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Ardelyx Receives $25 Million Milestone From AstraZeneca For Commencement Of Phase 2b Clinical Trial Of Tenapanor

Study will evaluate tenapanor for the treatment of hyperphosphatemia in ESRD patients on hemodialysis

FREMONT, Calif., May 15, 2014/PRNewswire/--Ardelyx, Inc., a clinical-stage biopharmaceutical company focused on cardio-renal, GI and metabolic diseases, today announced that it has received a $25 million milestone payment from AstraZeneca (NYSE:AZN, LON:AZN) for the initiation of a Phase 2b clinical trial evaluating tenapanor for the treatment of hyperphosphatemia, or elevated serum phosphorus, in patients with end-stage renal disease on hemodialysis (ESRD-HD). With this payment, Ardelyx has received a total of $75 million in upfront and milestone payments from AstraZeneca under a worldwide exclusive license agreement announced in October 2012.

"We are excited to embark with AstraZeneca on our first study specifically designed to evaluate the ability of tenapanor to reduce hyperphosphatemia in ESRD patients, which remains one of the key challenges in the management of patients on dialysis," commented Mike Raab, President and Chief Executive Officer of Ardelyx. "We believe that tenapanor, as a small molecule inhibitor of phosphate absorption with a significantly reduced pill burden, could be a paradigm shift for the treatment of hyperphosphatemia in patients with ESRD if tenapanor is successfully developed and commercialized."

The Phase 2b clinical trial in ESRD-HD patients with elevated serum phosphorus is a randomized, double-blind, placebo-controlled, multicenter, dose-finding study being conducted in the United States, United Kingdom, Poland, and Slovakia with an estimated enrollment of 150 subjects to evaluate the efficacy, safety and tolerability of tenapanor for the treatment of hyperphosphatemia. The clinical trial is part of a broad development program established pursuant to Ardelyx's license agreement with AstraZeneca, under which AstraZeneca paid to Ardelyx $35 million upfront, and could pay up to $237.5 million in total potential development milestones, as well as milestones related to launch and commercialization. Ardelyx expects results from this clinical trial in the first half of 2015. More information about the hyperphosphatemia trial can be found at clinicaltrials.gov.

About Tenapanor
Tenapanor, also known as AZD1722 and RDX5791, is a small-molecule, orally administered, non-systemic inhibitor of the NHE3 sodium transporter being studied for the treatment of patients with ESRD-HD and chronic kidney disease (CKD), as well as for constipation predominant irritable bowel syndrome (IBS-C). Ardelyx and AstraZeneca have evaluated tenapanor in eight human clinical trials in over 750 individuals. In Phase 1 and Phase 2 clinical trials, tenapanor was well-tolerated and has shown the ability to divert sodium into the stool in both healthy adult subjects and patients with ESRD-HD. In Phase 1 clinical trials in healthy adults, tenapanor also inhibited the absorption of dietary phosphorus, as demonstrated by increased phosphorus in the stool. In these studies, tenapanor demonstrated this effect with 15mg of tenapanor orally administered twice daily. Sodium and phosphorus are both key factors in the progression of kidney disease. Additionally, tenapanor has demonstrated activity consistent with an IBS-C drug to increase the frequency of bowel movements in IBS-C patients in a Phase 2a clinical trial.

About Hyperphosphatemia
Hyperphosphatemia is a significant medical problem worldwide in ESRD-HD patients. Phosphorus is present in almost every food in the Western diet, but it can accumulate to high levels in ESRD-HD patients, who cannot efficiently remove the mineral through hemodialysis. In ESRD-HD, excess levels of phosphorus have been shown to lead to increased risk of renal osteodystrophy, a condition of abnormal bone growth characterized by brittle bones, as well as increased risk of both cardiovascular disease and death. ESRD-HD patients are often prescribed phosphate binders, the only approved therapies for the treatment of hyperphosphatemia. About 270,000 ESRD-HD patients are currently prescribed phosphate binders in the United States. According to Infiniti Research Limited - TechNavio, the worldwide market for phosphate binders in 2011 was approximately $1.5 billion and is projected to reach $2.3 billion by 2015. Phosphate binders, including salts such as calcium and lanthanum, and polymers such as sevelamer, often result in tolerability issues and large pill burden. The phosphate binder-related pill burden for ESRD-HD patients is significant, consisting on average of around nine pills per day. Large pill burden often leads to non-compliance and lack of full efficacy of phosphate binders. Tenapanor is currently being evaluated at once and twice daily dosing of 45 mg or less per dose.

About Ardelyx
Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, non-systemic, small molecule therapeutics that work exclusively in the gastrointestinal tract to treat cardio-renal, gastrointestinal and metabolic diseases. The Company 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, Ardelyx has discovered and designed tenapanor, a product currently in Phase 2 clinical trials that has consistently demonstrated the ability to reduce the absorption of dietary sodium and phosphorus, both of which are recognized as key factors in the progression of kidney disease. In addition to tenapanor, the Company is evaluating small molecule NaP2b inhibitors for the treatment of hyperphosphatemia in ESRD, a program licensed to Sanofi, and independently is advancing three additional discovery and lead development programs focused in cardio-renal, GI and metabolic diseases. Ardelyx is located in Fremont, California. For more information, please visit Ardelyx's website at www.ardelyx.com.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: **www.astrazeneca.com**.

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