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# PATENCY-2 Top-Line Results

March 28, 2019

# Cautionary Note Regarding Forward-Looking Statements

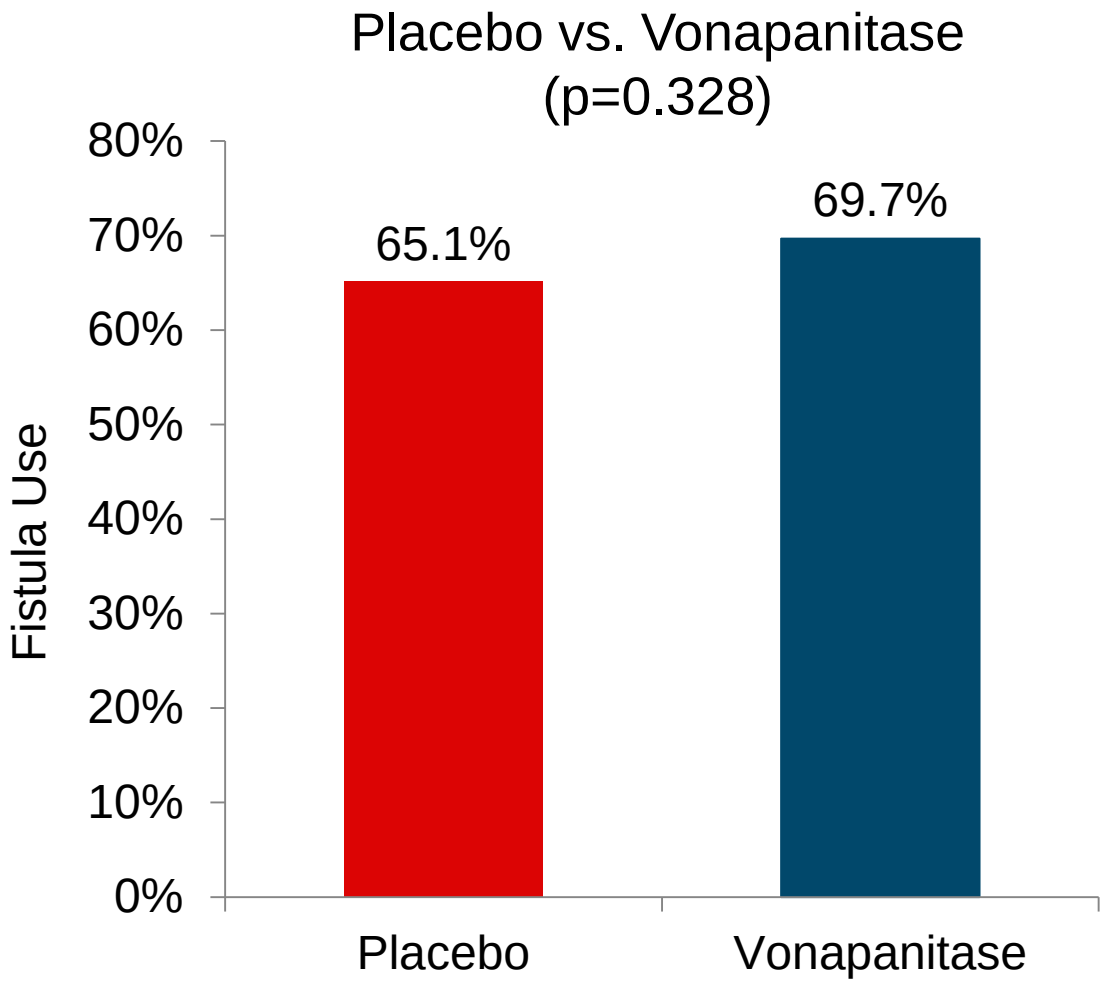
This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” "expects," “plans,” "intends," “may,” “could,” “might,” “will,” “should,” “approximately,” “potential,” or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including our interpretation of data from PATENCY-2 and other clinical and pre-clinical studies, the clinical and regulatory path forward for vonapanitase and whether additional studies will be necessary to support a Biologics License Application (BLA), whether and when we may submit a BLA or commercially launch in the United States, our ability to establish a commercially-ready supply chain, our intellectual property position, the significance or clinical utility of any approved product, the market opportunity, standard of care and reimbursement for improving fistula outcomes, and those relating to future events or our future financial performance or condition, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product candidates, involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors, including whether our cash resources will be sufficient to fund the our operating expenses and capital expenditure requirements for the period anticipated; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether vonapanitase will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether we can successfully commercialize and market our product candidates, are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (“SEC”) on March 13, 2019, and our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as filed with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this presentation represent our estimates and assumptions only as of the date of this presentation and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this presentation.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our drug candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

# Phase 3 PATENCY-2 Trial Design

| | |
|---|---|
| **Design** | Multicenter, randomized, double-blind, placebo-controlled |
| **N** | 603 treated patients in U.S. and Canada |
| **Patients** | Patients with CKD on or expecting to initiate hemodialysis and undergoing surgical creation of a radiocephalic fistula |
| **Dose** | Vonapanitase 30 mcg vs. placebo (2:1 randomization) |
| **Co-Primary Endpoints** | Fistula use for hemodialysis<br>Secondary patency (time from fistula surgical creation until fistula abandonment) |
| **Other Efficacy Endpoints** | Primary patency<br>Procedure rate<br>Fistula maturation |

# Co-Primary Endpoint: Fistula Use for Hemodialysis




- Defined as use of the fistula for two-needle hemodialysis for at least 90 days or, if hemodialysis was not initiated at least 90 days prior to the last study visit, for at least 30 days and including the patient's last study visit
- Results
  - No statistically significant difference between the arms (p=0.328)



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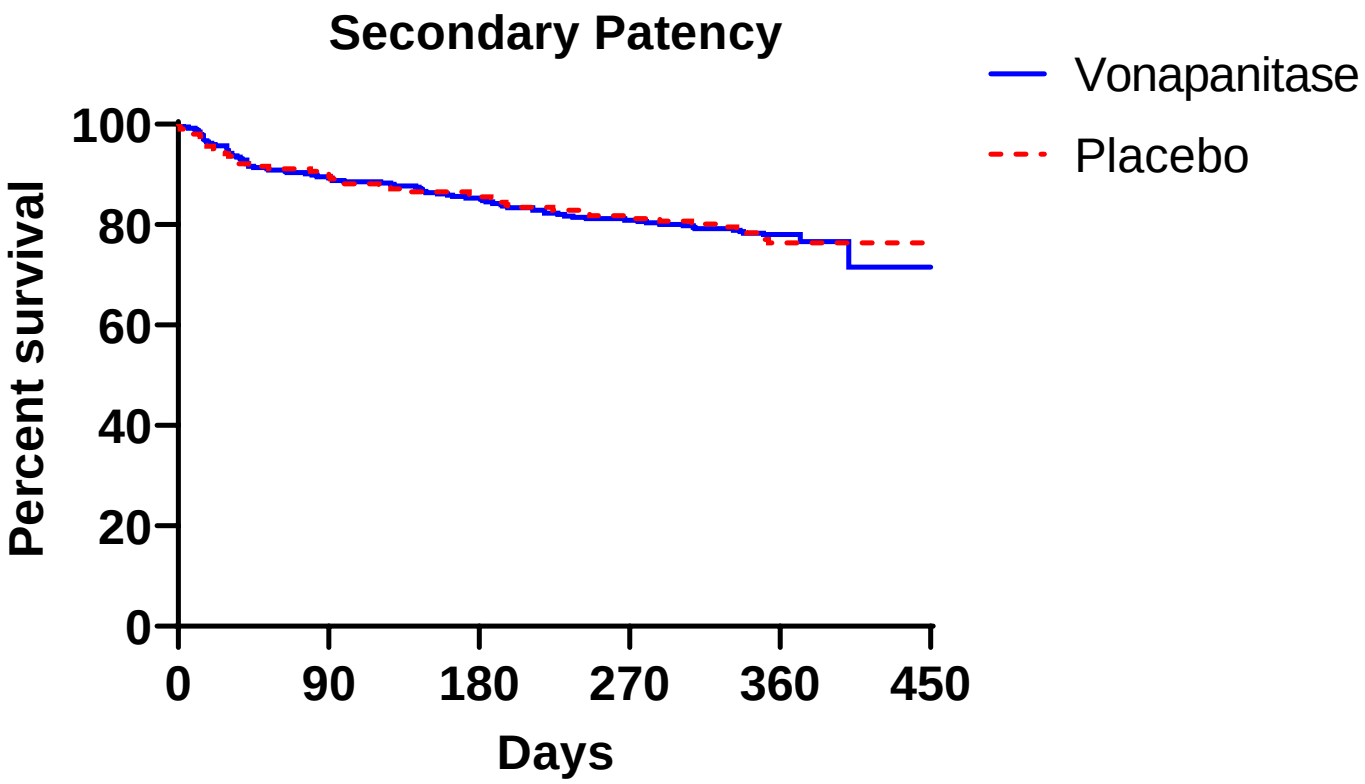
# Co-Primary Endpoint: Secondary Patency




Defined as time from fistula creation to abandonment

Results

- No statistically significant difference between the arms (p=0.932)



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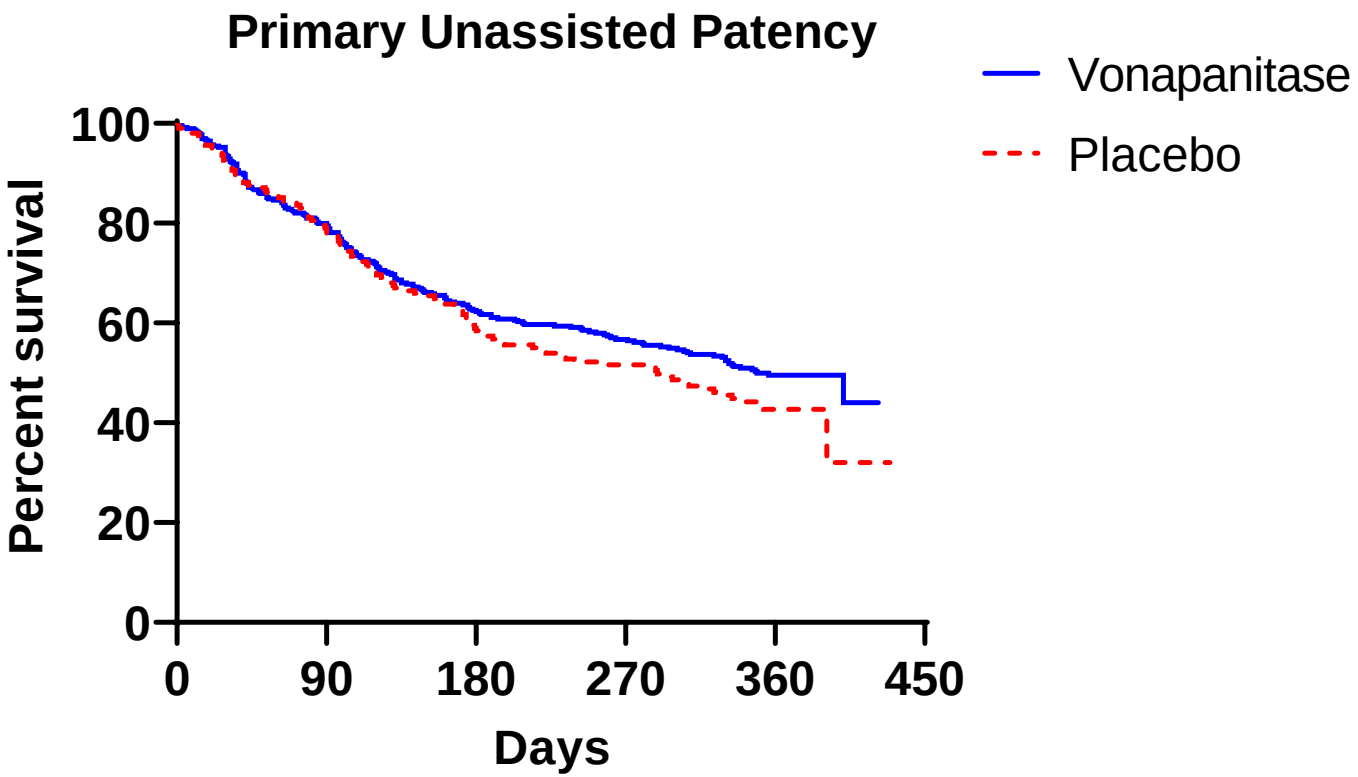
# Other Endpoint: Primary Unassisted Patency




Defined as time from fistula creation to first occurrence of a fistula thrombosis or corrective procedure to restore or maintain patency

Results

- No statistically significant difference between the arms (p=0.178)



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# PATENCY-2 Safety Profile

- No evidence of immunogenicity
- Adverse events consistent with medical conditions experienced by kidney disease patients undergoing fistula surgery
- Adverse events comparable for vonapanitase and placebo

| Adverse Events | Vonapanitase (n=399) | Placebo (n=204) |
|---|---|---|
| Vascular stenosis | 35.1% | 41.7% |
| Fistula thrombosis | 16.8% | 18.6% |
| Local swelling | 5.0% | 2.0% |
| Hematoma | 5.0% | 3.9% |

Includes any adverse event that occurred in at least 5% of patients in either treatment group.

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