Ardelyx Successfully Completes T3MPO-3 Safety Extension Study of Tenapanor for IBS-C

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Favorable Tolerability Profile Demonstrated in 1-year Safety Study

FREMONT, Calif., Jan. 3, 2018 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) today announced that the company successfully completed the safety extension portion of its Phase 3 T3MPO program, designed to support the registration of tenapanor for the treatment of patients with irritable bowel syndrome with constipation (IBS-C). People who had completed either T3MPO-1 or T3MPO-2, the two Phase 3 trials of tenapanor for IBS-C, were eligible to enter the safety extension study, T3MPO-3. Results from T3MPO-3 showed a mean tenapanor compliance rate of approximately 98 percent, and that tenapanor was well-tolerated among the 240 patients treated. Of patients treated, 9.2 percent reported experiencing diarrhea, with only 1.7 percent of patients discontinuing treatment due to diarrhea. The overall discontinuation rate in the study was just 2.1 percent.

"We are very excited to see that tenapanor was so well-tolerated in patients treated for up to a year, resulting in minimal treatment discontinuations," said David P. Rosenbaum, Ph.D., chief development officer of Ardelyx. "The rate of diarrhea reported among patients was lower than that observed in both the T3MPO-1 and T3MPO-2 trials, which may further suggest that diarrhea occurs early in treatment and bowel movements can be normalized over time. These findings, along with the large number of people who elected to stay on tenapanor treatment for such an extended period of time, reinforce tenapanor's potential as an effective and well-tolerated chronic treatment for people with IBS-C."

The positive results from both the T3MPO-1 and T3MPO-2 studies, combined with the extensive safety data, support Ardelyx's plans to submit its first New Drug Application to the U.S. Food and Drug Administration for this indication in the second half of 2018.

About Tenapanor for IBS-C
Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, minimally absorbed, oral, experimental medication. Two Phase 3 clinical trials for tenapanor in IBS-C have been completed by Ardelyx, each demonstrating statistical significance for the primary endpoint, the combined responder rate for six of 12 weeks, defined as a 30 percent reduction in abdominal pain and an increase of one or more complete spontaneous bowel movements (CSBM) in the same week, compared to baseline, for at least six of the 12 weeks of the treatment period. Tenapanor was well-tolerated in both trials. In the second half of 2018, Ardelyx plans to submit a New Drug Application requesting marketing authorization from the U.S. Food and Drug Administration (FDA) for tenapanor to treat IBS-C. Tenapanor has a unique mechanism of action that acts by inhibiting, or blocking, the NHE3 transporter in the gastrointestinal (GI) tract to reduce the absorption of dietary sodium, leading to increased sodium within the gut. This sodium increases fluid in the gut, loosening stool, thereby alleviating constipation. Preclinical studies demonstrate that tenapanor may reduce abdominal pain caused by IBS-C through the inhibition of TRPV-1 dependent signaling. Tenapanor has shown a desired benefit in the abdominal pain endpoint for IBS-C trials in its clinical studies to-date. Tenapanor is also in Phase 3 development for the treatment of hyperphosphatemia in patients with end-stage renal disease who are on dialysis.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way people with cardiorenal diseases are treated by developing differentiated, minimally systemic medicines. Ardelyx's cardiorenal 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 hyperkalemia. In addition to its cardiorenal pipeline, Ardelyx has completed Phase 3 development of tenapanor for the treatment of people with irritable bowel syndrome with constipation and anticipates submitting a New Drug Application to the U.S. Food and Drug Administration for this indication in the second half of 2018. To efficiently bring its treatments to market, Ardelyx is pursing strategic collaborations in the U.S. and beyond, with established agreements with Fosun Pharma in China and Kyowa Hakko Kirin in Japan. 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; Ardelyx's expected timing for the filing of its NDA for tenapanor for the treatment of IBS-C, and Ardelyx's ability to establish collaborations in the future. 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 research and 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 November 7, 2017, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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