Ardelyx Announces Updated Development Path for its Cardiorenal Pipeline

November 21, 2017

Company to Host Conference Call at 8:30 a.m. ET Today

FREMONT, Calif., Nov. 21, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) today provided an update on the development of its cardiorenal pipeline. The company's second registration study for tenapanor for the treatment of hyperphosphatemia will begin enrolling shortly, after having received feedback from the United States Food and Drug Administration (FDA) on the trial design. In addition, Ardelyx reported clinically meaningful potassium lowering activity from its onset-of-action study for RDX7675 for the treatment of hyperkalemia; however, the company also observed an unexpected side effect of decreased serum bicarbonate. The company believes this will limit the commercial potential of RDX7675 and, as a result, has decided to discontinue development of RDX7675. This change will result in a cash savings of approximately $40 million to Ardelyx over the next two years, extending the company's operating runway into 2019.

Hyperphosphatemia Program Update

As previously described, following learnings from Ardelyx's first successfully completed Phase 3 study of tenapanor for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients on dialysis, the company sought feedback from the FDA on the design of its second Phase 3 registration study. Based on the feedback recently received, the company will add an active control arm to the study for safety assessment only, consistent with the design of registration studies for phosphate binders. Ardelyx is updating the study protocol and preparing to begin enrollment.

"If approved, tenapanor would be the first non-phosphate binder treatment available for hyperphosphatemia in ESRD patients who are on dialysis, who currently rely on highly burdensome and difficult-to-take binders for treatment," said David P. Rosenbaum, Ph.D., chief development officer of Ardelyx. "In the first Phase 3 study, tenapanor, with just a few small pills, achieved the primary endpoint of meaningfully reducing serum phosphorus and was well-tolerated. The second Phase 3 trial is a crucial step toward advancing tenapanor to the market, and we look forward to beginning enrollment. In our view, tenapanor has the potential to dramatically improve phosphorus management and change the way patients are treated."

Hyperkalemia Program Update

Ardelyx today reported an update from the company's onset-of-action study for RDX7675 in patients with hyperkalemia. The trial demonstrated that RDX7675 significantly reduced serum potassium in patients treated across all dose levels. However, an unexpected and drug-related reduction in serum bicarbonate was also observed. Given the needs of this patient population, and the requirement for a treatment that can be used in a chronic setting, Ardelyx has made the decision to discontinue development of RDX7675, including both the onset-of-action and Phase 3 studies. Ardelyx will shift its hyperkalemia efforts to RDX013, its earlier-stage, small-molecule program.

"The goal for RDX7675 was to develop a palatable product that could be taken chronically to address an important medical need for patients with hyperkalemia. We are pleased by the activity observed; however, the unanticipated bicarbonate side effect creates a barrier for RDX7675, which we believe could limit its chronic use," said Mike Raab, president and chief executive officer of Ardelyx. "It is our vision to create novel, safe medicines that meet the needs of patients underserved by today's treatments. We are very optimistic about the future of our first-in-class pipeline. Tenapanor holds tremendous potential in the indications we've studied, and we are working hard to advance tenapanor for hyperphosphatemia and prepare for our New Drug Application submission for IBS-C in the second half of 2018. In addition, we have a number of promising earlier stage assets, and we look forward to assessing the opportunity for RDX013 as a non-binder for hyperkalemia."

Conference Call Information
The company will host a conference call today, November 21, 2017 at 8:30 a.m. ET to discuss the update on its cardiorenal pipeline. To participate in the conference call, please dial (855) 296-9612 (toll-free) or (920) 663-6277 (toll) and reference call ID number 5889997. A webcast of the call can be accessed by visiting the Investor page of the company's website www.ardelyx.com, and will be available on the website for 60 days following the call.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way patients with cardiorenal and gastrointestinal (GI) diseases are treated by using the gut as the gateway to delivering medicines that matter. The company has established unique cardiorenal and GI business portfolios aimed at bringing new, effective medicines with distinct safety and dosing advantages to underserved patients. Ardelyx's portfolio 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. The company's GI portfolio includes tenapanor for the treatment of people with irritable bowel syndrome with constipation (IBS-C), for which the company anticipates submitting a New Drug Application in the second half of 2018, and RDX8940, a TGR5 agonist. 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 the expected timing of the filing the 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 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.

View original content with multimedia:http://www.prnewswire.com/news-releases/ardelyx-announces-updated-development-path-for-its-cardiorenal-pipeline-300559943.html

SOURCE Ardelyx

Monique Allaire, THRUST IR, 781-631-0759, monique@thrustir.com, OR Alicia Davis, THRUST IR, 910-620-3302, alicia@thrustir.com