October 19, 2016

Ardelyx Announces the Presentation of Positive Global Endpoint Findings from Phase 2b Trial of Tenapanor in Patients with IBS-C at ACG Annual Meeting

Data Support Tenapanor Clinical Potential in Treating Patients with IBS-C

FREMONT, Calif., Oct. 19, 2016 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced the presentation of positive global endpoint data from its Phase 2b trial, completed in September 2014, which evaluated tenapanor for the treatment of patients with irritable bowel syndrome with constipation (IBS-C). These pre-specified analyses build off of positive efficacy findings on the study's primary and key secondary endpoints in the same patient population, as previously announced in October 2014 and presented at Digestive Disease Week in 2015. They also further validate the 50 milligram (mg), twice-daily dose of tenapanor chosen for the two ongoing Phase 3 studies, T3MPO-1 and T3MPO-2, in patients with IBS-C, which are expected to have data readouts in mid- and late-2017, respectively. The company is also evaluating tenapanor in a Phase 3 study for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients on dialysis, with data expected to be reported in the first quarter of 2017.

William D. Chey, M.D., the Timothy T. Nostrant professor of gastroenterology at the University of Michigan Health System, will present these secondary endpoint findings in an oral session today during the American College of Gastroenterology (ACG) Annual Scientific Meeting and Post Graduate Course.

"In this methodologically rigorous Phase 2b trial, 50 mg of tenapanor twice a day provided robust benefits for the key symptoms of IBS-C, including abdominal pain and stool frequency, compared to placebo," said Dr. Chey. "The results of this trial laid the groundwork for the ongoing Phase 3 clinical trials of tenapanor in patients with IBS-C. I eagerly await results of these trials and hope that tenapanor's unique mechanism of action will expand the list of options available to treat patients with IBS-C."

The IBS symptom global endpoints in the Phase 2b study included: adequate IBS symptom relief; improvements in IBS severity, constipation severity and treatment satisfaction. Compared to placebo, treatment with 50 mg of tenapanor twice a day resulted in statistically significant improvements in all global endpoints measured. Notably, 63.1 percent of patients treated with 50 mg of tenapanor twice a day reported adequate relief of IBS symptoms compared to 39.3 percent for patients on placebo ($p = 0.002$).

Additional clinically meaningful and statistically significant improvements with tenapanor 50 mg twice-daily dosing compared with placebo included reduction in IBS severity ($p = 0.024$); reduction in constipation severity ($p < 0.001$); increased mean satisfaction score ($p < 0.001$); and, improvement in the degree of IBS symptom relief ($p < 0.001$).

"IBS-C significantly impacts the quality of life of millions of people, but there are few, effective treatment options today," said Mike Raab, president and chief executive officer, Ardelyx. "These data further demonstrate the potential for tenapanor to effectively improve critical clinical symptoms in patients with IBS-C, and represent an important perspective for clinicians in evaluating patients' satisfaction and tolerability when treating with tenapanor. We look forward to sharing results from the Phase 3 trials throughout 2017 and believe that tenapanor's unique mechanism of action will provide a differentiated option for those affected by IBS-C."

Presentation Details

Title: The Effect of Tenapanor on Global Endpoints in Patients with Constipation Predominant Irritable Bowel Syndrome: Results from a 12-Week, Double-Blind, Placebo-Controlled, Randomized Phase 2b Trial
Date: Wednesday, October 19, 2016
Time: 8:30 a.m. - 8:40 a.m. PDT
Location: The Venetian Hotel, Las Vegas, NV

Room: Venetian Ballroom E

About Ardelyx, Inc.

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic, small molecule therapeutics that work exclusively in the gastrointestinal (GI) tract to treat GI and cardio-renal diseases. Ardelyx has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing this platform, Ardelyx has discovered and designed tenapanor, which it is evaluating for the treatment of irritable bowel syndrome with constipation (IBS-C) and for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) on dialysis. In addition to tenapanor, Ardelyx is developing RDX227675, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, a problem prevalent in patients with kidney and heart disease. Ardelyx is also advancing several research programs focused in GI and cardio-renal diseases. Ardelyx is located in Fremont, Calif. For more information, please visit Ardelyx's website at www.ardelyx.com.

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 of tenapanor in the treatment of IBS-C and the expected timing for the receipt of the results from Ardelyx's two on-going Phase 3 clinical trials evaluating tenapanor for the treatment of IBS-C and the expected timing for the receipt of the results from Ardelyx's on-going Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor 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. 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 8, 2016, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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