ZS Pharma

Compelling ZS-9 Profile Reinforced by Full Phase 3 Data Presentation at AHA - ALERT

Overweight

ZSPH, ZSPH US
Price: $38.17

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This morning at AHA, ZSPH announced full data from the Phase 3 ZS004 trial of ZS-9 in hyperkalemia. After a top-line release in Sept indicated all three doses of ZS-9 met the primary endpoint over the 28-day maintenance period, full data was unsurprising, in our view. As outlined in our preview note (here), we suspect that a positive efficacy outcome was largely expected, and attention would be on safety with this longer duration of treatment. Encouragingly, AEs in focus (GI and UTIs) were fairly benign. Hypokalemia was more frequent than we have seen in previous trials, though mild/transient and responsive to per protocol dosing adjustments. The new AE of interest is edema, but it 1) wasn't a big problem at the lower doses and 2) didn't require treatment in half of the pts. We also got a chance to speak with mgmt, who noted edema hasn't been an issue in ZS004E or ZS005 to date. Reiterate OW.

- **Focus is on the 28-day maintenance phase, where ZS-9 showed dose dependent efficacy with stat sig differences vs. placebo at all doses ($p \leq 0.0001$).** Additionally, the proportion of patients having mean serum K within the normal range was also stat sig at all doses (80%, 90% and 94% at the 5, 10 and 15g doses, vs. 46% on placebo). All but one secondary endpoint was met, including cumulative number of normokalemic days, time to relapse, and the proportion of normokalemic pts at the end of the study.

- **Higher rates of hypokalemia and edema than previously seen, but generally mild and manageable; overall ZS-9 continued to be safe and well tolerated.** The incidence of UTIs (a point of focus given an imbalance observed in an earlier trial) was 1.2% on placebo, 2.2% at 5g, 1.8% at 15g with no cases at 10g. While we did see more significant rates of hypokalemia (9.8% and 10.7% at 10 and 15g vs. no cases on placebo and 5g; 0.3% seen in the ZS003 trial) we note all were transient, mild and resolved after per protocol dosing adjustments (every day to every other day dosing). On edema (2.4% on placebo vs. 2.2%, 5.9% and 14.3% at the 5, 10 and 15g doses, respectively), mgmt highlighted about half of them didn't require treatment (the 2 pbo cases did) and that of ~200 pts now enrolled in the ZS005 study (began enrolling in June), only 1 case of edema has been reported.

- **Data from the open label acute phase was in line with previous trials and continues to highlight ZS-9's rapid onset of action.** 98% of pts reached normokalemia within 48 hrs (84% within 24 hrs), with stat sig reductions observed one hour after dosing. Median time to normokalemia was 2.2 hours. Importantly, results were consistent across subgroups, including patients on RAASi therapy.

- **We continue to view ZS-9 and patiromer as relatively equivalent on efficacy, with potential differentiation on safety.** We expect ZS-9's longer term data will continue to show it is effective in a maintenance setting (as is patiromer). We'll be keeping an eye on hypokalemia and edema, but at this point we aren't overly concerned, and we think ZS-9's GI AE benefit (generally numerically lower vs. placebo as compared to patiromer's 5-10% diarrhea/constipation rates in 52-wk Phase 3) could be a benefit longer term. However, we continue to think the market size/degree of unmet need is more than enough to sustain both.

See page 2 for analyst certification and important disclosures.

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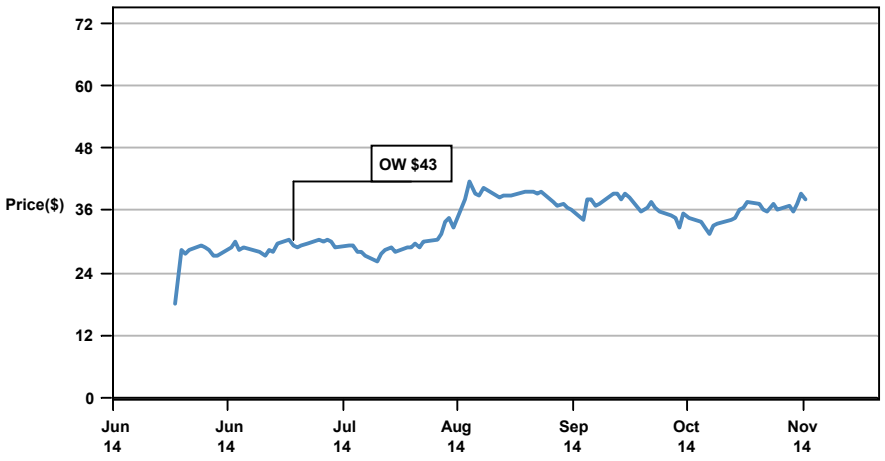
ZS Pharma (ZSPH, ZSPH US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
14-Jul-14	OW	30.49	43.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jul 14, 2014.

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