

Healthcare

7th August 2019

MORPHOSYS

HealthcareBiotech

BUY

Fair Value Under Review
Share price EUR109.30
EPS 3Y Cagr NM

MOR208: Acceleration of European filing and disclosure of B-MIND's biomarker

L-MIND based EMA filing should accelerate its launch in EU

While we thought at first that the European filing would be based on the back of the B-MIND data, MorphoSys just announced, alongside in—line H1 numbers, its intention to submit a Marketing Authorization Application (MAA) for MOR208 to the EMA based on the L-MIND study, thereby embracing the same strategy as in the US. As a reminder, while B-MIND is a randomized phase 3 trial comparing MOR208 associated to bendamustine to a combination of rituximab and bendamustine, the L-MIND study is only a single arm phase 2 trial evaluating MOR208 + lenalidomide controlled with a synthetic lenalidomide only-arm, a drug which is not approved for R/R DLBCL. We believe that it is good news for two reasons: 1/ this decision highlights that European regulators are open to review a single arm study such as L-MIND 2/ it will accelerate the EU launch. Indeed, given that the letter of intent was submitted to EMA in early July, it should allow the company to complete the MAA submission by mid-2020.

B-MIND biomarker revealed ahead of the futility analysis

In Q1, MorphoSys amended the protocol of the B-MIND trial to add an undisclosed biomarker. This was done in agreement with the FDA. Yesterday evening, the company announced that this biomarker is described as a low-baseline peripheral blood natural killer (NK) cell count. Multiple publications have indeed demonstrated that the number of NK cells in peripheral blood may affect the outcome of patients with B-cell non-Hodgkin lymphoma receiving anti-CD20 based immunochemotherapy. Therefore, if proven successful, MOR208 could further differentiated itself from competition by addressing patients with even higher unmet needs. As a reminder, we are expecting the results from the futility analysis before year-end. Depending on the results, we see three scenarios: 1/ all-comers pass futility then final data will be reported in Q1 2020; 2/ only subgroup passes futility, final data one year after in Q1 2021 and 3/ all-comers and subgroup fail, the whole study is futile.

Expected US BLA submission by end of year based on L-MIND

Beyond the futility analysis of the B-MIND trial, we are anticipating in H2 the submission of a BLA (eligible to priority review) with the FDA based on L-MIND data. This could allow the company to launch MOR208 in R/R DLBCL by mid-2020 in the US. In addition to the fact that European regulators seems keen to review such study, we believe that there are good reasons to think that MOR208 will be approved on the back of those results: 1/ the overall benefit demonstrated so far is clinically meaningful; 2/ MOR208 has been granted Breakthrough Therapy designation allowing an accelerated approval pathway; 3/ the FDA has recently shown flexibility in cancer indications with high unmet needs (Karyopharm's accepted NDA in RRMM) and 4/ synthetic arm in clinical trial is emerging trend validated by clear regulatory precedent

As we are transitioning coverage, we are putting the fair value under review with the perspective of meeting the new CEO in London in September.

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Bloomberg / Reuters	MOR GR/MORG.DE
Market Cap.	EUR3,480m
E.V.	EUR3,155m
Free Float	29%
Avg. Daily volume (6m)	146.8
12m high / low	EUR113.9 / EUR77.8
Ytd Perf.	22.9%

EURM	12/18	12/19e	12/20e	12/21e
Sales	76.4	44.8	131.3	114.8
% Change		-41.3%		-12.6%
EBITDA	-55.3	-120.0	-54.0	-83.2
% Change		NS	55.0%	-54.1%
EBIT	-59.1	-128.0	-62.0	-92.2
% Change		NS	51.6%	-48.7%
Net Income	-56.2	-126.0	-60.0	-89.2
% Change		NS	52.4%	-48.7%
ROE	-0.12	-0.35	-0.20	-0.42

	12/18	12/19e	12/20e	12/21e
EV/Sales	41.3x	73.2x	25.4x	29.9x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS
EPS	-1.79	-3.96	-1.88	-2.72
% change		NS	52.4%	-44.2%
P/E	NM	NM	NM	NM
Div Yield	NM	NM	NM	NM

Next Catalyst: Meet the Management (London, September 10th)

Last rating Change:

2018-2-27, Heading for a metaMORphoSys!

Last FV Change:

2018-12-13, Tremfya strong in phase III against Cosentyx

Last Reports:

2019-6-24, Tafasitamab: additional L-MIND results presented at ICML

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BUY ratings 48.8% NEUTRAL ratings 44.6% SELL ratings 6.5%

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