June 3, 2015

Ardelyx Regains Worldwide Development and Commercialization Rights for Its Late-Stage Development Candidate, Tenapanor, and Related Portfolio of NHE3 Compounds

Ardelyx to Initiate a Phase 3 Clinical Program in IBS-C Patients in the Fourth Quarter of 2015
Conference Call and Webcast Today at 8:30 am ET

FREMONT, Calif., June 3, 2015 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardio-renal, gastrointestinal and metabolic diseases, today announced that it has entered into a termination agreement with AstraZeneca (LSE: AZN, SSE: AZN, NYSE: AZN), such that all the rights to Ardelyx's portfolio of NHE3 inhibitors, including Ardelyx's lead product candidate, tenapanor, are returned to Ardelyx. Ardelyx has agreed to pay AstraZeneca $15 million upfront along with other future contingent payments. Concurrently, Ardelyx will pay an additional $10 million in R&D costs and for the acceleration of the transfer of the program back to Ardelyx. Ardelyx formed a partnership with AstraZeneca in October 2012 to develop and commercialize Ardelyx's internally discovered portfolio of NHE3 inhibitors including tenapanor.

With the acquisition of worldwide rights from AstraZeneca, Ardelyx plans to accelerate the clinical development path for tenapanor in constipation-predominant irritable bowel syndrome (IBS-C) by initiating a Phase 3 clinical program in IBS-C patients in the fourth quarter of this year. Additionally Ardelyx is planning to begin a Phase 2b clinical trial in the fourth quarter of this year to evaluate the optimal dosing regimen for tenapanor for the treatment of hyperphosphatemia in dialysis patients.

"By regaining the worldwide rights to tenapanor, we now have a late-stage clinical asset that has demonstrated significant promise for the treatment of IBS-C and hyperphosphatemia, both of which are conditions where we believe tenapanor could potentially transform the treatment paradigm," said Mike Raab, President and Chief Executive Officer.

"Ardelyx can now accelerate the clinical development of tenapanor to meet the needs of two underserved patient populations. We are grateful for the substantial investment that AstraZeneca has made in the NHE3 program, and we have been fortunate to have them as a partner," Mr. Raab added.

In a separate press release, Ardelyx announced today a new product candidate, RDX022, for which it will be pursuing a 505b (2) regulatory pathway in the United States. Ardelyx is developing RDX022 for the treatment of elevated potassium, or hyperkalemia. Ardelyx expects to initiate clinical trials with RDX022 in mid-2015. Ardelyx also announced today that it has entered into an agreement to sell shares of common stock and warrants to purchase common stock for the aggregate gross proceeds of approximately $77.8 million in a private placement. Proceeds from the private placement will be used to develop both tenapanor and RDX022, two wholly-owned programs that are targeted to begin Phase 3 clinical trials in the fourth quarter 2015 and second half of 2016, respectively.

About the Termination Agreement

Ardelyx and AstraZeneca have executed a termination agreement under which Ardelyx regained all rights for all NHE3 inhibitors previously licensed to AstraZeneca, including tenapanor.

Under the terms of the termination agreement, Ardelyx has agreed to pay AstraZeneca certain amounts for the return of the rights, including $15 million up front, royalties equal to 10% of net sales of tenapanor by Ardelyx or a licensee, and 20% of non-royalty payments that Ardelyx receives from a new partner should it elect to license, or otherwise provide rights to develop and commercialize tenapanor, with all such amounts not to exceed $90 million. Ardelyx has also agreed to pay AstraZeneca $10 million in R&D costs and in consideration of the acceleration of the transfer of information, data and materials to Ardelyx. In addition, AstraZeneca is obligated to complete the manufacture of clinical trial material necessary for the Phase 3 clinical program in IBS-C patients, and Ardelyx has agreed to purchase the Phase 3 clinical trial material and other drug product inventory from AstraZeneca for up to $10 million.

Tenapanor's Clinical Development

Tenapanor is a minimally-absorbed small molecule inhibitor of NHE3, a transporter of sodium in the gastrointestinal tract. Orally administered tenapanor has been shown in clinical trials to reduce the intestinal absorption of both dietary sodium and phosphorus. A total of 14 clinical trials of tenapanor have been completed, and over 1,000 subjects have been administered tenapanor to date.

In October 2014, Ardelyx reported positive Phase 2b data for the use of tenapanor in treating patients with IBS-C. At the twice-daily 50mg dose of tenapanor, the study met its primary efficacy endpoint of an increase in the complete spontaneous bowel movement (CSBM) responder rate ($p < 0.001$). Most secondary endpoints, including abdominal pain, the overall responder rate and other abdominal and IBS-C symptoms, demonstrated statistically significant and clinically meaningful improvements. Ardelyx plans to initiate a Phase 3 clinical program to further evaluate tenapanor in IBS-C patients in the fourth quarter of 2015, assuming the successful transfer of clinical trial material from AstraZeneca. In February 2015, Ardelyx announced results from a Phase 2b clinical study in hyperphosphatemic patients on dialysis with end stage renal disease, or CKD-5D. In the study, there was a statistically significant dose-related decrease in serum phosphate levels for tenapanor-treated patients compared to patients receiving placebo ($p=0.012$). It was noted, however, that the rate of diarrhea and the rate of discontinuations due to diarrhea were higher than expected based on previous clinical trials. Higher discontinuations rates due to diarrhea were observed primarily in the 30mg once daily and 30mg twice daily dose groups. Ardelyx plans to begin a second Phase 2b dose-ranging clinical program for tenapanor in hyperphosphatemia in dialysis patients during the fourth quarter of 2015 assuming successful transfer of clinical trial material from AstraZeneca.

Additional details on tenapanor and Ardelyx's research and development programs will be presented at Ardelyx's upcoming R&D Investor Day, planned for July 14, 2015, in New York, NY.

Conference Call & Webcast Information

Ardelyx will host a live conference call and webcast today at 8:30am Eastern Time. The live webcast and a replay may be accessed by visiting Ardelyx's website on the investor page of the Company's website at http://ir.ardelyx.com/

Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 1-855-296-9612 (US) or 920-663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 59352386. Please dial in approximately 10 minutes prior to the call. An archived webcast replay will be available on the Company's website for two weeks.

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 cardio-renal, gastrointestinal and metabolic 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. 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-5D, a program licensed to Sanofi. Ardelyx is also independently advancing several research programs focused in cardio-renal, gastrointestinal and metabolic 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, 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 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 quarterly report filed on Form 10-Q with the Securities and Exchange Commission on May 12, 2015, and its future periodic reports to be filed with the Securities and Exchange Commission.

Logo - http://photos.prnewswire.com/prnh/20140619/119451

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/ardelyx-regains-worldwide-development-and-commercialization-rights-for-its-late-stage-development-candidate-tenapanor-and-related-portfolio-of-nhe3-compounds-300093300.html

SOURCE Ardelyx