EDISON

Selvita

R&D news

Clinical hold on SEL24

Pharma & biotech

On 7 October 2017, Selvita announced that the FDA has placed a full clinical hold on the company's open-label, dose escalation Phase I/II clinical trial with SEL24 (dual PIM/FLT3 kinase inhibitor) in patients with relapsed/refractory acute myeloid leukemia (r/r AML). The decision was based on a fatal haemorrhagic stroke after venous thrombosis in one patient enrolled in the last cohort 5 in part 1 of the study designed to establish the recommended dose. The adverse event was classified as possibly related to the study treatment, which prompted the FDA to issue the clinical hold.

Year end	Revenue (PLNm)	PBT* (PLNm)	EPS* (PLN)	DPS (PLN)	P/E (x)	Yield (%)
12/14	41.6	5.4	0.56	0.0	N/M	N/A
12/15	56.1	7.6	0.84	0.0	N/M	N/A
12/16	66.7	4.6	0.64	0.0	N/M	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The dose of SEL24 was escalated from 25mg to 150mg from cohort 1 through to 5. There were three patients enrolled in the highest dose cohort 5, of whom one experienced the adverse event. The fatal stroke was associated with the treatment mainly because of the timing (the patient received four doses of SEL24). We note that from a clinical perspective, patients that have relapsed or have a refractory AML are usually frail. They also receive other medication and can have thrombosis risk factors. In this case, to prove or disprove the connection between SEL24 and the adverse event is not straightforward. Selvita indicated that as a next step it will respond to the FDA with all required data and study modification requested by the agency. Subsequently, the FDA will have to reply in 30 days as to whether the hold is lifted.

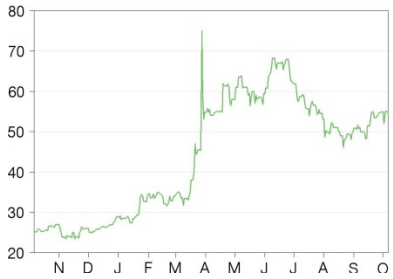
In preclinical development Selvita did not see evidence that SEL24 posed a thrombosis risk, but this is also the first time SEL24 is being administered to r/r AML patients. The asset is now partnered with Menarini Group, which should take over the development in due course. Selvita currently is still the sponsor of the trial and is working with Menarini to respond to the FDA. Selvita will also wait for the resolution of the clinical hold before continuing with its fundraising plans announced in August 2017. Our forecasts and valuation are under review.

9 October 2017

Price	**PLN54.5**
Market cap	**PLN752m**

Net cash (PLNm) in September 2017	38.0
Shares in issue	13.8m
Free float	45%
Code	SLV
Primary exchange	WSE
Secondary exchange	N/A

Share price performance



Business description

Selvita is a drug developer and drug discovery services company. It employs more than 400 staff (30% PhDs) and operates two main business units: Innovations Platform (internal NME pipeline) and Research Services (medicinal chemistry/biology, biochemistry).

Analyst

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Edison profile page

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