Ardelyx Showcases New Data from T3MPO-3 Long-Term Safety Trial of Tenapanor for IBS-C in Presidential Poster at ACG 2018 Annual Meeting

October 8, 2018

FREMONT, Calif., Oct. 8, 2018 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), today announced that new data from its long-term safety trial of tenapanor for irritable bowel syndrome with constipation (IBS-C), the T3MPO-3 trial, were presented this weekend at the American College of Gastroenterology (ACG) 2018 Annual Meeting. The poster (P0338), titled "An Open Label Long-Term Safety Trial (T3MPO-3) of Tenapanor in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)," was recognized as a Presidential Poster at this year's meeting, a recognition that fewer than five percent of accepted abstracts receive for high quality, novel, unique and interesting research. Tenapanor, Ardelyx's lead product candidate, is a minimally-systemic small molecule that acts locally in the gastrointestinal (GI) tract to inhibit the sodium transporter NHE3 and reduce sodium uptake from the gut.

Ardelyx recently submitted a New Drug Application for marketing authorization of tenapanor for the treatment of people with IBS-C to the U.S. Food and Drug Administration, which was supported by a robust set of nonclinical studies and an extensive clinical data package in more than 3,100 people supporting the efficacy and safety profile of tenapanor. The data include results from the completed IBS-C registration T3MPO program, which consisted of two Phase 3 trials, T3MPO-1 and T3MPO-2, and the long-term safety extension trial, T3MPO-3. Both the T3MPO-1 and T3MPO-2 trials achieved statistical significance for their primary endpoint and demonstrated the ability of tenapanor to have a durable effect on reducing the constipation and abdominal pain that patients with IBS-C experience. The favorable safety profile of tenapanor, which has been shown across all trials, was further supported by the completed T3MPO-3 study.

The T3MPO-3 trial enrolled a total of 240 patients who completed either the T3MPO-1 or T3MPO-2 Phase 3 trials. All participants in T3MPO-3 received 50 mg of tenapanor twice-daily for up to 55 weeks. Importantly, results from T3MPO-3 showed a mean compliance rate with tenapanor of approximately 98 percent. Overall, tenapanor was well-tolerated, with the most common adverse event being diarrhea (9.2%). There were limited discontinuations (2.1%), with only 1.7 percent of patients discontinuing due to diarrhea.

"Tenapanor offers a novel inhibitor of the gastrointestinal sodium hydrogen exchanger, NHE3, which has been shown to be effective in patients suffering with IBS-C," said Anthony Lembo, M.D., associate professor of medicine at Harvard Medical School and director of the GI Motility Center at Beth Israel Deaconess Medical Center. "The safety and tolerability data from this study, as well as the efficacy and tolerability demonstrated in the T3MPO program, suggest that tenapanor could make a meaningful impact in patients' lives. I look forward to the potential opportunity to use tenapanor in practice with my patients in the future."

"The T3MPO-3 data further enhance our confidence in the approvability of tenapanor for people with IBS-C, and its potential role as a highly differentiated treatment for this incredibly burdensome disorder," said David P. Rosenbaum, Ph.D., chief development officer of Ardelyx. "We are delighted that these data have been recognized as a Presidential Poster, an honor ascribed to fewer than 5 percent of all abstracts at the congress. Tenapanor offers a completely new mechanism of action that works by reducing sodium uptake from the gut, rather than through secretion of chloride in the GI tract. This, combined with our preclinical evidence that tenapanor reduces pain associated with IBS-C through the inhibition of TRPV-1 signaling, supports its potential to change the way patients who suffer from the life-altering symptoms of IBS-C are treated. We are excited to have submitted our NDA in September and look forward to the possibility of providing IBS-C patients with an alternative medication for those who may need it."

About Tenapanor for IBS-C
Tenapanor is a minimally-systemic small molecule that acts locally in the gastrointestinal (GI) tract to inhibit the sodium transporter NHE3 and reduce sodium absorption in the GI tract, thus increasing intestinal fluid. In addition, data from preclinical studies suggest that tenapanor reduces abdominal pain caused by IBS-C through the inhibition of TRPV-1 dependent signaling. TRPV-1, better known as the "hot chili pepper receptor," is a well-established pain target known for transmitting painful stimuli from a variety of sources including heat, protons and inflammatory molecules.

About IBS-C
Irritable bowel syndrome with constipation (IBS-C) is a GI disorder in which abdominal pain is associated with constipation, and significantly affects the health and quality of life of at least 11 million people in the US. A study published in the American Journal of Gastroenterology in 2015 showed that over 50 percent of IBS-C patients rated their pain, constipation and straining as being "extremely bothersome." In the same study, GI symptoms led to an average 4.9 days of "disrupted productivity" and 0.8 days of missed work per month.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way people with renal diseases are treated by developing first-in-class medicines. Ardelyx's renal pipeline includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease who are on dialysis and RDX013, a potassium secretagogue program for the potential treatment of high potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease. In addition, Ardelyx has completed Phase 3 development of tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C) and submitted a New Drug Application to the U.S. Food and Drug Administration seeking U.S. marketing approval for this indication. To efficiently bring its treatments to market, Ardelyx is pursuing strategic collaborations for tenapanor for IBS-C and hyperphosphatemia in certain territories. Ardelyx has established agreements with Kyowa Hakko Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada. For more information, please visit http://www.ardelyx.com/ and connect with us on Twitter @Ardelyx.

Forward Looking Statements
To the extent that statements contained in this press release are not descriptions of historical facts regarding Ardelyx, they are forward-looking

statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including the potential for Ardelyx's product candidates in treating the diseases and conditions for which they are being developed and Ardelyx's belief regarding the approvability of Ardelyx's NDA for tenapanor for the treatment of IBS-C. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of Ardelyx's product candidates or Ardelyx's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical development process, including the regulatory approval process. Ardelyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ardelyx's business in general, please refer to Ardelyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2018, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

View original content to download multimedia:http://www.prnewswire.com/news-releases/ardelyx-showcases-new-data-from-t3mpo-3-long-term-safety-trial-of-tenapanor-for-ibs-c-in-presidential-poster-at-acg-2018-annual-meeting-300726693.html

SOURCE Ardelyx

Chelcie Lister, THRUST Strategic Communications, 910-777-3049, chelcie@thrustsc.com