

Clovis Oncology

LEAP Takes a Step in the Right Direction - ALERT

This morning, CLVS announced a promising positive data point from the ongoing pivotal LEAP trial, which is evaluating the company's lead oncology asset (CO-101) for pancreatic cancer. Recall that the product is being evaluated for improved survival in patients with low levels of the hENT1 transporter. Today's disclosure is that the proportion of hENT1 low patients in the LEAP trial is 65%, in line with more recent data and above the trial's conservative design assumption of 50% hENT1 low. Importantly, this not only increases the pivotal study's powering to detect a survival benefit, but it also eliminates one of the key risks associated with the study. So the bottom line, in our view, is that today's news validates the more recent analyses, ensures more robust powering and reinforces our optimism in the LEAP study. Reiterate OW.

- **Greater hENT1 low distribution increases LEAP's powering for survival.** With the hENT1 low % now known, powering for improved survival in the hENT1 low group vs. the high group is also now more robust. Specifically, the LEAP trial is now 98% powered to detect a hazard ration (HR) of 0.55 ($p = 0.05$) or over 80% powered to show a HR of 0.65 (where no survival difference is set at $HR = 0$). This is a more favorable scenario compared to when the hENT1 low group was conservatively assumed to be 50% (95% powered to detect a HR of 0.55 or 75% powered to detect a HR of 0.65).
- **Further evidence that our hENT1 low assumptions might be conservative.** In our recent [initiation report](#), we highlighted three potential upside levers, one of which was a higher hENT1 low proportion compared to the historically set 50% assumption. While the company conservatively designed the LEAP study for the 50% scenario (despite 3 recent studies suggesting a % closer to two-thirds), we also conservatively assumed a 50% hENT1 low proportion in our model. By our scenario analysis in our report, changing the hENT1low proportion to 65% changes 2019 US sales to ~\$655M from \$506M if all else (market penetration and price) remain the same.
- **Survival data in 4Q is the main event for CLVS in 2012.** Recall that the top-line survival data for LEAP will likely be available in 4Q. While this seems like a long time, we believe today's update should sit well with investors and perhaps draw more interest heading in the data point.
- **Clovis presenting tomorrow at J.P. Morgan Healthcare conference.** The company's presentation is at 2:30pm PT on Tues 1/10.

Overweight

CLVS, CLVS US

Price: \$14.52

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Biotechnology

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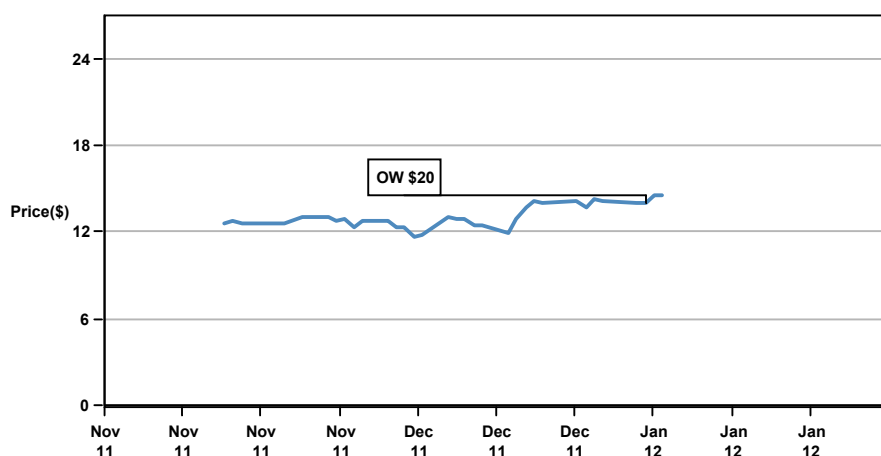
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Clovis Oncology (CLVS) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
03-Jan-12	OW	13.98	20.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jan 03, 2012.

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