ANI Pharmaceuticals Announces Launch of Bretylium Tosylate Injection, USP 50 mg/mL

December 18, 2019

BAUDETTE, Minnesota (December 18, 2019) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced the launch of Bretylium Tosylate Injection USP, 50 mg/mL. Bretylium Tosylate is a class III antiarrhythmic medication approved for the treatment of ventricular fibrillation and life-threatening ventricular arrhythmias such as ventricular tachycardia. ANI estimates that the current annual U.S. antiarrhythmic market is approximately $915 million, based on data from IQVIA.

In the United States, out-of-hospital cardiac arrests (OHCAs) have a reported incidence of 395,000 events per year, while in-hospital cardiac arrests (IHCAs) are estimated at 200,000 per year. 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 that treatment of the typical patient will require two to four vials.

Arthur S. Przybyl, ANI’s President and CEO stated, "We are excited to launch this important cardiac drug and provide physicians with another valuable therapy to treat patients with ventricular arrhythmias. With this launch, ANI has introduced our first injectable drug and our second hospital-based product, underscoring our strategy to diversify our commercial portfolio with additional dosage forms and through previously untapped customer channels.”

Dr. Kurt R. Nielsen, President and CEO of Pharmaceutics International Inc., added, “Bretylium Tosylate is a promising addition to the limited number of medications indicated for the acute and short-term management of shock-refractory ventricular fibrillation and ventricular tachycardia during advanced cardiac life support.”

ANI has established a website for patients, physicians and healthcare professionals (www.bretylium.com) that makes available for download new resources including a Monograph and Therapeutic Review Kit, Product Information Sheet, Dosing and Administration Guide and Ordering information to assist the healthcare community in evaluating Bretylium Tosylate.

About Bretylium Tosylate Injection

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 doses 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.

Following injection of Bretylium Tosylate, there may be a delay of 20 minutes to 2 hours in the onset of antiarrhythmic action, although it appears to act within minutes in ventricular fibrillation. The delay in effect appears to be longer after intramuscular than after intravenous injection.

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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