Arena Pharmaceuticals Announces First Subject Dosed in CAPTIVATE Phase 2 Trial Evaluating Olorinab in Abdominal Pain Associated with Irritable Bowel Syndrome

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- CAPTIVATE clinical trial initiated and enrollment progressing
- Evaluating patients with the clinical diagnosis of either constipation or diarrhea predominant irritable bowel syndrome (IBS)
- Significant unmet need for pain management in gastrointestinal disorders

SAN DIEGO, July 25, 2019 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced that the first subject has been dosed in the Phase 2 CAPTIVATE trial evaluating olorinab, an investigational, oral, highly-selective, full agonist of the cannabinoid type 2 receptor (CB_2) in development for the treatment of visceral pain associated with gastrointestinal (GI) disorders. The trial will evaluate the efficacy and safety of three dose levels of olorinab for 12-weeks in approximately 240 subjects experiencing abdominal pain associated with IBS, including IBS with constipation (IBS-C) or IBS with diarrhea (IBS-D).

"I am thrilled that the first subject has enrolled in Arena's CAPTIVATE trial, supporting the advancement of novel pain management options within the digestive disease field," said Lin Chang, MD, Professor of Medicine at the Vatche and Tamar Manoukian Division of Digestive Diseases at the University of California, Los Angeles. "The majority of IBS patients describe their most problematic symptom as frequent abdominal pain, which often significantly impacts their quality of life. With limited pain management options available for GI disorders, there is a clear unmet medical need and an opportunity to improve the lives of patients."

"The initiation of the CAPTIVATE clinical trial is a significant milestone for Arena as we strategically expand our pipeline portfolio, with the goal of validating the broad potential impact of olorinab and ultimately delivering a novel option for chronic pain relief to patients worldwide," stated Preston Klassen, MD, MHS, Executive Vice President, Research and Development and Chief Medical Officer of Arena. "We believe that olorinab has the potential to be a first-in-class therapy to address the strong clinical need to manage pain in patients with GI disorders, and we are committed to advancing the program expeditiously."

About CAPTIVATE
CAPTIVATE is a Phase 2, multi-center, randomized, double-blind, placebo-controlled, 12-week study of olorinab in patients with irritable bowel syndrome (IBS), experiencing abdominal pain. The study will evaluate change in abdominal pain in patients with the clinical diagnosis of IBS with predominant constipation (IBS-C) or diarrhea (IBS-D). The primary objective of this trial is to assess the safety and efficacy of olorinab administered three times daily (TID). The primary endpoint is improvement in the weekly Average Abdominal Pain Scale (AAPS) from baseline. The CAPTIVATE trial will enroll approximately 240 patients and will be conducted in study sites across the United States.

About Olorinab
Olorinab (APD371) is an oral, peripherally acting, highly-selective, full agonist of the cannabinoid type 2 receptor (CB_2). Olorinab is an internally discovered investigational drug candidate that Arena is exploring for development in several indications, with an initial focus on visceral pain associated with gastrointestinal disorders. This compound, through its selectivity for CB_2, versus cannabinoid type 1 receptor (CB_1), is designed to provide pain relief without psychoactive adverse effects.

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

About IBS
Irritable bowel syndrome (IBS) is a common disorder of the gastrointestinal (GI) tract. Signs and symptoms include cramping, abdominal pain, bloating, gas, and predominant constipation (IBS-C) or diarrhea (IBS-D), or mixed (IBS-M). IBS is a chronic condition that needs to be managed long term. There are approximately 25 million patients in the United States with IBS, with approximately 80% reporting frequently recurring or continuous abdominal pain.

About Arena Pharmaceuticals
Arena Pharmaceuticals is driven to deliver novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Arena's proprietary pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility. Etrasimod (APD334), with potential utility in a broad range of immune and inflammatory conditions, is being evaluated in later-stage clinical programs in ulcerative colitis (UC) and Crohn's disease (CD), as well as in programs for other indications such as atopic dermatitis. Arena is also evaluating olorinab (APD371) in a Phase 2 program for gastrointestinal pain. Arena continues to assess other earlier research and development stage drug candidates, including APD418 for decompensated heart failure.

Arena has additional license agreements and partnerships, including with United Therapeutics (ralinepag in a Phase 3 program for pulmonary arterial hypertension), Everest Medicines Limited (etrasimod in Greater China and select Asian countries), Boehringer Ingelheim International GmbH (undisclosed target – preclinical), Outpost Medicine, LLC (undisclosed target – preclinical), and Eisai Co., Ltd. and Eisai Inc. (BELVIQ® – marketed product).

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 accompanied by words such as "potential," "believe," "will," "goal," "objective," "designed to," "driven to," "potentially," "being evaluated for," "evaluating", "assess," or words of similar meaning, or they may be identified by the fact that they do not relate strictly to historical or

current facts. Such forward-looking statements include, without limitation, statements about the following: the opportunity, development and potential of olorinab, including regarding its design, broad potential impact, and ability to deliver pain relief, improve lives, and satisfy an unmet medical or clinical need; the CAPTIVATE trial, including trial enrollment and design; the significance of a milestone; the expansion of our pipeline; Arena's drive, the ability to expand of our pipeline, and commitment to advance programs; and the potential of Arena's assets, programs, licenses, and collaborations, including to be first- or best-in-class or have broad clinical utility. 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: the timing and outcome of research, development and regulatory review is uncertain; 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; clinical trials and other studies may not proceed at the time or in the manner expected or at all; enrolling patients in our ongoing and intended clinical trials is competitive and challenging; 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 developing and commercializing drugs; risks related to relying on partners and other third parties; 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 (SEC), including but not limited to its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. 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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