Long-term Safety and Efficacy of Tenapanor for the Control of Serum Phosphorus in Patients with CKD on Dialysis --Comprehensive datasets demonstrate tenapanor’s ability to control serum phosphorus in patients with chronic kidney disease (CKD) on dialysis --

Three poster presentations highlight data from several Phase 3 trials in the U.S., including the BLOCK, AMPLE-1 and PYRENE studies. Additionally, the company’s partnership for tenapanor in Japan, Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4188), will present results from two Phase 2 studies evaluating the efficacy and safety of tenapanor in Japanese patients on hemodialysis.

Abstract: The American Society of Nephrology's (ASN) Annual Meeting, to be held October 22-25, 2020, in Fremont, Calif., will unite to champion the interests of patients worldwide with kidney disease. Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on developing innovative, first-in-class, orally-administered treatments for patients with impaired kidney function and other diseases associated with kidney disease, today announced the following presentations of data supporting the efficacy and safety of tenapanor, a first-in-class, oral, non-ionic phosphate absorption inhibitor, for the control of serum phosphorus and hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis.

Ardelyx Announces Data Supporting Efficacy and Safety of Tenapanor, a First-in-Class Phosphate Absorption Inhibitor, to be Presented at ASN’s Kidney Week 2020

October 12, 2020

--Comprehensive datasets demonstrate tenapanor’s ability to control serum phosphorus in patients with chronic kidney disease (CKD) on dialysis--

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Ardelyx’s product candidates or business in general, please refer to Ardelyx's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission or Ardelyx's website at http://www.ardelyx.com. Ardelyx’s filings are free of charge at the SEC's website at http://www.sec.gov.

About Tenapanor

Tenapanor, which was discovered and developed by Ardelyx, is an investigational, first-in-class, non-ionic phosphate absorption inhibitor. For the control of serum phosphorus in patients with CKD on dialysis, tenapanor has been studied in three Phase 3 clinical trials in the U.S., all of which have met their primary endpoint, and support the role of tenapanor as foundational treatment in the management of hyperphosphatemia in patients on chronic kidney dialysis.

About Hyperphosphatemia

Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphorus in the blood that is an independent risk factor for cardiovascular morbidity and mortality. Hyperphosphatemia is a nearly universal condition among people with CKD on dialysis. Despite treatment with standard-of-care therapies, phosphorus levels greater than 5.5 mg/dL have been shown to be an independent risk factor for cardiovascular morbidity and mortality. All patients on dialysis have elevated phosphorus levels, but when kidney function is significantly impaired, phosphorus is not adequately eliminated from the body. As a result, hyperphosphatemia is a nearly universal condition among people with CKD on dialysis. Despite treatment with standard-of-care therapies, phosphorus levels greater than 5.5 mg/dL have been shown to be an independent risk factor for cardiovascular morbidity and mortality.

About Tenapanor

Tenapanor, which was discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor, for which an NDA is currently under review by the FDA (PDUFA date: October 22, 2020), for the control of serum phosphorus in adult patients with CKD on dialysis. Tenapanor has a unique mechanism of action that acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3). This results in a conformational change of the epithelial cell junctions, thereby significantly reducing paracellular phosphate absorption, the primary pathway of phosphate absorption. Tenapanor has been studied in three Phase 3 clinical trials in the U.S., all of which have met their primary endpoint, and support the role of tenapanor as foundational treatment in the management of hyperphosphatemia in patients on chronic kidney dialysis.

For more information, please visit the Ardelyx website at https://www.ardelyx.com. For investor information, please visit the Ardelyx website at https://ir.ardelyx.com. Ardelyx’s filings are free of charge at the SEC's website at http://www.sec.gov.

About the American Society of Nephrology

The American Society of Nephrology (ASN), founded in 1966, is the largest professional society dedicated to the global advancement of nephrology. The Society, with more than 13,000 members worldwide, and its subsidiary the Kidney Disease Outcomes Quality Initiative (KDOQI), is dedicated to the highest standards of scientific practice and excellence in the field of nephrology.

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