Care Life Support (ACLS) guidelines and algorithms recommended by the American Heart Association (AHA) in the 1990s. Due to raw material shortages, the drug has not been available in the United States since 1999.

Prior to its discontinuation, Bretylium Tosylate was commonly stocked as a standard drug on crash carts. ANI estimates that there are approximately 180,000 crash carts in the U.S. and will recommend at least two vials of Bretylium Tosylate per crash cart.

Arthur S. Przybyl, ANI’s President and CEO commented, “We are excited to introduce this important life-saving cardiac drug and provide physicians with another valuable tool to treat patients with ventricular arrhythmias. ANI will be supporting the launch of this drug with a broad awareness campaign to educate healthcare professionals on the availability, uses and utility of this important drug.”

Dr. Kurt R. Nielsen, President and CEO of Pii, added, “Partnering with the team at ANI Pharmaceuticals to develop and supply this uniquely effective therapy to health care providers and their patients, is further testament to the value of Pii’s Pharmaceutics Know-How™. Pii will exclusively manufacture Bretylium Tosylate Injection, USP, for commercialization by ANI.”

About Bretylium Tosylate Injection, USP

Bretylium Tosylate Injection, USP is indicated in the prophylaxis and therapy of ventricular fibrillation. Bretylium Tosylate Injection, USP is also indicated in the treatment of life-threatening ventricular arrhythmias, such as ventricular tachycardia that have failed to respond to adequate dose of a first-line antiarrhythmic agent, such as lidocaine.

Use of Bretylium Tosylate Injection, USP should be limited to intensive care units, coronary care units or other facilities where equipment and personnel for constant monitoring of cardiac arrhythmias and blood pressure are available.
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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