

9 March 2020

## AltaThera Pharmaceuticals Announces FDA Approval for New Indications of Sotalol IV: A New and Faster Way to Initiate Sotalol Therapy for Atrial Fibrillation (AFib) Patients

- Sotalol IV is now approved for 1-day hospital outpatient initiation of AFib therapy and faster dose escalations for existing patients
- New FDA-approved dosing, monitoring and evaluation shortens the hospital stay from 3 days to 1 day
- The new initiation provides physicians with a faster and safe way to start new sotalol patients, potentially reducing hospital costs and improving patient satisfaction

Chicago, IL, US – 8 March 2020: AltaThera Pharmaceuticals, LLC, a hospital specialty pharmaceutical company focused on commercializing innovative drugs aimed at improving outcomes and reducing hospital costs, announces that the US Food and Drug Administration (FDA) has approved new indications for Sotalol IV in AFib patients. “The new indications for Sotalol IV represent a significant advance that decreases length of stay for new patients starting sotalol for AFib” said Jodi Devlin, AltaThera’s CEO. “We are proud to continue our leadership in cardiac and critical care medicine as we work diligently to bring innovative therapies to patients in the United States. We are on target with our commercial launch preparations and expect to launch Sotalol IV’s new indications in the second half of the year.”

Atrial fibrillation is a common heart arrhythmia in adults. Approximately 1 in 4 adults over the age of 40 years will develop AFib<sup>1</sup>. The American Heart Association estimates that nearly \$6 Billion is spent on AFib hospitalizations in the U.S. each year<sup>2</sup>. Sotalol is one of several different therapies offered for patients living with AFib.

Today’s standard of care for initiating sotalol in a new patient involves a hospital stay of 3 days to monitor the patient’s heart rhythm. The new FDA approval will reduce a 3-day hospital stay to a 1-day hospital outpatient procedure, thereby providing benefits to patients, physicians and

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potential cost savings to hospitals<sup>3</sup>. This new procedure of starting with Sotalol IV and then transitioning to oral sotalol, thereby reducing hospital length of stay is consistent with the company's vision of addressing serious healthcare needs while reducing cost to the healthcare system. The new indications for Sotalol IV in AFib are a significant milestone for AltaThera's growth.

The FDA approval is based on the new Model-Informed Drug Development (MIDD) regulatory path. MIDD involves developing and applying exposure-based, biological and statistical models derived from historical preclinical and clinical data sources to improve clinical trial efficiency and increase the probability of regulatory success. When successfully applied, MIDD can optimize drug dosing/therapeutic individualization in the absence of dedicated trials. Sotalol IV is one of the first drugs to be reviewed under this new program by the FDA.

"We are delighted with the new indications for Sotalol IV", said John Somberg, M.D., Clinical and Regulatory Consultant to AltaThera, Cardiology Professor Emeritus, Rush University. "Sotalol is an antiarrhythmic drug that has been trusted for years and the new FDA-approved dosing will make initiation of sotalol faster and much easier for patients and physicians. We are especially grateful to the FDA and to Sander Vinks, PharmD, PhD, FCP and professor of pediatrics and pharmacology at the University of Cincinnati, College of Medicine who worked closely with AltaThera throughout the process of determining the correct dosing and monitoring for these new AFib indications of initiation and escalation of sotalol."

### **About AltaThera Pharmaceuticals**

AltaThera is a commercial-stage, hospital pharmaceutical products company focused on solving serious and costly problems. AltaThera is developing novel, patient-focused solutions that apply innovative science and technologies to already-approved pharmacological agents for hospitalized patients.

AltaThera holds exclusive US rights to intravenous (IV) sotalol, an NDA Class III antiarrhythmic agent.

For more information, visit [www.altathera.com](http://www.altathera.com)

### **About Intravenous Sotalol**

Sotalol IV is a Class III rhythm control drug.

Sotalol IV is indicated for:

- Substitution for oral sotalol therapy
  - Delay in Recurrence of Atrial Fibrillation / Atrial Flutter
  - Documented Life-Threatening Ventricular Tachycardia
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- Loading and Dose Escalation In-Hospital

### **Important Safety Information**

To minimize the risk of drug induced arrhythmia, patients initiated or re-initiated on sotalol should be in a facility that can provide cardiac resuscitation, with continuous electrocardiographic monitoring. Sotalol can cause life threatening ventricular tachycardia associated with QT interval prolongation. Do not initiate sotalol therapy if the baseline QTc is longer than 450ms. If the QT interval prolongs to 500 ms or greater, the dose must be reduced, the duration of the infusion prolonged or the drug discontinued. Adjust the dosing interval based on creatinine clearance.

### **Contraindications**

- Sinus bradycardia (<50 beats per minute), sick sinus syndrome or 2nd or 3rd degree AV block without a pacemaker
- Congenital or acquired long QT syndromes, QT interval >450 ms
- Cardiogenic shock, decompensated heart failure
- Serum potassium <4 mEq/L
- Bronchial asthma or related bronchospastic conditions
- Known hypersensitivity to sotalol

### **Adverse Reactions**

Most common adverse reactions (>2%) seen with sotalol (dose-related) are fatigue (4%), dizziness (2%), asthenia (2%), dyspnea (3%), bradycardia (3%), and pro-arrhythmia (3%).

### **Pediatrics**

Sotalol IV is currently used in pediatric patients and dose adjustments are made based on body surface area (BSA) or weight.

### **Forward looking statements**

This announcement includes forward-looking statements, which are based on current expectations and projections about future events. These statements are generally identified by words such as “may,” “could,” “should,” “would,” “anticipate,” “believe,” “estimate,” “expect,” and other words and terms of similar meaning or the negative thereof. Forward-looking statement may and often do differ materially from actual results. These forward-looking statements are subject to risks, uncertainties and assumptions about the Company including, among other things, the development of its business, trends in the operating industry, and future capital expenditures. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Any forward-looking

statements reflect the Company's current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's business, results of operations, financial position, prospectus, growth or strategies and the industry in which it operates. Save as required by law or applicable regulation, the Company expressly disclaim an obligation or undertaking to update, review or revise any forward-looking statement contained in this announcement whether as a result of new information, future developments or otherwise. Forward-looking statements speak only as of the date they are made.

## References

1. Rosenfield *et al.* *Heart Rhythm*. 2019; 16(8): 59-65
2. Ptaszek et al. *Journal of the American Heart Association*. 2019; 8(18): 119.012656: 1-12
3. Sotalol IV [package insert]. Chicago, IL: AltaThera Pharmaceuticals, LLC: 2020