Sage Therapeutics

SAGE-547 Phase 3 Trial in Line with Expectations; Will Begin Enrolling Mid-2015 - ALERT

Overweight

SAGE, SAGE US
Price: $50.86

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We are reiterating our OW rating on SAGE after this morning's announcement of Phase 3 trial plans for SAGE-547 in SRSE (super refractory status epilepticus) following the company's End of Phase 2 meeting with the FDA. SAGE will initiate enrollment of a randomized, placebo-controlled Phase 3 trial in 126 patients at ~150 sites in the US and Europe around midyear. Overall this update is in line with our expectations; we believe most investors were anticipating a randomized study (question of pbo vs. active control). We'd also note that the label from a randomized study could be meaningfully better than what would be possible with a single-arm trial. Importantly, SAGE will also initiate an open-label, Expanded Access Protocol (EAP), in which the design/outcome measures will be consistent with Phase 3. Updates from this EAP could provide additional de-risking as the Phase 3 trial is ongoing. SAGE indicated it will present updated data from the ongoing Phase 1/2 trial at the Antiepileptic Drug and Device Trials XIII Conference (Miami, May 13-15). Bottom line, we continue to think SAGE is well positioned headed into 2H15 with initiation of the Phase 3 trial and continued updates from the Phase 1/2 trial/EAP program to continue to provide news flow.

- **The Phase 3 trial in 126 patients will begin enrolling midyear at 150 sites across the US and EU; we expect data ~YE16/early 2017.** The trial will enroll pts aged 2 and up who will be randomized to receive SAGE-547 or placebo on top of third-line anti-seizure agents for 6 days (~in line with the Phase 1/2). The primary endpoint will be successful resolution of SE after wean of all 3rd line anti-seizure medications and SAGE-547/placebo, without recurrence of SE within 24h post SAGE-547/placebo administration. Patients who fail to respond to initial blinded treatment may be eligible to be treated with an open-label, higher dose of SAGE-547. Secondary endpoints include the rate of recovery, regaining of consciousness, mental status and functional outcome. The company has indicated that the trial has 90% power (although we await details on the assumptions for each arm).

- **In the Phase 1/2 trial, 71% of patients have been successfully treated with SAGE-547, consistent with the ~78% seen in the eIND protocol.** An update from this trial was last announced in January 2015 (see our note here). In the 17 evaluable patients in Phase 1/2, all 71% who met the primary endpoint (successful wean from anesthetics with SAGE-547 on board) were also weaned off SAGE-547 without recurrence of SRSE. An additional update is expected in May. In the eIND setting 10 pts have been treated, and 7 of 9 patients (78%) had resolution of SRSE during or soon after 547 treatment.

- **Upcoming events: Full Phase 1/2 547 data in May.** SAGE expects to report final results from the Phase 1/2 trial of SAGE-547 in SRSE at the Antiepileptic Drug and Device Trials XIII Conference (Miami, May 13-15). The Phase 3 trial of SAGE-547 in SRSE will begin enrolling midyear. SAGE also plans to report data from the ongoing POC trials of SAGE-547 in essential tremor and severe postpartum depression also in mid-2015. The next two candidates – SAGE-217 and SAGE-689 – are expected to enter the clinic by year-end.

See page 2 for analyst certification and important disclosures.

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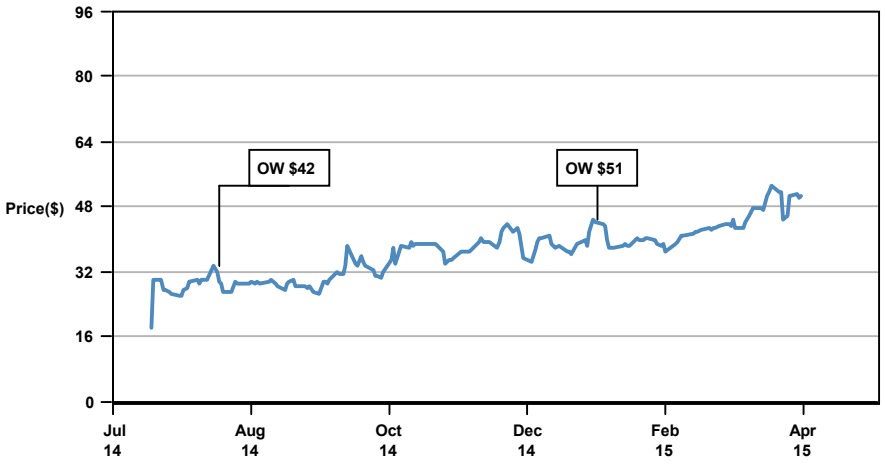
Sage Therapeutics (SAGE, SAGE US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
12-Aug-14	OW	33.40	42.00
09-Jan-15	OW	44.73	51.00

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

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