Ardelyx Announces License Agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited for Tenapanor in China

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Ardelyx to Receive Up to $125 Million in Upfront Payment and Subsequent Milestones

FREMONT, Calif., Dec. 11, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) today announced that the company has entered into a license agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited (Fosun Pharma) providing Fosun Pharma with the exclusive rights to develop and commercialize Ardelyx's lead product, tenapanor, in China for the treatment of patients with irritable bowel syndrome with constipation (IBS-C) and for the treatment of hyperphosphatemia related to chronic kidney disease. The agreement also provides Fosun Pharma the rights to commercialize tenapanor for other indications for which it is approved in the United States. Tenapanor is an investigational oral, minimally systemic NHE3 inhibitor discovered and developed by Ardelyx.

Under the terms of the agreement, Ardelyx will receive an upfront payment of $12 million and is eligible to receive additional milestones of up to $113 million, as well as tiered royalty payments on net sales ranging from the mid-teens to 20 percent. Fosun Pharma will have the exclusive rights to market and sell tenapanor in China.

"As one of the leading healthcare companies in China, Fosun Pharma is an ideal partner to commercialize tenapanor in the Chinese market. Their strong focus on and track record of successfully marketing cardiorenal medicines in China, as well as their experience in GI, were critical decision-making factors in this collaboration," said Mike Raab, president and chief executive officer of Ardelyx. "Now, with our recent collaboration with Kyowa Hakko Kirin for tenapanor in hyperphosphatemia in Japan, together with this second regional collaboration with Fosun Pharma for both indications in China, we are successfully executing our strategy to bring tenapanor to patients and physicians as efficiently as possible, while also enhancing our cash runway. We look forward to working with the Fosun Pharma team to bring tenapanor to the many patients in China who suffer from IBS-C and hyperphosphatemia."

"We are pleased to partner with Ardelyx to bring a potential first-in-class treatment option to patients suffering from IBS-C and cardiorenal diseases, including hyperphosphatemia," said Yifang Wu, president and chief executive officer of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., the parent company of Shanghai Fosun Industrial Development Company Limited. "Tenapanor's potential as a differentiated treatment for both cardiorenal and GI diseases is impressive. The data generated by Ardelyx to-date gives us confidence that tenapanor could be a leading treatment option for both therapeutic areas, offering unique advantages to patients. We look forward to Ardelyx's regulatory approval of tenapanor in the U.S., so we can ultimately bring this treatment to patients in China."

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 also seen a desired benefit in the abdominal pain component of IBS-C in its clinical studies to-date. Two Phase 3 clinical trials for tenapanor in IBS-C have been completed by Ardelyx, each demonstrating statistical significance for the primary endpoint, the combined responder rate for six of 12 weeks, defined as a 30 percent reduction in abdominal pain and an increase of one or more complete spontaneous bowel movements (CSBM) in the same week, compared to baseline, for at least six of the 12 weeks of the treatment period. Tenapanor was well-tolerated in both trials. In the second half of 2018, Ardelyx plans to submit a New Drug Application requesting marketing authorization from the U.S. Food and Drug Administration (FDA) for tenapanor to treat IBS-C.

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 designed a second Phase 3 clinical trial with input from FDA and is currently updating the protocol and preparing to begin enrollment.

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; the potential for Ardelyx to receive upfront, milestone and royalty payments from Shanghai Fosun Pharmaceutical Industrial Development; Ardelyx's expected timing for the filings of its NDA for tenapanor for the treatment of IBS-C, 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 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.

SOURCE Ardelyx

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