FDA Grants Fast Track Designation to Arena Pharmaceuticals' APD418 for Development in Decompensated Heart Failure Patients

January 16, 2020

- APD418 currently in Phase 1 clinical investigation - data expected this year

SAN DIEGO, Jan. 16, 2020 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for APD418, a β_3-adrenergic receptor (AdrR) antagonist and cardiac myotrope, in development for the treatment of decompensated heart failure (DHF).

"With approximately 10 million DHF patient hospital visits expected in the US by 2025 and few viable treatment options, we believe that APD418 has the potential to make a significant impact for these patients," stated Chris Cabell, MD, MHS, FACC, Arena's Senior Vice President and Chief Medical Officer. "We are pleased with the Fast Track designation and look forward to advancing this program as part of our cardiovascular focus."

About APD418
APD418 is a first-in-class β_3-adrenergic receptor (AdrR) antagonist and cardiac myotrope for decompensated heart failure (DHF). APD418 is a selective antagonist designed to improve cardiac contractility with minimal effect on heart rate, blood pressure and myocardial oxygen consumption, thus potentially avoiding adverse events associated with current inotrope therapies. Arena discovered and developed this investigational drug candidate internally.

About Arena Pharmaceuticals
Arena Pharmaceuticals is uniquely positioned to develop best-in-disease medicines with optimized efficacy and safety for patients globally. Our drive to deliver a robust pipeline of novel, transformational medicines is grounded in two decades of world class G-protein-coupled receptor (GPCR) discovery research.

It is the breadth and depth of the portfolio, the prioritization of drug development to meet unmet patient needs, the strong financial health and the growing, bold-thinking world-class team that gives Arena the ingredients and passion to build a sustainable, vibrant next generation pharmaceutical company.

Forward-Looking Statements
Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements may be identified by introductory words such as "expected", "potential", "look forward", "designed to", "uniquely positioned to," "drive to," "will", or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include statements about expected patient hospital visits, the potential of our drug candidates, our development programs, the potential of our drug candidates to avoid adverse events, and Arena's position, including to develop best-in-disease medicines, Arena's drive, portfolio, prioritization, and financial position, and Arena's team, including its growth, thinking, and ability to build the company. 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, without limitation, the following: Fast Track designation may not result in an expedited regulatory review process; the timing and outcome of research, development and regulatory review is uncertain; clinical trials and other studies may not proceed at the time or in the manner expected or at all; enrolling subjects in our ongoing and intended clinical trials is competitive and challenging; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; nonclinical and clinical data are 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; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; risks related to unexpected or unfavorable new data; risks related to relying on partners and other third parties; risks related to developing and commercializing drugs; Arena's and third parties' intellectual property rights; and satisfactory resolution of litigation or other disagreements with others. 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. 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.

Corporate Contact:
Kevin R. Lind
Arena Pharmaceuticals, Inc.
Executive Vice President and
Chief Financial Officer
klind@arenapharm.com
858.210.3636

Arena Media Contact:
IR@arenapharm.com
858-453-7200

View original content to download multimedia:http://www.prnewswire.com/news-releases/fda-grants-fast-track-designation-to-arena-pharmaceuticals-apd418-for-development-in-decompensated-heart-failure-patients-300988176.html

SOURCE Arena Pharmaceuticals, Inc.