

## Event - Clovis hopes for a great leap forward with trial results



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It does not get much more nerve wracking to know that the next event your company faces will result in it either coming up with what could be the new standard of care for an extremely hard-to-treat form of cancer, or alternatively seeing its share price fall through the floor.

The US oncology group Clovis Oncology is waiting for phase II overall survival data for its lead product, the pancreatic cancer drug CP-4126 (CO-101), due by the end of the year. It is a readout that will determine whether the compound and Clovis's management team – packed with former biotech stars – live up their promise or become another statistic in the notoriously difficult pancreatic space ([Key data readouts in the second half of 2012, July 20, 2012](#)).

Company	Clovis Oncology
Product	CP-4126 (CO-101)
Market cap	\$457m
Product NPV	\$679m
% of market cap	148%
Event type	Phase IIb Leap trial results
Date	Q4

### Subgroups

CP-4126 is being studied in the 360-patient Leap trial to see if it improves overall survival compared with the current standard of care in inoperable pancreatic cancer, gemcitabine, in a subset of hENT1-low pancreatic cancer patients whose tumours have spread. hENT1 is the dominant transporter for gemcitabine, meaning that tumours with low hENT1 expression are resistant to gemcitabine treatment.

It is now thought that up to 65% pancreatic tumours fall into this subgroup, making treating them a big unmet medical need, and a significant opportunity for Clovis, which licensed the drug from Clavis Pharma in 2009 as part of a \$380m deal ([Clavis calls on experience of newcomer Clovis in cancer deal](#), November 24, 2009).

The primary endpoint in the Leap study will be the overall survival in the subset of patients with low hENT1 expression.

### Managing expectations

So far the existing data looking at CP-4126's effectiveness in this patient population have been positive, with phase II trials showing a median survival of 9.1 months compared with 3.3 months for those on gemcitabine.

But excitement should be tempered by the fact that this was in a small, abbreviated trial of only 21 patients, so a truer test of effectiveness, and equally importantly, safety, will be the Leap results.

Another factor that could upset the apple cart for Clovis is that the whole hENT1 hypothesis is based on retrospective analysis of previous trials and not in standard clinical studies, so the data might throw up unexpected results.

### Testing times

Analysts at JP Morgan also point out that while Leap may be the first study to use a companion diagnostic in metastatic pancreatic cancer to identify low-hENT1 patients, this carries both risks and rewards.

Come approval time the FDA is likely to look kindly on a drug that can show exactly in which populations it is effective. But the fortunes of both the drug and the test are inextricably linked and if the test were to fail so would the drug, although few are expecting this scenario given the standard format of the test.

If the trial is positive, Clovis intends to file in both the US and Europe by the middle of 2013. As CP-4126 has been given orphan drug status in both regions, approval before the end of 2013 is likely, especially given the poor outcomes and limited choices for patients. Licensing partner Clavis holds the option for a 50/50 co-promote outside of the US.

### **Peak sales**

It is this lack of alternatives that has seen JP Morgan estimate peak sales of \$600m in the US and \$300m in Europe. Consensus sales for 2018 are set to hit \$1.35bn, according to *EvaluatePharma*. The drug is also worth \$679m to Clovis, which has a market cap of \$457m, illustrating the pounding the shares would take if the Leap trial were to fail. About 6% of Clovis' shares are held in short positions, a proportion that has doubled since the end of 2011.

Conversely, there is also massive upside and analysts are currently forecasting around a 55% probability of success. JP Morgan believes approval could see Clovis shares, which have lost 27% of their value in the last six months, hit \$28 next year. The stock is currently trading at \$17.49.

For Clavis, analysts at Edison Investment Research believe that strong data could not only result in a significant price revision, but also strategic interest in Clavis.

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