Arena Pharmaceuticals Reports Topline Results from Phase 2b CAPTIVATE Clinical Trial

March 2, 2021

- Olorinab investigated in three doses, 10 mg, 25 mg, and 50 mg, for abdominal pain associated with IBS-C & IBS-D

- Trial did not meet primary endpoint in broad study population

- Moderate to severe pain population at 50 mg showed statistically significant, clinically meaningful improvement vs placebo in Average Abdominal Pain Score (AAPS)

- Olorinab was generally well tolerated consistent with the safety profile of previous trials

- Company to evaluate possible strategic options for program

PARK CITY, Utah--(BUSINESS WIRE)--Mar. 2, 2021-- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced topline results from the randomized, double-blind, placebo-controlled Phase 2b CAPTIVATE clinical trial evaluating three doses of olorinab, a novel, oral, peripherally acting, highly selective, full agonist of the cannabinoid receptor 2 (CB_2), in participants with abdominal pain due to Irritable Bowel Syndrome (IBS).

The CAPTIVATE trial randomized a total of 273 participants and was conducted in study sites across the United States. The results show that, although olorinab was well tolerated, it did not meet the primary efficacy endpoint of statistically significant improvement in the overall AAPS from baseline to week 12.

A pre-specified analysis assessed participants with baseline AAPS ≥ 6.5 (median), representing those with moderate to severe pain. This subgroup accounted for 50% of the overall study population. Within this subgroup, the 50 mg treatment group showed a clinically meaningful[1] and statistically significant (p=0.01) reduction in AAPS of 1.64 points compared to placebo and 3.93 points from baseline at week 12.

Olorinab was generally safe and well tolerated in the study, consistent with the safety profile of previous trials. Discontinuation rates and adverse events were similar to placebo, notably with no worsening of bowel habits and no treatment interruptions. There were no serious adverse events observed in the study.

“The CAPTIVATE Study was the first study to examine a full agonist of CB_2 in IBS pain. As a Phase 2 trial we were evaluating safety in this population as well as looking for an initial signal of efficacy,” said Paul D. Streck, MD, Arena’s Senior Vice President, Clinical Development, and Chief Medical Officer. “We are encouraged by the signal in this moderate to severe group and look forward to sharing the full data from this well-executed trial at an upcoming medical meeting.”

“There is a significant unmet need for a novel, non-opioid drug that treats moderate to severe pain with IBS, while not worsening associated constipation or diarrhea. While these data will need to be replicated in a Phase 3 registration program, the data from the CAPTIVATE Study are promising and give me hope that we may have a valuable therapeutic option in the future,” said Lin Chang, MD, Vice-Chief of the Vatche and Tamar Manoukian Division of Digestive Diseases at UCLA.

“These data are quite promising. There appears to be a strong signal that the drug has effect in abdominal pain in the moderate to severe population at the 50 mg dose. Importantly, the magnitude of effect in this cohort surpasses the bar for clinically meaningful benefit,” said Anthony Lembo, MD, Professor of Medicine at Harvard Medical School and Director of the GI Motility Laboratory at Beth Israel Deaconess Medical Center in Boston, MA.

“We expect to evaluate possible strategic options for olorinab, while maintaining our commitment to the GI community and remaining focused on advancing our clinical programs for etrasimod in ulcerative colitis, Crohn’s disease, and eosinophilic esophagitis,” added Amit Munshi, President and Chief Executive Officer at Arena. “We want to thank the participants, clinicians, site staff, and the Arena team who participated in this important trial.”

About CAPTIVATE

CAPTIVATE is a Phase 2b, multi-center, randomized, double-blind, placebo-controlled, 12-week study of olorinab in 273 study participants with irritable bowel syndrome (IBS) experiencing abdominal pain. The study will evaluate change in abdominal pain in participants 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 Score (AAPS) from baseline. The CAPTIVATE trial is being conducted at approximately 70 study sites across the United States. Additional information on this clinical trial can be found at clinicaltrials.gov (NCT04043455).

About Olorinab

Olorinab (APD371) is an oral, peripherally acting, highly selective, full agonist of the cannabinoid receptor 2 (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 in gastrointestinal disorders. This compound, through its selectivity for CB_2, versus the cannabinoid receptor 1 (CB_1), was designed to provide pain relief while minimizing the risk of psychoactive adverse effects.

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

About Arena Pharmaceuticals

ARENA Pharmaceuticals is a team with a singular purpose – deliver our 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 our 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.*

---

[1] Minimal clinically important difference is defined as improvement of at least 2.2 from baseline per Spiegel B et al. “Measuring irritable bowel syndrome patient-reported outcomes with an abdominal pain numeric rating scale.” *Aliment Pharmacol Ther.* 2009;30(11-12):1159-1170.

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 "will," "look forward," "upcoming," "committed," "objective," "designed to," and "planned," and include, without limitation, statements about the following: olorinab's potential utility and clinical benefits, Arena's plans to present additional data from the CAPTIVATE trial at a future medical meeting, the exploration of strategic options for olorinab, and Arena's purpose, work, understanding, ideas, execution, pipeline, planned clinical trials, discovery engine, and portfolio expansion. 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: topline data may not accurately reflect the complete results of a particular study or trial; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; 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 participants in Arena's ongoing and intended clinical trials is competitive and challenging; the coronavirus disease (COVID-19) pandemic, including but not limited to the impact on Arena's clinical operations, the operations of Arena's suppliers, partners, collaborators, licensees, and capital markets, which in each case remains uncertain; risks related to developing and commercializing drugs; Arena will need additional funds to advance all of its programs, and you and others may not agree with the manner Arena allocates its resources; the impact of competition; risks related to unexpected or unfavorable new data; the risk that 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; satisfactory resolution of litigation or other disagreements with others; and risks related to the enforcement of 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 Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on February 23, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210302006098/en/

Investors and Media:
Patrick Malloy
Arena Pharmaceuticals, Inc.
Vice President, Investor Relations & Corporate Communications
pmalloy@arenapharm.com
847.987.4878

Source: Arena Pharmaceuticals, Inc.