Sage Therapeutics

SAGE-547 Continues to Impress in SRSE - ALERT

Overweight

SAGE, SAGE US
Price: $38.72

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Biotechnology
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This morning SAGE announced promising top-line results from the ongoing Phase 1/2 trial of SAGE-547 in patients with super refractory status epilepticus (SRSE). In total, 12 pts have been enrolled (vs. 4 previously), 11 were evaluable for efficacy, and 8 met the key endpoint. Recall that at the time of the company's June IPO, we knew that the first 4 pts had responded to 547 (successfully weaned from a medically induced coma). Today's update confirms that 4 of 7 newly evaluable pts also responded. It was obviously unrealistic to expect the 100% RR to continue. We believe the current RR of ~73% in a hard to treat population is impressive (with a similar 71% response rare in 7 eIND pts, also updated this morning), and more importantly is still well in excess of what docs suggested to us as theoretical hurdles. We also find the acceleration in patient enrollment notable, as we had some concern around the number of SRSE pts/ability to find them. Overall, we continue to see Sage as well positioned with additional data updates and regulatory progress throughout 2015 that could continue to de-risk the story and drive upside. Maintain OW.

- **We are encouraged by the 73% response rate in this acutely ill patient population with difficult to treat SRSE.** All 12 pts enrolled met the safety/tolerability endpoint with no drug-related SAEs. Mean exposure levels were ~200nm. Of the 12 pts enrolled (8 male, 4 female) the mean age was 54. Of the 8 pts who met the primary efficacy endpoint, all were weaned off of SAGE-547 without recurrence of SRSE. The press release notes the trial will continue to enroll pts under the recently approved protocol amendment (to allow for treatment of pediatric pts as young as 2 and increased doses of 547). In the eIND program, 7 pts have been treated (4 male, 3 female) with a mean age of 12.5 and a 71% response rate.
- **Differences between eIND and trial pts could lead to differential longer term outcomes.** We recently hosted meetings with SAGE (see note here), during which it noted that pts in the Phase 1/2 trial are acutely ill with the underlying etiology at the time of treatment, which is different from the eIND pts whose other conditions were largely stabilized by the time 547 was tried. As 547 isn't treating the underlying etiology (e.g. viral infection, blood on the brain post head trauma), SE could recur once 547 is tapered (or in the 30-day follow-up period). This generally wasn't the case in the eIND pts who had been in comas for >30+ days, such that their underlying issue was largely resolved.
- **A pivotal trial is on track to start in 1H15.** Management has scheduled an End of Phase 2 mtg with the FDA to finalize details for a pivotal trial. Specifically on endpoints, mgmt noted that they may end up switching around the endpoints in the pivotal vs. the Phase 1/2 trial as the FDA may find the current secondary endpoint (ability to remain SE free w/o 547 on board) to be more clinically relevant (vs. the current primary endpoint of resolution of SE with 547 on board post wean). Importantly, those two endpoints have correlated with each other to date.
- **We expect full detailed will be presented at an upcoming medical meeting, likely in early 2015.** In the full data detail, we will be focused on the details/history of the pts who did not meet the endpoint (keeping an eye on exposure levels and underlying etiology).

See page 2 for analyst certification and important disclosures.

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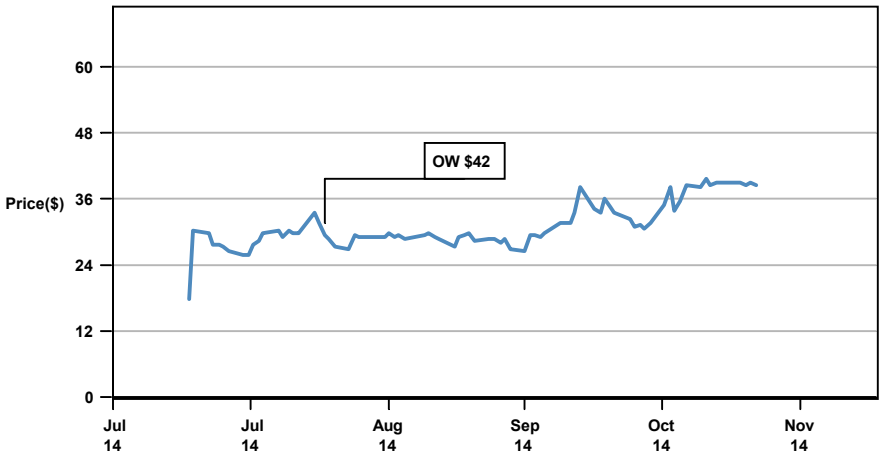
Sage Therapeutics (SAGE, SAGE US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
12-Aug-14	OW	31.81	42.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Aug 12, 2014.

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