Atrium Therapeutics Announces FDA Clearance of Investigational New Drug Application for ATR 1072 for Treatment of PRKAG2 Syndrome

-- ATR 1072 is the company's first precision cardiology program to enter the clinic --

-- Corventis™ will be the first clinical trial for people living with PRKAG2 syndrome that evaluates a potential treatment for the underlying cause of the disease --

SAN DIEGO, July 14, 2026 /PRNewswire/ -- Atrium Therapeutics, Inc. (Nasdaq: RNA) (the "Company"), a biopharmaceutical company dedicated to delivering RNA therapeutics to the heart, announced today that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application allowing the Company to move forward with its Corventis™ Phase 1/2 clinical trial designed to evaluate ATR 1072 for the treatment of Protein Kinase AMP-activated non-catalytic subunit Gamma 2 (PRKAG2) syndrome.

"PRKAG2 syndrome and other rare genetic cardiomyopathies represent a profound unmet need — these are progressive, life-altering and life-threatening diseases that often strike early, affect multiple members of the same family, and have no approved therapy to address their root cause," said Kathleen Gallagher, President and Chief Executive Officer, Atrium Therapeutics. "FDA clearance of our IND and the launch of the Corventis™ Phase 1/2 trial reinforce our team's ability to move with speed on behalf of patients with the goal of delivering potential disease-modifying treatments."

Corventis™ is a Phase 1/2 open-label, multicenter clinical trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of ATR 1072. The study will enroll approximately 37 participants across two parts: Part A, multiple ascending dose cohorts to characterize safety and support dose selection, and Part B, a single-arm expansion cohort at the recommended Phase 2 dose to further evaluate safety and efficacy trends in cardiac structure and function.

Clinical site initiation activities are currently underway, and Atrium expects the first participant to be enrolled by the end of 2026. Initial trial data demonstrating proof of concept is anticipated in the second half of 2027.

About ATR 1072

ATR 1072, the company's lead product candidate, is a potentially disease-modifying treatment for PRKAG2 syndrome. Using Atrium's precision RNA delivery technology, ATR 1072 uses small interfering RNA (siRNA) to silence mutant PRKAG2 messenger RNA (mRNA), normalize AMP-activated protein kinase (AMPK) activity and reduce pathogenic glycogen accumulation, potentially leading to improved heart function.

About PRKAG2 Syndrome

PRKAG2 syndrome is a rare, autosomal dominant, early-onset cardiomyopathy caused by mutations in the PRKAG2 gene, which encodes the Gamma 2 regulatory subunit of AMPK. Mutations enhance AMPK activity leading to abnormal glycogen accumulation in the heart, thickened heart muscles, electrical conduction problems, and arrhythmias. Based on current scientific literature estimates, there are at least 1,000 – 2,000 people with PRKAG2 syndrome in the US. Current management is limited to symptomatic treatment; no approved therapies exist to address the underlying genetic driver of disease.

About the Corventis™ Trial

Corventis™ is a Phase 1/2 open-label, multicenter clinical trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of ATR 1072 in participants living with PRKAG2 syndrome. The study will enroll approximately 37 participants across two parts: Part A, multiple ascending dose cohorts to characterize safety and support dose selection, and Part B, a single-arm expansion cohort at the recommended Phase 2 dose to further evaluate efficacy trends in cardiac structure and function. Additional information about the trial is available at www.corventistrial.com.

About Atrium Therapeutics

Atrium Therapeutics, Inc. (Nasdaq: RNA) is pioneering targeted delivery of ribonucleic acid (RNA) therapeutics to the heart to transform the standard of care for people living with cardiomyopathies. The Company's proprietary technology - designed at Avidity Biosciences, Inc. - combines the tissue selectivity of monoclonal antibodies (mAbs) and other targeted delivery ligands with the precision of oligonucleotides. Atrium Therapeutics' platform is designed to selectively target the underlying drivers of genetically driven cardiac diseases through targeted, non-viral delivery of small interfering RNA (siRNA). This approach builds upon learnings from demonstrated delivery to the skeletal muscle and applies it for efficient delivery to the heart with the potential to overcome challenges associated with non-specific tissue delivery. The Company's pipeline consists of two precision cardiology candidates, ATR 1072 for PRKAG2 (Protein Kinase AMP-activated non-catalytic subunit Gamma 2) syndrome and ATR 1086 for PLN (phospholamban) cardiomyopathy, and two undisclosed research targets in rare cardiomyopathies.

For more information about our RNA delivery platform, development pipeline and people, please visit https://atriumtherapeutics.com/ and engage with us on LinkedIn.

Availability of Other Information About Atrium Therapeutics

Investors and others should note that Atrium Therapeutics communicates with its investors and the public using its website https://atriumtherapeutics.com/, including, but not limited to, Atrium Therapeutics' disclosures, investor presentations and FAQs, Securities and Exchange Commission (SEC) filings, press releases, public conference call transcripts and webcast transcripts, as well as on LinkedIn. The information that Atrium Therapeutics posts on its website or on LinkedIn could be deemed to be material information. As a result, Atrium Therapeutics encourages investors, the media and others interested to review the information that it posts there on a regular basis. The contents of Atrium Therapeutics' website or social media shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding: the safety, efficacy, success, positioning and advancement of our clinical program for ATR 1072 for the treatment of PRKAG2 syndrome pursuant to our IND application, including the expected timing of initiation, enrollment, dosing, availability of data and completion of Corventis™, our Phase 1/2 clinical trial evaluating ATR 1072; the study design and conduct of Corventis™; the disease-modifying potential of ATR 1072 to treat PRKAG2 syndrome; the therapeutic potential of our RNA delivery platform; and statements regarding our strategy, pipeline, and future operations. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events and are subject to significant, known and unknown risks and uncertainties. Particular areas where risks or uncertainties could cause Atrium's actual results to be materially different than those expressed in Atrium's forward-looking statements include but are not limited to: the initiation, timing, progress, potential registrational quality, and results of our research and development programs, preclinical studies, any clinical trials, and other regulatory submissions; the potential for clinical trial results to differ from our preclinical studies; our ability to timely enroll a sufficient number of patients in our clinical trials, such as Corventis™; the beneficial characteristics, including potential safety, efficacy and therapeutic effects of our product candidates and the potential advantages of our product candidates compared to alternative therapies; the success and capabilities of the RNA delivery platform; the prevalence of certain diseases and conditions we intend to treat and our estimates of the potential market opportunity for our product candidates; the timing of and costs involved in obtaining and maintaining regulatory approval of our current and any future product candidates; our ability to develop our current and future product candidates; the implementation of our strategic plans for our business, product candidates, research programs and technologies; developments related to our competitors and our industry; our competitive position and the success of competing therapies that are or may become available; our reliance on third parties for manufacturing and to conduct preclinical studies and clinical trials of our product candidates; our ability to efficiently and cost-effectively conduct our current and future clinical trials; the costs of operating as a public company; the accuracy of our estimates regarding future expenses, future revenue, capital requirements and the need for additional financing; the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; and other factors specified in Atrium's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 publicly filed by Atrium with the SEC and in other filings and furnishings made by Atrium with the SEC from time to time. Atrium is providing the information in this communication as of this date and does not undertake any obligation to update any forward-looking statements contained in this communication as a result of new information, future events or otherwise, except as required by law.

SOURCE Atrium Therapeutics

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