8th June 2016

Healthcare

Bone Therapeutics

Price EUR18.36

Long-term data confirming PREOB superiority vs current SOC in osteonecrosis

Fair Value EUR30 (+63%) **BUY**

Bloomberg	BONE FP
Reuters	BONE.PA
12-month High / Low (EUR)	23.0 / 15.2
Market Cap (EURk)	125,732
Avg. 6m daily volume (000)	2.90

	1 M	3 M	6 M	31/12/15
Absolute perf.	8.0%	-4.5%	2.0%	-5.8%
Healthcare	7.7%	4.9%	-5.1%	-6.5%
DJ Stoxx 600	3.2%	0.2%	-7.6%	-6.4%

	2014	2015e	2016e	2017e
P/E	x	x	x	x
Div yield (%)	NM	NM	NM	NM

ANALYSIS

- Bone Therapeutics has announced detailed results of its PREOB-ON2 phase IIB trial in osteonecrosis at EULAR 2016. At 24-months, 70% of the patients responded to PREOB vs. 37% in the reference arm (core decompression with bone graft), p=0.011. Top-line results were already presented. Moreover, patients treated with PREOB had their risk of fracture decreased by 50%. At 36 months, results were consistent with 60% of patients still responding to PREOB compared to 35% in the reference arm. 2.7% of adverse events (n=15) across the trial were equally balanced between the active and reference arms and mainly related to reaction at site or bone marrow puncture. No data at 48 months has been provided yet. Although we believe that at the latter time-point, the difference in between PREOB and the active treatment is still statistically significant, we do not rule out that the label will only consider 24 months (*cf. phase III design*).
- As a reminder, 63 patients suffering from osteonecrosis (stage I and II) of the hip were enrolled in this double-blind trial. While the mainly used clinical endpoint was radiological progression of the disease (hip fracture risk), Bone Therapeutics' strategy of adding clinical symptom measurement (reduction of pain) as a co-primary endpoint has been proven successful, placing the bar high for one of the largest ever trials conducted in this indication. We believe that the treatment should have no difficulty in gaining physician's attention should the development be a success. Indeed, core decompression is not very efficacious with 25% to 85% second surgery rates reported.
- The Phase III trial is ongoing (130 patients to be recruited). The trial is de-risked in our view as it compares PREOB to placebo at 24-months. It is impossible to have a double-blind phase III study while using core decompression and/or a bone marrow graft, which is an invasive procedure compared to a mini-invasive percutaneous administration of PREOB. The design of the trial is compliant with FDA requirement and the US trial is expected to be initiated by the end of the year.

VALUATION

- As top-line results were already known, we have not changed our PS related to the project. The osteonecrosis opportunity represents EUR6 and EUR1 of our Fair Value in Europe and in the US respectively.

NEXT CATALYSTS

- H2 2016:
  - Spinal fusion results in 4 patients and DSMB in Delayed-Union
  - Initiation of US trial in Osteonecrosis and interim results from the European phase III trial (6 patients)

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Distribution of stock ratings

BUY ratings 72% NEUTRAL ratings 0% SELL ratings 28%

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