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Ardelyx Inc. (ARDX - OUTPERFORM): ARDX Releases Additional Data from Phase IIb ESRD Trial, Reiterate OUTPERFORM

Price: $15.78 **12-Month Price Target: $31**

- **ARDX released additional efficacy and tolerability data from its Phase IIb trial of tenapanor in end-stage renal disease (ESRD) patients with hyperphosphatemia.**
- **Importantly, there was a dose-dependent reduction of phosphate, with the 10 mg and 30 mg BID patients experiencing a 1.7 and 1.98 mg/dL reduction, respectively, vs. a 0.54 mg/dL mean reduction for the placebo group (see Figure 1).** The LS mean reduction for the 3 mg BID and 30 mg QD groups were -1.18 and -1.11 mg/dL, respectively, whereas the 1 mg BID and 3 mg QD groups were similar to placebo.
- **While diarrhea rates were higher than anticipated, we note that it led to only one more patient discontinuing in the 10 mg BID compared to placebo (3 vs 2), indicating that the AEs observed may be effectively managed; indeed at this dose, there were no other discontinuations for reasons other than diarrhea.** No AEs of vomiting were reported and only one AE of nausea (4%), similar to placebo.
- **Tenapanor's tolerability and efficacy profile in ESRD patients at 10 mg BID compares favorably to currently-approved phosphate binders (see Figure 3).** Indeed, the reported trial discontinuation rates for Renvela and Auryxia were 27% and 21%, respectively, vs. active control groups of 10% and 14%.
- **We continue to believe tenapanor may represent a highly competitive alternative for ESRD patients.** Note that in contrast to fixed dosing regimens used in clinical trials, the clinical management of hyperphosphatemia in ESRD patients in practice involves the titration of phosphate binders. We therefore expect a future Phase III trial design to incorporate more flexible dosing, which in turn may allow tenapanor to avoid elevated diarrhea rates.
- **In addition, tenapanor's unique mechanism of action potentially allows for clinical management of hyperphosphatemia in combination with phosphate binders.** This could potentially reduce the substantial pill burden patients currently endure – note that hyperphosphatemic CKD patients on hemodialysis treated with Renagel were dosed at an average of 4900 mg/day to achieve a similar mean serum phosphate reduction as that exhibited by the 10 mg and 30 mg BID tenapanor groups.
- **Reiterate OUTPERFORM rating and $31 price target.** Our price target of $31 is derived by applying a 6 multiple to ARDX's share of 2022 tenapanor sales in the US, added to a 15 multiple of the royalty ARDX is expected to receive in 2022 for ex-US sales of tenapanor.
- Risks to the achievement of our price target include clinical or regulatory failure for tenapanor and failure to achieve sales or earnings estimates.

Figure 1: Tenapanor Effects on Serum Phosphate

Group	n	LSMean*	95% CI
1 mg BID	23	-0.47	(-1.18, 0.24)
3 mg BID	21	-1.18	(-1.93, -0.44)
10 mg BID	23	-1.70	(-2.41, -0.99)
30 mg BID	24	-1.98	(-2.67, -1.28)
3 mg QD	22	-0.56	(-1.28, 0.17)
30 mg QD	21	-1.11	(-1.85, -0.37)
Placebo	26	-0.54	(-1.21, 0.13)

*LSMean = Least square mean. Change from Baseline at End of Treatment (mg/dL)

Source: Company data

Figure 2: Adverse Events Leading to Discontinuations

Adverse Event Term	1 mg BID	3 mg BID	10 mg BID	30 mg BID	3 mg QD	30 mg QD	Placebo
n/group	23	21	23	25	22	21	26
Discontinuations due to AE/group**	3	3	3	9	1	7	2
Abdominal Pain				1			
Diarrhea*	2	3	3	8		6	
Nausea						1	
Vomiting						1	
Serum Calcium Decrease					1		
Hyperphosphatemia	1				1		2
Dizziness						1	
Atherosclerosis		1					

Source: Company data

Figure 3: Adverse Events Observed in Select Phosphate Binders

Adverse Events*	Renvela®#	Fosrenol®**	Auryxia®
Abdominal Pain	9%	5%	
Constipation	8%		8%
Diarrhea	19%		21%
Nausea	20%	11%	11%
Vomiting	22%	9%	7%

Source: Company data (data from package inserts)

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Company	Disclosure
Ardelyx Inc.	1,3,4,5

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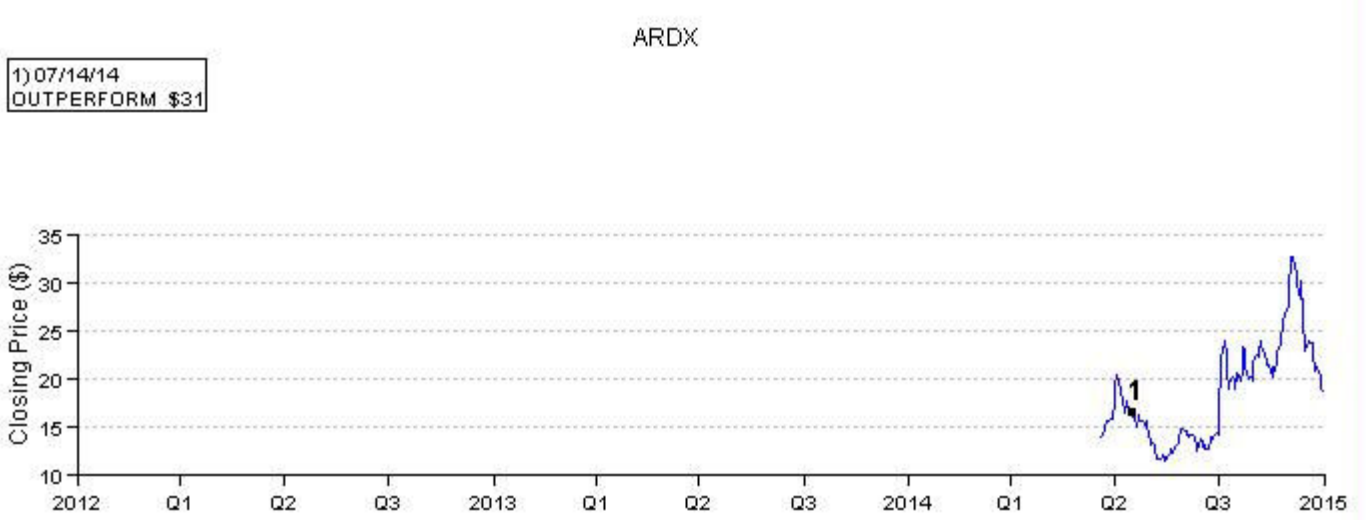

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