Ardelyx Receives Notice of Allowance of Composition of Matter Patent Covering its Novel Potassium Binder RDX227675

August 1, 2016

FREMONT, Calif., Aug. 1, 2016 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for its composition of matter patent application (U.S. Patent Application No. 15/052,186). Upon issuance, the patent will provide key intellectual property protection for RDX227675, the Company's proprietary oral, non-absorbed, potassium-binding polymer, through 2035, exclusive of any patent term extensions or adjustments that may be available. The Company has additional patent applications pending in the United States and internationally covering the composition and methods of using RDX227675.

"When we originally conceived of the program we set a number of very specific goals for ourselves. Eliminate sodium, optimize binding capacity, improve mouth feel, and develop formulations that would taste pleasant and be easier to ingest. We continue to believe that each of these characteristics is critical for the management of patients who have been prescribed beneficial medications such as ACE inhibitors and angiotensin II receptor blockers. This patent is a recognition that what we've accomplished is novel, and we expect RDX227675 will become be an important tool for physicians to help manage hyperkalemia," commented Mike Raab, President and Chief Executive officer of Ardelyx.

"With the $110M private placement financing we completed last month, we will confidently enter our third Phase 3 program as we advance RDX227675 into a Phase 3 trial in the fourth quarter of this year. With the receipt of this intellectual property protection for RDX227675, we are quite excited about the benefit we believe we will ultimately be able to provide to patients," commented Mike Raab, President and Chief Executive Officer of Ardelyx.

In the fourth quarter 2016, Ardelyx plans to initiate a clinical trial designed to evaluate the onset-of-action of RDX227675 along with safety and efficacy in hyperkalemic patients with chronic kidney disease (CKD), with or without heart failure (HF), one of the target patient populations for RDX227675. This trial will enroll approximately 60 patients and results are expected in the first half of 2017. Additionally, in the fourth quarter of 2016, Ardelyx also plans to initiate a Phase 3 clinical trial evaluating RDX227675 for the treatment of hyperkalemia in the same patient population. The Company is pursuing a 505(b)2 pathway in the United States for RDX227675.

About RDX227675

RDX227675 is Ardelyx's proprietary oral, minimally-absorbed, potassium-binding polymer based on sodium polystyrene sulfonate (SPS), a well-known and well-characterized polymer, also known as Kayexalate®. Ardelyx has made numerous improvements to the polymer by engineering into RDX227675 several key physical and chemical modifications in an effort to improve various properties. In a single center, randomized, crossover study to evaluate various oral formulations of RDX227675 in healthy adult volunteers, RDX227675 consistently outperformed SPS in all aspects of the taste assessments, including mouth feel, texture, and flavor. A human adult pharmacodynamic study has shown that 13.8 g of RDX227675, whether delivered once, twice or three times daily, results in a similar increase of stool potassium of about 1,500 mg/day, with decrease in urinary potassium of about 900 mg/day. The Company believes that hyperkalemia affects about 900,000 individuals with Stage 3b or Stage 4 CKD in the United States as well as approximately 900,000 patients with heart failure and up to 200,000 ESRD patients on dialysis in the United States. In July 2016, Ardelyx received notification that the United States Patent and Trademark Office has issued a Notice of Allowance for Ardelyx's patent application covering the composition of matter of RDX227675, providing intellectual property protection for RDX227675 through 2035.

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 (GI) tract to treat GI and cardio-renal 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, Ardelyx has discovered and designed tenapanor, which it is evaluating for the treatment of irritable bowel syndrome with constipation (IBS-C) and for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) on dialysis. In addition to tenapanor, Ardelyx is developing RDX227675, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, a problem prevalent in patients with kidney and heart disease. Ardelyx is also advancing several research programs focused in GI and cardio-renal 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 of tenapanor in the treatment of IBS-C and hyperphosphatemia in end-stage renal disease on dialysis, the potential of RDX227675 in the treatment of hyperkalemia, Ardelyx's future development plans for RDX227675, including the timing of the initiation of the onset-of-action clinical trial and the Phase 3 clinical trial for RDX227675, and the timing of receipt of results from the onset-of-action clinical trial . Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, RDX227675, 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 research and development process and the uncertainties in the manufacture of clinical trial material. 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 May 9, 2016, and its current and 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-receives-notice-of-allowance-of-composition-of-matter-patent-covering-its-novel-potassium-binder-rdx227675-300306733.html

SOURCE Ardelyx

News Provided by Acquire Media