Galapagos

Gilead all but dropping Jyseleca, Galapagos assuming all EU rights

European Life Sciences 16 December 2020, 08:09

Galapagos and Gilead announced an amended agreement on Jyseleca following an unfavorable Type A meeting with the FDA regarding the approvability of the 200 mg dose in rheumatoid arthritis (RA). As a result, Gilead no longer sees a future for Jyseleca in the US except for IBD, pending further FDA consultations after the MANTA study. Galapagos will now assume all European development and commercialization of Jyseleca in exchange for €160m from Gilead (€110 in 2021 and €50 in 2022) and payment of tiered 8-15% sales royalties as of 2024. In addition, Galapagos will redesign the trials in psoriatic arthritis (PsA), ankylosing spondylitis (AS), and non-infectious uveitis to fit the smaller commercial opportunity. With respect to the 50/50 trial cost split, it will largely continue only for IBD trials. While we are not surprised by the announcement, the timing (just after the meeting) suggests that it might have been already a foregone conclusion just after the CRL in August. Our current PT ascribes €81 to cash, which could serve as a bottom today (ADRs AH ~€86). We plan to update our PT in a follow-up note but safe to say we foresee a dramatic decrease, given we will be taking out all indications but IBD for the US, and we expect a significant increase in cash burn in the coming years.

The FDA is raising the bar for MANTA. In a further twist, Gilead and Galapagos disclosed that the FDA now wants to see 52-week follow-up for patients in the MANTA/MANTA-RAy studies that had a >50% decrease in semen parameters by week 26. Data for week 26 will be available by mid'21 and was supposed to sufficient for continuing the review in RA and future indications. As a consequence, any decision on the future of Jyseleca in the US for IBD is now likely to come in 2022.

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Rating	BUY
Price Target	€160.00
Closing price (15 Dec 2020)	€97.06

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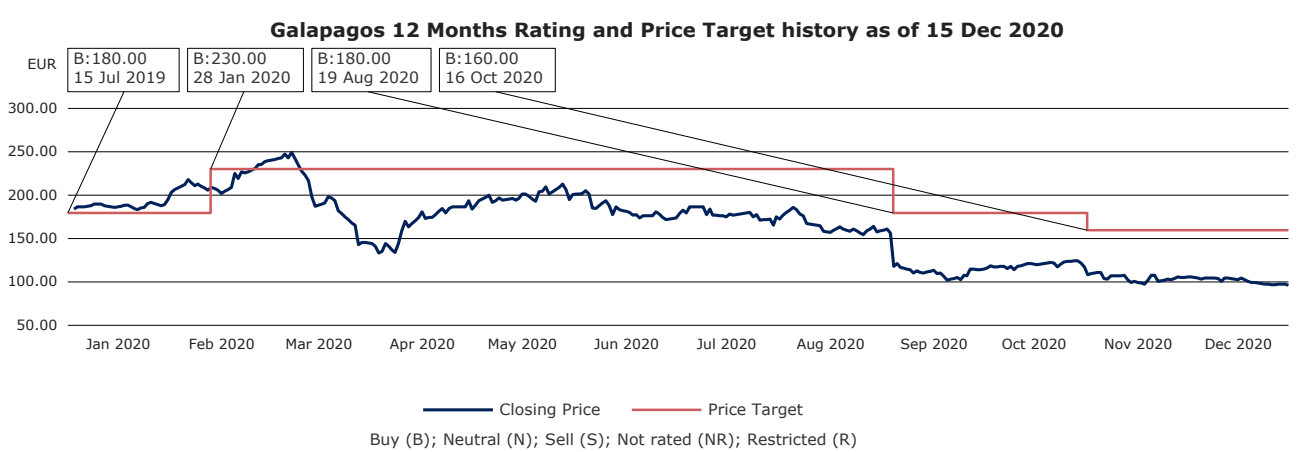

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