Ardelyx Presents New Preclinical Data Demonstrating Synergy between Tenapanor and Sevelamer When Dosed in Combination for Elevated Serum Phosphorus

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Company Plans to Commence a Phase 2/3 Clinical Study Evaluating Tenapanor in Combination with Phosphate Binders

PRESIDENT’S CULI, Calif., Oct. 26, 2018 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), today announced the presentation of new preclinical data supporting therapeutic synergy of tenapanor in combination with sevelamer, the currently standard of care phosphate binder treatment for hyperphosphatemia, or elevated serum phosphorus. The data, showing that the combination meaningfully reduced serum phosphorus, were presented today in a poster titled “Combination treatment with tenapanor and sevelamer synergistically reduces serum phosphorus in rats,” at the American Society of Nephrology (ASN) Annual Meeting. Tenapanor, Ardelyx’s lead product candidate, is a sodium/hydrogen exchanger 3 (NHE3) inhibitor that is currently being evaluated as a monotherapy in a second Phase 3 registration trial, the PRINCIPLE trial, for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis. Data from that study are anticipated in 2019.

The preclinical data presented today support Ardelyx’s in-vehicle synergism in combination with phosphate binders to address the unmet need in the treatment of hyperphosphatemia among dialysis patients. The data provide a rationale to support the progression of tenapanor, in combination with binders, to a Phase 2/3 clinical study aiming to evaluate the combination for the treatment of hyperphosphatemia in dialysis patients.

“If we are able to replicate what we’ve seen in these preclinical studies in our clinical trials, the potential for the use of tenapanor in combination with phosphate binders as an additional therapeutic option for the management of hyperphosphatemia is quite meaningful. This synergistic effect could bring a meaningful reduction in serum phosphorus and ultimately improve patient outcomes,” said David P. Rosenbaum, chief development officer of Ardelyx. “Most dialysis patients have phosphate levels that are significantly higher than normal, but to date, the only options for treatment have been to add more phosphate binders, which all have similar mechanisms of action. If we are successful in replicating this synergistic effect in the clinic, we believe our combination therapy could extend the clinical benefit of binders to a large patient population.”

The Phase 2/3 clinical study will evaluate tenapanor, administered as an oral once daily pill, in combination with the currently standard of care phosphate binder treatment for hyperphosphatemia. This study will aim to demonstrate that combination treatment with tenapanor and sevelamer is noninferior to the current standard of care in reducing serum phosphorus, and thereby improve patient outcomes.

“Combination treatment with binders is the mainstay of therapy for hyperphosphatemia, yet this treatment is associated with pill burden and patient non-compliance. By improving the treatment of hyperphosphatemia, the addition of tenapanor to currently used binders could offer additional benefits,” said Monique Allaire, THRUST Strategic Communications. “Ardelyx is committed to finding better ways to treat kidney disease and these results provide a strong scientific basis for the upcoming Phase 2/3 trial.”

Combination treatment of hyperphosphatemia is associated with a pill burden of phosphate binders. We are excited to see if this effect is supported by our planned human study.”

Ardelyx’s product candidates or the development of Ardelyx’s business in general, please refer to Ardelyx’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2018, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

SOURCE Ardelyx


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