



July 14, 2015

Ardelyx to Provide Updates on Research and Development Programs at Today's Inaugural R&D Day in New York City

Tenapanor development plans will be presented along with new data demonstrating sustained response in IBS-C

Development plans will be presented for RDX022, Ardelyx's next generation potassium binder for the treatment of hyperkalemia

IND filing targeted in 2H16 for RDX009, a TGR5 agonist that stimulates local secretion of GLP-1 and GLP-2 in the gut

Webcast Today at 8:00 am EDT

FREMONT, Calif., July 14, 2015 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced that the Company will provide a detailed overview of its development programs at its inaugural R&D Day, which is being held today from 8:00a.m. to 11:30a.m. EDT in New York City.



"We have transformed Ardelyx into a company that has a balanced pipeline with multiple, wholly-owned programs spanning all stages of development across our primary areas of therapeutic focus, gastrointestinal and cardio-renal diseases. Following our reacquisition of the global rights for tenapanor from AstraZeneca and our recent financing that raised \$78M, we are advancing this pipeline and expect to have, by the end of 2015, an ongoing Phase 3 program in IBS-C, a Phase 2b program for patients on dialysis with hyperphosphatemia and will have made significant progress on our development program for RDX022, our non-absorbed potassium binder," said Mike Raab, President and Chief Executive Officer.

"By year-end 2016, we anticipate having three ongoing Phase 3 clinical programs for what we believe will be best-in-class treatments for IBS-C, hyperphosphatemia, and hyperkalemia," Mike Raab continued. "This is an exciting time for the Company as we advance multiple clinical programs, and look towards the next phase of our evolution and the potential commercialization of our own products."

At its inaugural R&D Day, Mr. Raab will review Ardelyx's overall strategy and the Company's RDX022 potassium-binding polymer for the treatment of hyperkalemia. David Rosenbaum, Ph.D., Senior Vice President Drug Development, will review tenapanor clinical data and development plans. Jeremy Caldwell, Ph.D., Executive Vice President and Chief Scientific Officer, will review several research programs, including RDX009, a TGR5 agonist that stimulates local secretion of GLP-1 and GLP-2 in the gut, the preclinical evidence demonstrating gut repair and healing with RDX009 and ongoing plans to evaluate RDX009 in several potential indications including its utility in the treatment of chemotherapy-induced diarrhea. Dr. Caldwell will also provide a comprehensive overview of the Company's proprietary drug discovery and design platform.

Ardelyx's executive management team will be joined by Geoffrey A. Block, M.D., Associate Clinical Professor in Medicine at the University of Colorado Health Sciences Center. Dr. Block will provide his perspectives on new and emerging therapies for the treatment of hyperphosphatemia and hyperkalemia.

Overview of Ardelyx's Research and Development Programs

Tenapanor for Constipation-Predominant Irritable Bowel Syndrome (IBS-C)

- Following the reacquisition of global rights for tenapanor from AstraZeneca (NYSE:AZN, LON:AZN) in June 2015, the Company intends to initiate a Phase 3 clinical program in patients with IBS-C in the fourth quarter of 2015.
- The Company will present new data from its previously reported Phase 2b IBS-C clinical study demonstrating that the sustained overall responder rate was 14.6 percent greater than the placebo group. A sustained overall responder is a patient who has (i) an increase of ≥ 1 CSBM from baseline and ≥ 3 CSBM and (ii) a decrease of 30% mean abdominal pain from baseline, both during the same week for 9 of 12 weeks and 3 of the last 4 weeks.

Tenapanor for ESRD Hyperphosphatemia in Dialysis Patients

- The Company will present results of an exploratory analysis of its initial Phase 2b trial in patients with hyperphosphatemia demonstrating a significant decrease of FGF-23.
- The Company plans to commence a Phase 2b clinical trial in patients with hyperphosphatemia on dialysis in the fourth quarter 2015 to evaluate dosing regimens and expects results from this trial in the second half of 2016.

RDX022, a Potassium-Binding Polymer to Treat Hyperkalemia

- Ardelyx expects to initiate, in the fourth quarter of 2015, a pharmacodynamic (PD) study for RDX022, which is currently undergoing early-stage human trials. This new study will evaluate safety and PD effects of RDX022 and results are expected in the first half of 2016.
- The Company has met with the FDA and, based on those discussions, intends to pursue an accelerated 505(b)2 development pathway for RDX022. Additionally, the Company expects to initiate a Phase 3 clinical trial to evaluate RDX022 for the treatment of hyperkalemia in the second half of 2016.

RDX009, a Locally-Acting GLP-1 & GLP-2 Secretagogue

- The Company will present new data for RDX009, a TGR5 agonist that stimulates local secretion of GLP-1 and GLP-2 in the gut. The Company targets an IND filing for RDX009 in the second half of 2016.
- While Ardelyx continues to evaluate various potential indications for RDX009, it is currently most encouraged about recent preclinical studies demonstrating its potential in chemotherapy-induced diarrhea.

RDX013, a potassium secretagogue

- The Company will present proof-of-concept data demonstrating potassium secretion in a pre-clinical model.

Additional new programs

- The Company today announced a new program based on its growing understanding of the broad and complex biology, mechanisms and physiology involved in NHE3 modulation, building upon its leadership position in this area.
- In addition, the Company is initiating two new programs in the GI and cardio-renal fields based on the Company's proprietary drug discovery and design platform.

The R&D Day presentation will be available through a live audio webcast accessible through a link in the investor relations section of the Ardelyx website at ir.ardelyx.com. A replay of the webcast will be available for 30 days on the website after the presentation.

About Ardelyx

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 tract to treat gastrointestinal 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, the Company has discovered and designed tenapanor, which it is evaluating for the treatment of IBS-C and hyperphosphatemia in chronic kidney disease patients on dialysis. In addition to tenapanor, Ardelyx is developing RDX022, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, in kidney and heart disease patients, and has discovered small molecule NaP2b inhibitors for the treatment of hyperphosphatemia in CKD patients on dialysis, a program licensed to Sanofi. Ardelyx is also independently advancing several research programs focused in gastrointestinal and cardio-renal diseases. Ardelyx is located in Fremont, California. 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 for tenapanor in treating IBS-C patients, the potential for tenapanor in treating hyperphosphatemia in patients with end stage renal disease on dialysis, Ardelyx's future development plans for tenapanor and the timing thereof, the potential for RDX022 in treating hyperkalemia, Ardelyx's future development plans for RDX022 and the timing thereof, the potential of RDX009 in treating chemotherapy induced diarrhea, and the potential timing for filing an IND for RDX009, and the potential of Ardelyx's drug discovery and design platform. 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 research and the clinical development process, Ardelyx's reliance upon AstraZeneca for the timely delivery of clinical trial material required for the initiation of the Phase 3 clinical program in IBS-C and the Phase 2b clinical trial in hyperphosphatemia, and Ardelyx's reliance upon AstraZeneca to facilitate a complete and timely transition of the tenapanor program from AstraZeneca to Ardelyx. 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 current report filed on Form 8-K with the Securities and Exchange Commission on July 14, 2015, and its future periodic reports to be filed with the Securities and Exchange Commission.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/ardelyx-to-provide-updates-on-research-and-development-programs-at-todays-inaugural-rd-day-in-new-york-city-300112720.html>

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