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Relypsa (RLYP - OUTPERFORM): New Analysis of Patiromer Phase 3 Results Supports Use in Heart Failure Patients with Hyperkalemia. Reiterate OUTPERFORM and \$57 PT

Price: \$25.20

12-Month Price Target: \$57

- In a late-breaking oral presentation at the 18th Annual Scientific Meeting for the Heart Failure Society of America (HFSA, September 14-17, 2014 Las Vegas), Relypsa presented new analysis of their two-part phase 3 trial showing that the administration of patiromer normalizes high serum potassium in heart failure (HF) patients who are taken RAAS inhibitors. In part A, which was a single-blinded trial containing 243 patients (102 HF, 141 non-HF), the primary endpoint was met with a statistically significant reduction (1.06 mEq/L; $p < 0.001$) in serum potassium from baseline to week 4 for HF patients (Fig. 2). A similar reduction was observed for non-HF patients (Fig. 2). Part B of the trial was a placebo controlled randomized withdrawal study containing patients from Part A who had a baseline serum potassium ≥ 5.5 mEq/L and a week 4 serum potassium level that was controlled. HF and non-HF patients were randomized into groups that received patiromer (27 HF, 28 non-HF) or placebo (22 HF, 30 non-HF) for eight weeks. The primary endpoint, the difference in median change between the patiromer and placebo was 0.64 mEq/L (95% CI, 0.29, 0.99; $p < 0.001$) for HF patients (Fig. 3). Similar results were observed for non-HF patients (Fig. 3). Additionally, fewer HF patients treated with patiromer experienced recurrent hyperkalemia compared to placebo (8% compared to 52%; $p < 0.001$). Results were similar for non-heart failure patients compared to placebo (23% compared to 66%; $p < 0.001$). We estimate U.S. patiromer gross peak sales for HF patients with hyperkalemia could reach about \$300MM.

Figure 1: MILESTONES (*our estimates)

Q4:14	PATIROMER NDA SUBMISSION
Q2:15*	POTENTIAL FDA ADVISORY COMMITTEE FOR PATIROMER (*IF NECESSARY)
Q3:15	POTENTIAL FDA APPROVAL OF PATIROMER
Q4:15*	POTENTIAL U.S. LAUNCH OF PATIROMER
2014/2015*	POTENTIAL PATIROMER PARTNERSHIP(S)

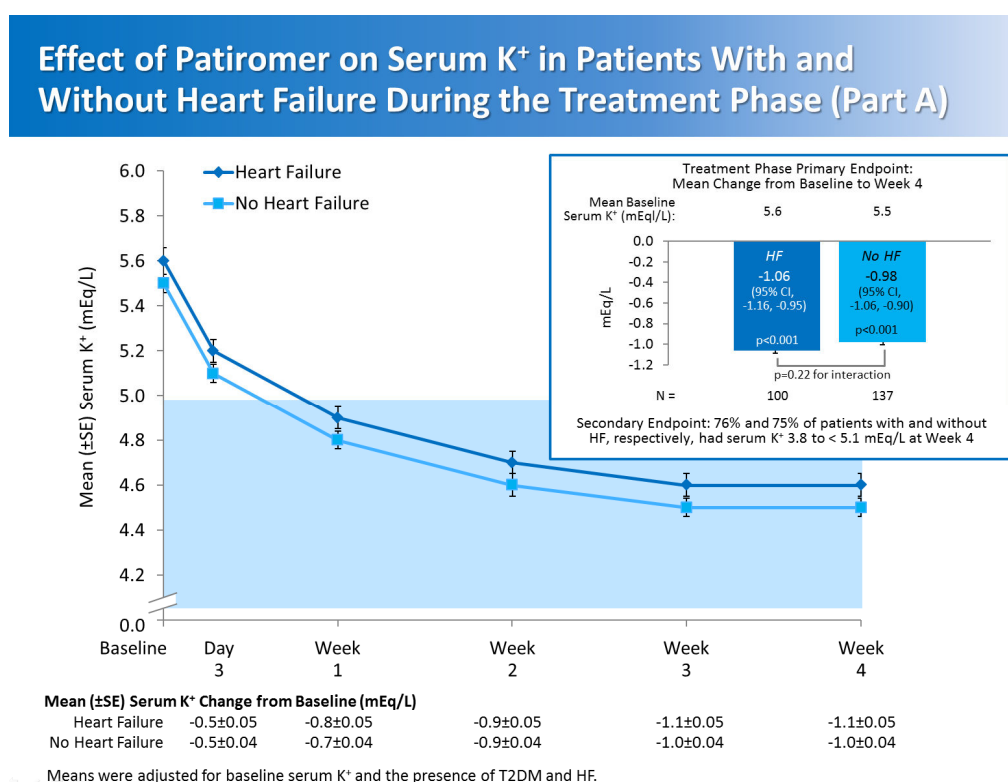
Source: Company data, Wedbush Securities, Inc.

- Patiromer NDA filing is expected to occur in early Q4 2014.** The FDA has 60 days to respond to an NDA submission suggesting potential FDA acceptance in Q4 2014. The company estimates an FDA advisory committee (if necessary) could potentially occur in Q2:15, followed by potential approval in late 2015 and we continue to project U.S. launch by year-end 2015. With regulatory and commercial success, we project gross peak annual U.S. sales for patiromer could reach about \$1.4 billion.
- We reiterate our OUTPERFORM rating and our 12-month price target of \$57.** Our price target is calculated based on sum-of-parts for each drug/indication combination using a 30% annual discount from our peak annual revenues projections and 1-10x multiple, depending on stage of development to reflect risk followed by a 365-day projection for time value.

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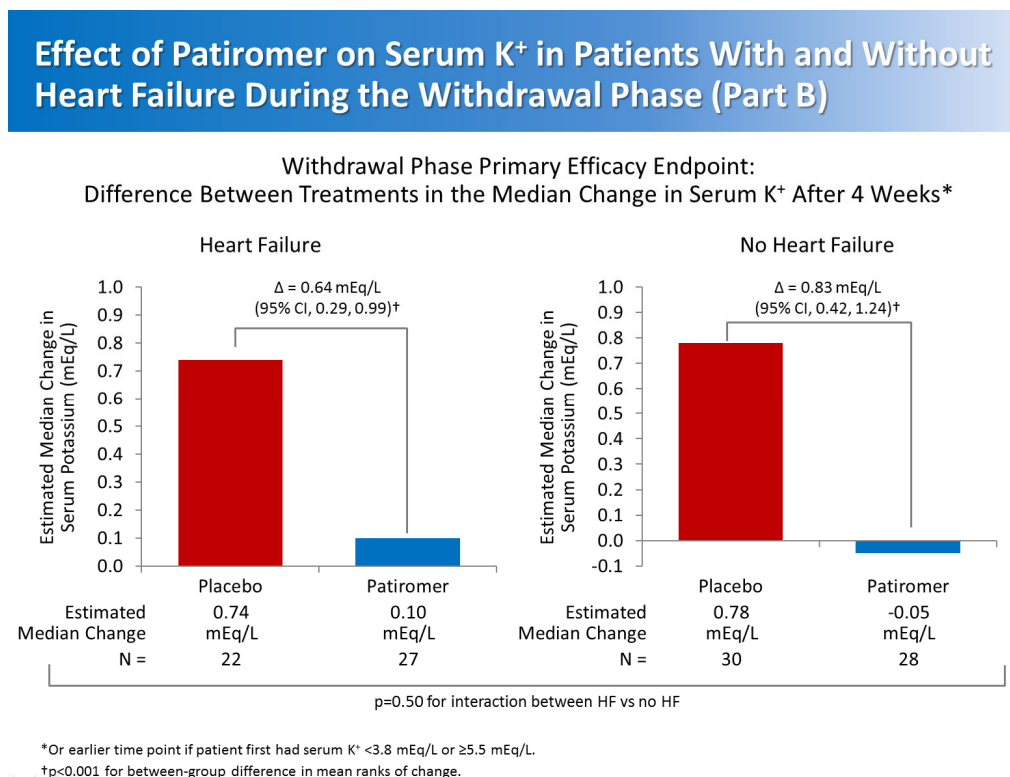
Investment Thesis: Relypsa is an emerging pharmaceutical company focused on the development and commercialization of cutting-edge treatments for renal, cardiovascular, and metabolic disorders. Its polymer drug discovery platform was in-licensed from Ilypsa, Inc., a subsidiary of Amgen (AMGN). Patiromer is the lead drug candidate emerging from this platform and is a non-absorbed, optimized potassium-binding polymer which is dosed twice daily as an oral suspension powder to normalize hyperkalemia in patients with chronic kidney disease (CKD) and/or heart failure (HF). Hyperkalemia (HK), a chronic condition characterized by excessive potassium, typically occurs in CKD and HF patients due to the body's inability to properly clear potassium. Furthermore, renin-angiotensin-aldosterone system inhibitors (RAASi), the standard-of-care for CKD and HF, can actually cause hyperkalemia themselves. Due to the lack of effective, safe, and tolerable treatments for hyperkalemia, treatment guidelines recommend reducing or discontinuing RAASi therapy if hyperkalemia develops—despite their protective effects on the kidney. This situation has created an unmet medical need for CKD and HF patients. In our view, patiromer has the potential to be best-in-class and the first breakthrough treatment for hyperkalemia since 1958. Compared to the only currently approved treatment for hyperkalemia, Kayexalate (an absorbed polymer), the physical and chemical properties of patiromer confer several advantages, including better binding capacity, tolerability and compliance. In fact, Kayexalate has never shown statistically significant reductions in serum potassium levels in prospective clinical trials. In addition, its poor tolerability profile makes it unsuitable for chronic administration. In contrast, patiromer was shown to be effective at lowering serum potassium levels into the normal range while also reducing the incidence of recurrent hyperkalemia with chronic dosing in the Phase 3 and Phase 2b programs. Given the clinical profile of patiromer, we believe it has the potential to fill an unmet need for CKD and HF patients with mild or moderate-to-severe hyperkalemia as well those on a suboptimal dose of a RAASi due to recurrent hyperkalemia. In the U.S., we estimate there are about 2.4 million CKD and HF patients who would be immediately eligible for patiromer treatment, with additional opportunities to further expand and grow the market. We anticipate the company will file an NDA in Q3:14, setting the stage for potential approval and launch in H2:15. With a small specialty sales force of about 100 reps, we project peak annual sales of patiromer could reach about \$1.4 billion in the U.S. alone.

Figure 2: Results from Part A presented at HFSA



Source: Company data

Figure 3: Results from Part B presented at HFSA



Source: Company data

Risks to attainment of our fair value include: 1) Clinical – There is risk that results from the ongoing Phase 1 onset-of-action study are negative, but we view this is unlikely.; 2) Regulatory – Although the Phase 3 program was successful and conducted under a special protocol assessment (SPA), the FDA may fail to approve patiromer in a timely fashion, if at all.; 3) Manufacturing – Relypsa relies on third-party suppliers to manufacture patiromer and there is risk that those parties may not meet their obligations. In addition, they may not be able to successfully scale up manufacturing in a timely and cost efficient manner.; 4) Commercial – As with all new product launches, initial sales of patiromer could be slower than anticipated and call into question its ultimate sales potential. Furthermore, patiromer could face competition from potential new drugs for hyperkalemia including ZS Pharma's late-stage candidate, ZS-9.; 5) Financing – The company ended Q2 2014 with about \$160.4MM in cash and investments. We project runway into Q4 2015—when we estimate potential FDA approval of patiromer. Therefore, we believe Relypsa will likely need to raise additional funds in order to commercially launch patiromer (and/or work with a strategic partner for primary care and/or exUS commercialization) and to ultimately reach profitability which we model to occur in 2018.

Analyst Certification

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Company	Disclosure
Relypsa	1,3,4,5,7

Research Disclosure Legend

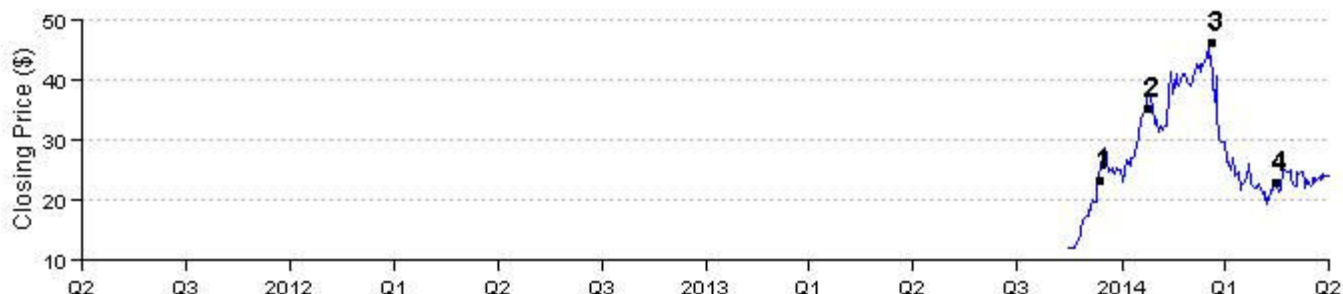
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RLYP

1) 12/10/13	2) 01/21/14	3) 03/18/14	4) 05/13/14
OUTPERFORM \$34	OUTPERFORM \$46	OUTPERFORM \$56	OUTPERFORM \$57



* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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