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Asco – Clovis price is twice as nice following double cancer win

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The dual successes of Clovis Oncology's CO-1686 and rucaparib in lung cancer and ovarian cancer, respectively, has doubled the company's share price and erased the blot on the company's copybook that was the resounding failure of its pancreatic cancer candidate, CP-4126.

Clovis's share price now stands at $74.59, up $38.01 from close yesterday, the highest it has reached since the company's IPO in November 2011. Clovis's shares have risen by 493% in just 18 months, but even this seems reasonable given its startlingly positive phase I/II data in two very hard to treat indications.

Unparalleled

The data on CO-1686, released at Asco, concerns a small number of patients – just six – but they belong to a particularly intractable population: those with the T790M resistance mutation. This mutation occurs in around half of patients with non-small cell lung cancer and limits the efficacy of existing EGFR tyrosine kinase inhibitors; no treatment is currently approved.

CO-1686 does not appear to be subject to this problem. Four of the six patients, who had already failed on treatment with an EGFR inhibitor, showed a partial response to the disease following treatment, with tumours in two of the patients shrinking by more than 20%.

Analysts from Leerink Swann wrote that the data were "extremely impressive" and stated that the drug had paradigm-changing potential for treatment-refractory patients with the T790M mutation. CO-1686 has an "unparalleled" partial response rate of 75%, and stable disease rate of 25%, they wrote.

The analysts increased the probability of success for '1686 from 50% to 58%.

Furthermore, despite the dose being escalated to 400mg three times a day, the maximum tolerated dose (MTD) had not been reached, with the researchers saying that a recommended phase II dose "is expected to be reached soon". CO-1686 was also better tolerated than other EGFR inhibitors; higher doses could bring even better results.

Solid

As for rucaparib, the PARP1/2 inhibitor caused objective responses in ovarian, breast and pancreatic cancer patients and disease control – stable disease or better beyond 12 weeks after study initiation – in eight of nine heavily pre-treated ovarian cancer patients, giving a rate of 89%.

The drug was well tolerated, which Clovis points out is important for a drug intended to be used in a maintenance setting, and again no MTD was reached. Leerink Swan analysts increased their expectations of success for rucaparib from 20% to 25%. Phase III trials of rucaparib are due to begin in the second half of this year.

With Sanofi's decision yesterday for drop its PARP inhibitor iniparib, rucaparib is close to the top of the pile (*Sanofi cleans house following pipeline setbacks, June 3, 2013*). But, since the CP-4126 debacle, CO-1686 and rucaparib are Clovis's most advanced pipeline products (*Leap failure sends Clavis and Clovis crashing back to earth, November 12, 2012*). And the company has yet to bring a drug to market.

These data are undoubtedly positive, but they are early stage. Only when evidence of improvements on patients' survival emerges will a doubling in the stock be justified.

Trial	Trial ID
Phase I/II trial of CO-1686 in previously treated T790M resistance mutation-positive NSCLC patients	NCT01526928
Phase I/II trial of oral rucaparib in patients with gBRCA-mutation breast or ovarian cancer, or other solid tumours	NCT01482715

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