Ardelyx and Knight Collaborate to Bring Tenapanor to Patients in Canada

March 19, 2018

License Agreement Advances First-in-Class Tenapanor for IBS-C and Hyperphosphatemia in Canada
Ardelyx to Receive Up to CAD 25 Million in Upfront Payment and Subsequent Milestones

FREMONT, Calif., March 19, 2018 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) today announced a license agreement with Knight Therapeutics, Inc. (TSX: GUD) (Knight) that provides Knight with exclusive rights to commercialize tenapanor in Canada. Tenapanor is Ardelyx's oral, first-in-class small molecule treatment that has completed Phase 3 development for irritable bowel syndrome with constipation (IBS-C) and is being evaluated in a second Phase 3 study for hyperphosphatemia.

Under the terms of the agreement, Ardelyx is eligible to receive up to CAD 25 million in total payments including an upfront payment and development and sales milestones, as well as double-digit tiered royalties on net sales. Knight will have the exclusive rights to market and sell tenapanor in Canada.

"We are excited to bring Canadian patients a product like tenapanor with its differentiated mechanism and established efficacy and safety profiles in both IBS-C and hyperphosphatemia," said Jonathan Ross Goodman, chief executive officer of Knight. "The addition of tenapanor to our pipeline will further enhance Knight's leadership in GI disorders. Because of its novel mechanism, we believe tenapanor will have advantages in treating IBS-C through an entirely new approach than those of today's approved medicines. In addition, we see great potential for tenapanor as the first and only new option outside of phosphate binders to treat hyperphosphatemia, with an opportunity to make an important difference for patients who would benefit from a new safe, effective and easy to take alternative. We look forward to working with the Ardelyx team and Health Canada to bring tenapanor to Canadian patients."

"Knight has a proven approach of successfully collaborating with biotechnology companies to bring forward important medicines, which makes them an invaluable component to our strategy of working with industry leaders to bring tenapanor to patients with IBS-C and hyperphosphatemia," said Mike Raab, president and chief executive officer of Ardelyx. "This agreement marks the third collaboration we have now put in place to support the development and marketing of tenapanor in key geographies outside of the U.S. With a highly differentiated product profile, we believe that tenapanor will make a meaningful impact on Canadian patients and are pleased to be collaborating with the experienced and proven Knight team to make this a reality."

About Tenapanor

Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, minimally absorbed, oral, experimental medication in late-stage clinical development. It has a unique mechanism of action that, in IBS-C, acts by inhibiting, or blocking, the NHE3 transporter in the gastrointestinal (GI) tract to reduce the absorption of dietary sodium, which leads to an increased amount of sodium within the gut. This increased sodium increases water in the gut, which loosens stool, helping to alleviate constipation. Preclinical studies have shown that tenapanor may work to reduce abdominal pain caused by IBS-C through the inhibition of TRPV-1 dependent signaling. Ardelyx has successfully completed its T3MPO program designed to support the registration of tenapanor for the treatment of IBS-C. Collectively, the T3MPO-1 and T3MPO-2 Phase 3 trials demonstrated that tenapanor had a durable effect on reducing constipation and abdominal pain caused by IBS-C, in many patients treated. The favorable safety profile of tenapanor is supported by the completed T3MPO-3 long-term, safety extension study. With the completion of this program, Ardelyx is preparing a New Drug Application for tenapanor for IBS-C, which the company intends to submit to the U.S. Food and Drug Administration in the second half of 2018.

Tenapanor is also in Phase 3 development for the treatment of hyperphosphatemia in patients with end-stage renal disease who are on dialysis. In hyperphosphatemia, tenapanor blocks the NHE3 sodium transporter in the GI tract, reducing the absorption of dietary sodium and resulting in increased protons within the cells. The increase in protons causes a reduction in phosphate uptake by tightening junctions or pores that regulate phosphate absorption in the GI tract. Overall, this mechanism appears to be preferential to phosphate absorption given that Ardelyx has not observed any meaningful changes in other ions, other than sodium, in preclinical or clinical studies. Ardelyx completed its first Phase 3 clinical trial for tenapanor in hyperphosphatemia, which demonstrated a statistically significant primary endpoint, the difference in change in serum phosphorus between the pooled tenapanor-treated patients and placebo-treated patients from the end of the eight-week treatment period to the end of the four-week randomized withdrawal period, in the responder population. Tenapanor was well-tolerated in the trial. Ardelyx has begun treating patients in a second Phase 3 clinical trial, the Phreedom Trial, with data anticipated in 2019.

About Ardelyx, Inc.

Ardelyx is focused on enhancing the way people with renal diseases are treated by developing first-in-class medicines. Ardelyx's renal 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 high potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease. In addition, Ardelyx has completed Phase 3 development of tenapanor for the treatment of 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 Kyowa Hakko Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada. For more information, please visit http://www.ardelyx.com/ and connect with us on Twitter @Ardelyx.

About Knight Therapeutics Inc.

Knight Therapeutics Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian and select international markets. Knight Therapeutics Inc.'s shares trade on TSX under the symbol GUD. For more information about Knight Therapeutics Inc., please visit the company's web site at www.gudknight.com or www.sedar.com.

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; the potential for Ardelyx to receive upfront, milestone and royalty payments from Knight Therapeutics, Inc.; Ardelyx's expected timing for the filings of its NDA for tenapanor for the treatment of IBS-C, Ardelyx's expected timing of its receipt of data from its second Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2018, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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