Ardelyx Submits New Drug Application for U.S. Marketing Authorization of Tenapanor for IBS-C to U.S. Food and Drug Administration

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FREMONT, Calif., Sept. 13, 2018 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting U.S. marketing authorization of tenapanor for the treatment of patients with irritable bowel syndrome with constipation (IBS-C). 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.

"This NDA submission represents an important advancement in the treatment of people with IBS-C," said William Chey, M.D., professor gastroenterology and nutrition at the University of Michigan and an investigator in Ardelyx's IBS-C clinical trials. "Despite the high prevalence of this disorder and the extremely burdensome symptoms associated with it, there are limited treatment options available. Current FDA approved treatments work to alleviate constipation through the secretion of chloride in the GI tract, and improve symptoms in only some patients. If approved, tenapanor would be the first medication available that works by reducing sodium uptake from the gut. The resulting increased fluid in the gut softens stools and improves bowel regularity. In addition, in clinical trials, tenapanor has demonstrated a statistically significant reduction in pain associated with IBS-C, a critical and difficult-to-manage symptom for these patients. In preclinical work, Ardelyx found that this reduction in pain is associated with the inhibition of TRPV-1 dependent signaling, which is unique from other current IBS-C therapies. I believe tenapanor has the potential to be an important new treatment and look forward to the potential opportunity to use it with my patients in the future."

"We are excited to have submitted our first NDA, which is the culmination of eight years of work by our team and a commitment from patients and our investigators, to whom we are very thankful," said Mike Raab, president and chief executive officer of Ardelyx. "Tenapanor has demonstrated clear efficacy and tolerability in our Phase 3 clinical program. With its novel mechanism of action, we believe it could make a significant difference in the lives of patients who struggle with the symptoms of IBS-C and provide physicians a new option for treating their patients. If accepted, our partners, Knight Therapeutics and Fosun Pharma will be able to leverage our NDA, bringing them closer to filing in their territories and launching tenapanor for IBS-C in Canada and China. We will continue to evaluate additional collaborations to bring tenapanor to patients and physicians in the United States and around the world who need another treatment option."

Ardelyx's NDA submission is supported by a clinical package encompassing more than 3,100 patients and healthy volunteers who have participated in Ardelyx trials and an extensive clinical and preclinical data package supporting the excellent safety profile. 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 a long-term safety extension trial, T3MPO-3. Both the T3MPO-1 and T3MPO-2 trials achieved statistical significance for their primary endpoint and demonstrated that tenapanor had a durable effect on reducing 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.

Based on standard FDA review timelines, Ardelyx expects to receive notification of acceptance of the filing for substantive review before the end of the year.

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 expected timing for receipt of notification from the FDA of acceptance for substantive review 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.

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