Galapagos

Hedges testicular tox risk with new MANTA 2.0 study

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According to the European clinical trial registry (here), the twin study to MANTA in patients in RA, PSA and AS has been opening sites, first in Estonia and additional countries likely to follow soon. The completion date is not disclosed, but given less restrictive recruitment criteria, established filgotinib's benefit in this population, limited competition from the ongoing filgotinib trial, and the already established infrastructure, we expect Galapagos to be able to recruit the trial significantly faster than the original MANTA study. Thus the data from this trial could serve as the back up for MANTA for the RA filing (if still required after the pre-NDA meeting with the FDA), address any questions for the phase III trials in AS and PSA if those ever arise, and would put all the discussions of sperm tox to rest.

Similar design suggests a high likelihood of success. Galapagos is running the trial in patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PSA) in ex-US centers (EU, India, Russia, and Ukraine). Approx. 250 patients will be randomized to filgo 200mg QD or placebo. The primary endpoint is the proportion of patients with >50% decrease in sperm concentration at 13w (the trial will be unblinded after 13w) with the follow-up till 26w. Given the trial size, we expect that it was powered for a similar ~20-30% non-inferiority margin customary to other sperm tox studies and thus have a low chance of failure. Read more in the "Everything you wanted to know about MANTA" report in the library here for a detailed discussion on the trial set up.

Broad patient population facilitates recruitment. While the recruitment for MANTA appears to have picked up, judging by Gilead comments in the Q1 call and accelerated trial site opening (127/150 targeted), we believe MANTA 2.0 could have faster recruitment as it resolved main bottlenecks with MANTA:

- **Established infrastructure for sperm analysis.** FDA requires sperm to be analyzed in a standardized way that raises the requirement for infrastructure, which likely slowed MANTA expansion to Russia and India We expect to see significant overlap between study sites participating in MANTA and MANTA 2.0. While the protocol for the new study needs to be cleared separately in every new jurisdiction and trial site, the already established infrastructure should facilitate completion of the trial, especially in Eastern Europe and India.
- **Less restrictive recruitment criteria.** While the recruitment criteria still require semen quality a bit below "normal" characteristic, which is a challenge on its own, otherwise the trial just plain RA/AS/PSA patients that would have qualified for the majority of the filgo trials with no additional screening challenge like endoscopic confirmation for UC.
- **Patients should be more willing to participate.** MANTA recruitment for a large part went against the large phase III SELECTION trial in

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Rating	BUY
Price Target	€135.00
Closing price (09 Apr 2019)	€111.00

UC, while the efficacy of filgo in UC is not established. On the contrary, with FINCHes in RA no longer recruiting, PSA phase III planned for later this year, and well-established efficacy in these indications, there is no other options for patients to get filgo aside from participating in MANTA 2.0.

Data could come already next year. In our discussions with European rheumatology KOLs, there was a willingness to support the trial and according to the company, there was a positive reception of the trials in European centers. The completion date is not disclosed, but looking at PSA and AS trials (~130 patients each) that were completed within a 12-15 month timeframe, we could expect results in mid'20, which is already earlier that the original MANTA completion date in 2021.

MANTA 2.0 could act as a back up for RA filing. According to Galapagos, the partners could use data from both trials to meet the FDA requirement for testicular tox data. Thus MANTA 2.0 could serve as the back-up for the regulatory filings if the recruitment for MANTA does not pick up the pace.

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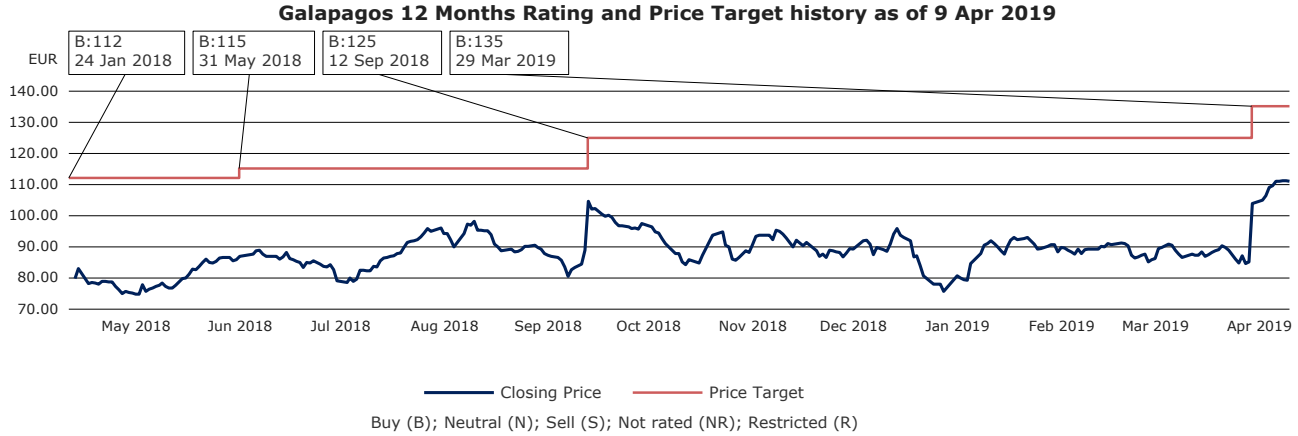

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