

## NASDAQ: CORV TSX: CORV

# CORREVIO PROVIDES U.S. REGULATORY UPDATE FOR BRINAVESS

Correvio to schedule a Pre-NDA meeting to discuss the content and format of a potential resubmission of the NDA

**Vancouver, Canada, June 11, 2018** – Correvio Pharma Corp. (NASDAQ: CORV) (TSX: CORV), a revenue-generating, specialty pharmaceutical company focused on providing innovative, high-quality brands that meet the needs of acute care physicians and patients, today announced that it has received a response from the U.S. Food and Drug Administration (FDA) regarding the regulatory path forward in the US for BRINAVESS<sup>®</sup> (vernakalant hydrochloride, IV), Correvio's antiarrhythmic drug for the rapid conversion of recent onset atrial fibrillation (AF). In its written reply, the FDA informed Correvio that it would be permissible to resubmit the BRINAVESS New Drug Application (NDA) and agreed that the Company may schedule a Pre-NDA meeting. Correvio currently expects that the Pre-NDA meeting with the FDA will take place in the fourth quarter of 2018.

"In our most recent communication with the FDA, we asked the Agency if the Division of Cardiovascular and Renal Products would be willing to meet to discuss a regulatory path forward for Brinavess," said William Hunter, MD, CEO and President of Correvio. "We are pleased that the Agency has agreed to discuss Brinavess in a pre-NDA meeting, which we will seek to have in the fourth quarter."

While there can be no assurance that the Company can address all matters that the FDA may consider relevant, in its communication, the Agency noted that Correvio, "consider collecting data from electronic health records or administrative claims from health systems in countries where vernakalant is marketed as a source of additional data that could be informative to the FDA's evaluation of the NDA resubmission." BRINAVESS<sup>®</sup> has received marketing authorizations in 42 countries outside the US and accumulated eight years of post-marketing data, in addition to completing SPECTRUM, a 2,000-patient prospective, post-authorization safety study in the European Union.

#### **About Atrial Fibrillation**

Atrial Fibrillation (also known as AFib or AF) is a supraventricular tachyarrhythmia with uncoordinated atrial activation resulting in ineffective atrial contraction and if left untreated, structural and/or electrophysiological atrial tissue abnormalities.<sup>1</sup> AF is a common cardiac rhythm disturbance that increases in prevalence with advancing age.<sup>1</sup> According to the American Heart Association, estimates of the prevalence of AF in the U.S. ranged from 2.7 million to 6.1 million in 2010, and is expected to rise to between 5.6 million to 12 million in 2030.<sup>2</sup> There are two strategies to manage AF, namely, rhythm- or rate-control. A rhythm-control strategy may be used in patients who are severely compromised, remain symptomatic despite adequate rate control, when adequate rate control is difficult to achieve, when long term rhythm control therapy is preferred, younger patient age, presence of tachycardia-mediated cardiomyopathy, and first episode of AF.<sup>1,3</sup> Early intervention with a rhythm-control strategy to prevent progression of AF may be particularly beneficial to the AF patient.<sup>1</sup>

### **About BRINAVESS®**

Brinavess<sup>®</sup> (vernakalant HCl, IV) is an antiarrhythmic drug that acts preferentially in the atria by prolonging atrial refractoriness and slowing impulse conduction in a rate-dependent fashion. Brinavess is approved for marketing in Europe, Canada and several other countries worldwide. In Europe, it is approved for the rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults: 1) for non-surgery patients: atrial fibrillation < 7 days duration; and 2) for post-cardiac surgery patients: atrial fibrillation < 3 days duration. Vernakalant IV is not approved for use in the United States.

#### References

- 1. January CT et al. 2014 AHA/ACC /HRS guideline for the management of patients with atrial fibrillation. J AM Coll Cardiol. 2014;34:e1-e76.
- 2. Mozaffarian D et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. Circulation. 2016 Jan 26;133(4):e38-60.
- 3. Kirchhof P et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS European Heart Journal (2016) 37, 2893–2962.

## About Correvio Pharma Corp.

Correvio Pharma Corp. is a revenue-generating, specialty pharmaceutical company focused on providing innovative, high-quality brands that meet the needs of acute care physicians and patients. With a commercial presence and distribution network covering over 60 countries worldwide, Correvio develops, acquires and commercializes brands for the in-hospital, acute care market segment. The Company's portfolio of approved and marketed brands includes: Xydalba<sup>™</sup> (dalbavancin hydrochloride), for the treatment of acute bacterial skin and skin structure infections (ABSSSI); Zevtera<sup>®</sup>/Mabelio<sup>®</sup> (ceftobiprole medocaril sodium), a cephalosporin antibiotic for the treatment of community- and hospital-acquired pneumonia (CAP, HAP); Brinavess<sup>®</sup> (vernakalant IV) for the rapid conversion of recent onset atrial fibrillation to sinus rhythm; Aggrastat<sup>®</sup> (tirofiban hydrochloride) for the reduction of thrombotic cardiovascular events in patients with acute coronary syndrome, and Esmocard<sup>®</sup> and Esmocard Lyo<sup>®</sup> (esmolol hydrochloride), a short-acting betablocker used to control rapid heart rate in a number of cardiovascular indications. Correvio's pipeline of product candidates includes Trevyent<sup>®</sup>, a drug device combination that is designed to deliver treprostinil, the world's leading treatment for pulmonary arterial hypertension.

Correvio is traded on the NASDAQ Capital Market (CORV) and the Toronto Stock Exchange (CORV). For more information, please visit our web site <u>www.correvio.com</u>.

#### **Forward-Looking Statement Disclaimer**

Certain statements in this news release contain forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 or forward-looking information under applicable Canadian securities legislation ("forward-looking statements") that may not be based on historical fact, including without limitation statements containing the words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect" and similar expressions. These forward-looking statements include, but are not limited to, possible future meetings with the FDA, including the risks associated with regulatory reviews, as well as any possible regulatory path forward with respect to BRINAVESS<sup>®</sup>. Such forward-

looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. A discussion of the risks and uncertainties facing Correvio are discussed in the most recent annual and quarterly reports of our former parent company Cardiome Pharma Corp., and detailed from time to time in our other filings with the Securities and Exchange Commission ("SEC") available at www.sec.gov and the Canadian securities regulatory authorities at www.sedar.com. In particular, we direct your attention to the risks titled "Clinical trials for our product candidates are expensive and time consuming, and their outcome is uncertain" and "The results of pre-clinical studies and initial clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later trials or in the commercial setting" in Correvio's Annual Report on Form 20-F for the year ended December 31, 2018. All of the risks and certainties disclosed in these filings are hereby incorporated by reference in their entirety. While Correvio makes these forward-looking statements in good faith, given these risks, uncertainties and factors, you are cautioned not to place undue reliance on any forward-looking statements made in this press release. All forward-looking statements made herein are based on our current expectations and we undertake no obligation to revise or update such forward-looking statements to reflect subsequent events or circumstances, except as required by law.

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