

Eagle Pharmaceuticals Inc. (EGRX)

Overweight

Orphan Status For Enhanced Form of Bendamustine; Nearer-Term Launch Possible

CONCLUSION

This morning, Eagle announced that its lower-volume liquid formulation of bendamustine (known as EP-3102) that requires a shorter infusion time compared to Teva's product (i.e., Treanda) was granted Orphan Drug designation by the FDA for chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin's lymphoma (NHL). Recall that the drug's infusion time is only 10 minutes, compared to 30-60 minutes for Treanda. The orphan status for EGRX's product now enables a potential launch ahead of the expiry of Teva's orphan status on Treanda in September 2015 (provided of course that the patent litigation outcome is favorable to EGRX). We continue to view EGRX shares as attractive, with two products (enhanced forms of bendamustine and dantrolene) potentially driving profitability by 2016 all in the context of a market cap of around \$200M. We reiterate our Overweight rating and \$22 price target.

- **EGRX gets around Teva's orphan status on Treanda.** EP-3102 is EGRX's second bendamustine product in development. The first of Eagle's products (known as EP-3101; recall that this product received a tentative approval (TA) last week) is an enhanced liquid formulation of bendamustine that is ready-to-dilute (RTD), though like the innovator product is infused over 30-60 minutes. In contrast, EP-3102 has a 10 minute infusion time, pointing to increased chair turnover and cost savings to hospitals and infusion centers as a result. It is our understanding that EP-3102 gained its orphan status based on its "clinical superiority" over Treanda related to its shorter infusion time (i.e., at a minimum, the shorter infusion time translates into a better patient experience). We note that Treanda has orphan exclusivity for NHL through October 2015, and also gained another six months of pediatric exclusivity that extends orphan protection through April 2016. For CLL, Treanda has orphan exclusivity until September 2015, including six months of pediatric exclusivity.
- **What this could mean in terms of an expedited launch timeline for EGRX.** It had been thought that the FDA may be precluded from issuing final approval of EGRX's filings for its bendamustine products for CLL and NHL until the orphan exclusivities granted to Treanda expire. However, with its orphan designation for EP-3102 now in place, we believe the expiries of Treanda's orphan exclusivities are no longer road blocks to a commercial launch for this particular product (provided EGRX is able to prevail in its patent litigation versus Teva). In a conversation with management this morning, EGRX noted it that it could be in a position to file for approval of EP-3102 before the end of 2014. We note that Teva's liquid formulation of Treanda was granted priority review by the FDA and approved in September 2013. As such, we would not be surprised if EGRX's filing were also granted a six-month priority review, pointing to a potential approval and launch by mid-2015. To be fair, it is not clear if we will have a lower court ruling by then, though a decision on EGRX's motion for summary judgement is expected later this year, and a granting of that motion would most certainly pave the way for a possible launch by the middle of next year. We would keep in mind that a mid-2015 launch for EGRX would give them ample lead time over other competitors given that 30-month stay expiries for conventional abbreviated NDA (aNDA) filers on the lyophilized form of Treanda expire as early as 2Q16.

COMPANY DESCRIPTION

Eagle is focused on optimized generic injectibles.

PRICE: US\$14.42

TARGET: US\$22.00

17x 2018E non-GAAP EPS of \$2.20, disc.
20%

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Related Companies:

EGRX
TEVA

Share Price:

14.42
54.20

RISKS TO ACHIEVEMENT OF PRICE TARGET

Pipeline setbacks and risks related to patent litigation.

Price Performance - 1 Year



Source: Bloomberg

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 S: Suspending Coverage
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 N: Neutral
 UW: Underweight
 NA: Not Available
 UR: Under Review

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