



Arena Pharmaceuticals Announces First Participant Randomized in Phase 2 Trial Evaluating Temanogrel in Coronary Microvascular Obstruction (cMVO)

June 8, 2021

– *Evaluating the safety, tolerability, and efficacy of intravenous (IV) temanogrel for cMVO in adult participants undergoing percutaneous coronary intervention (PCI)*

– *Currently no FDA approved therapies indicated for the treatment of cMVO*

– *Temanogrel was granted FDA Fast Track Designation for the treatment of cMVO*

PARK CITY, Utah--(BUSINESS WIRE)--Jun. 8, 2021-- [Arena Pharmaceuticals, Inc.](https://www.arena-pharm.com) (Nasdaq: ARNA) today announced that the first participant has been randomized in a Phase 2 trial evaluating IV temanogrel, an investigational, peripherally acting, and selective 5-HT_{2A} receptor inverse agonist, for the potential treatment of coronary microvascular obstruction (cMVO) in patients undergoing percutaneous coronary intervention (PCI).

"Despite aggressive treatment with dual anti-platelet therapies, approximately 40-60% of patients undergoing PCI for acute coronary syndrome, or ACS, fail to achieve full myocardial reperfusion," said Andy Yong, MBBS, PhD, FRACP, FACC, Director of the Cardiac Catheterisation Lab at Concord Hospital, and Associate Professor of Medicine at the University of Sydney and Macquarie University. "cMVO increases negative cardiovascular outcomes and mortality by 2-3 fold. As there are no currently FDA-approved treatment options for patients with cMVO, the clinical advancement of a novel molecule like temanogrel for this patient population is exciting."

The Phase 2, multi-center, randomized, placebo-controlled trial is being conducted in the US, Australia, Sweden, Netherlands, and UK, and will assess the safety, tolerability, and efficacy of two doses of intravenous temanogrel on cMVO in patients undergoing PCI. The primary endpoint is the change in Index of Microcirculatory Resistance (IMR) from baseline (prior to administration of study treatment) to post-PCI on day 1. The trial is expected to enroll 99 participants.

"The dosing of our first patient in the Phase 2 study for the potential treatment of cMVO is a significant advancement for Arena's Cardiovascular Portfolio," stated Paul Streck, MD Senior Vice President and Chief Medical Officer of Arena. "To date, we have seen pre-clinical and scientific validation supporting the rationale for studying the use of temanogrel in patients undergoing PCI to prevent cMVO. We expect the availability of the Phase 2 data during the second half of 2022."

About Coronary Microvascular Obstruction

Coronary microvascular obstruction (cMVO) is a condition characterized by the failure to achieve full myocardial or microcirculatory reperfusion despite resolution of epicardial coronary occlusion and flow by a percutaneous coronary intervention (PCI). PCI results in activation of platelets and release of serotonin (5-HT), which is thought to mediate platelet aggregation and vasoconstriction.

About Temanogrel

Temanogrel (APD791) is an investigational, peripherally acting, and selective 5-HT_{2A} receptor inverse agonist discovered by Arena, and is designed to inhibit serotonin (5-HT)-mediated amplification of platelet aggregation and vasoconstriction.

In addition to cMVO, Temanogrel is being investigated for the treatment of Raynaud's Phenomenon secondary to Systemic Sclerosis.

Temanogrel is an investigational compound that is not approved for any use in any country.

About Arena Pharmaceuticals

[ARENA Pharmaceuticals](https://www.arena-pharm.com) is a team with a singular purpose – deliver important medicines to patients.

In a rapidly changing global market, we work with a sense of urgency every day to understand the needs of all our stakeholders, identify bold, sometimes disruptive, ideas to get medicines to patients, and relentlessly execute until it's done.

We are developing a richly diversified portfolio of therapeutic candidates targeting gastroenterology, dermatology and cardiology. Our pipeline includes four investigational medicines in eight indications and eleven ongoing or planned clinical trials. To fuel our growth, we are unlocking the value of our historical GPCR research with a sustainable discovery engine for broad portfolio expansion.

ARENA - *Care More. Act Differently.*

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements may be identified by words such as "evaluating," "potential," "will," and "expect," and include, without limitation, statements about the following: the opportunity, development and potential of temanogrel, including regarding its design, its safety and efficacy, its therapeutic potential in cMVO, and its ability to satisfy an unmet medical or clinical need; the Phase 2 trial, including enrollment, study sites, trial design, and timing of Phase 2 data; the significance of the trial and its initiation; and Arena's purpose, work, understanding, ideas, and execution. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, the following: clinical trials and

other studies may not proceed at the time or in the manner expected, or at all; the timing and outcome of research, development and regulatory review is uncertain, and Arena's drug candidates may not advance in development or be approved for marketing; enrolling patients in Arena's ongoing and intended clinical trials is competitive and challenging; the duration and severity of the coronavirus disease (COVID-19) pandemic, including but not limited to its impact on Arena's clinical trials and operations, the operations of Arena's suppliers, partners, collaborators, licensees, and the capital markets, which in each case remains uncertain; risks related to developing and commercializing drugs; Arena may need additional funds to advance all of its programs; risks and uncertainties relating to cash and revenues that may be generated from product sales or other sources, including the impact of competition; risks related to unexpected or unfavorable new data; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline data may not accurately reflect the complete results of a particular study or trial; satisfactory resolution of litigation or other disagreements with others; government and third-party payor actions, including relating to reimbursement and pricing; risks related to relying on licenses or collaborative arrangements, including lack of control and potential disputes; the entry into or modification or termination of licenses or collaborative arrangements; and Arena's and third parties' intellectual property rights. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission (SEC), including but not limited to Arena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, which was filed with the SEC on May 5, 2021. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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