BofA SECURITIES

Merck & Co.

Sotatercept label expectations: thoughts ahead of FDA decision

Maintain Rating: BUY | PO: 135.00 USD | Price: 121.52 USD

REMS/monitoring requirement not a barrier to uptake

Following the EMA's decision to change sotatercept's review from an accelerated to a standard timeline, there is growing concern among investors that what was once assumed to be a sure approval with a clean label is now less certain. Indeed, as we highlighted in our prior note (see PVRI conf note), the increased risks of bleeding (especially GI bleeds) and increased hemoglobin levels, reported at the recent conference, have raised awareness among docs regarding sotatercept's side effects and the need to mitigate risks. However, based on our checks and conversations with KOLs, we expect sotatercept adoption to remain robust, even with potential black box warnings and REMS/monitoring requirements. Notably, nearly all respondents believe the FDA will likely approve at-home administration (vs in-office). Overall, we maintain our confidence in sotatercept's upcoming PDUFA on March 26 and remain bullish on its commercial outlook (2030e rev: $4.6B BofA vs $4.7B cons). Maintain Buy, $135 PO. We thought to address investors' questions and provide a summary of our survey findings and KOL conversations below.

What constitutes a "clean" label?

We believe a clean label includes a monitoring requirement but does not include black box warnings or REMS. While most docs believe that there should be a monitoring requirement to check on hemoglobin level prior to sotatercept administration, their views were more mixed on REMS (50/50 chance). Indeed, docs cited that anticoagulants do not require black box warnings or REMS even though they have much higher bleeding rates than sotatercept. Of note, the key difference between a monitoring language in the label vs. REMS is that the former is based on guidelines and professional judgement ("more leeway") while the later has a strict implementation requirement. That said, regardless of what's included in the label, docs see the benefit far outweighs the risk.

What's the likelihood of CRL or black box warnings?

As noted above, we think the likelihood of CRL and black box warnings is low (<5% and <10%, respectively) based on doc feedback. In addition, docs do not believe the absence of AdComm meeting is a concern given the unmet needs and a clear favorable efficacy/safety profile, despite sotatercept being a first-in-class agent for PAH. That said, a key unknown is the medical history of the eight patients with GI bleeding, which the FDA has access to and could impact decision for black box and REMS. Should there be black box warnings, they're likely to include bleeding risks abnormal platelet counts.

What would a monitoring requirement look like?

Most docs believe patients should be monitored for hemoglobin level and platelet count, at least initially. Monitoring is expected to be once every three weeks prior to administration, in alignment with the trial protocol. Notably, getting a lab test for hemoglobin/ platelet count is not burdensome since it provides a binary output (yes or no) and does not require any input from a provider. Longer-term, the frequency of monitoring may be extended from 3 to 12 weeks.

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Stock Data

Price	121.52 USD
Price Objective	135.00 USD
Date Established	26-Jan-2024
Investment Opinion	A-1-7
52-Week Range	99.14 USD - 130.24 USD
Mrkt Val (mn) / Shares Out (mn)	307,767 USD / 2,532.6
Free Float	99.6%
Average Daily Value (mn)	936.83 USD
BofA Ticker / Exchange	MRK / NYS
Bloomberg / Reuters	MRK US / MRK.N
ROE (2024E)	53.4%
Net Dbt to Eqty (Dec-2023A)	94.7%

See abbreviations on page 2:

Will the bleeding AEs and risks increase over time?

It's difficult to tell at this point since we don't have enough long-term safety data, which is why most docs believe that monitoring is warranted given the increased bleeding rates and hemoglobin level. Additionally, we don't know if there's a subgroup of patient population that's at a higher risk of bleeding with sotatercept treatment (e.g., patients on anticoagulant).

How would REMS/ black box affect prescribing pattern?

As noted previously, docs believe FDA should allow at-home administration for sotatercept after initial training and education. Importantly, whether there are REMS and/or black box warnings, none of these warnings would likely reveal anything new beyond what is already known and would have no impact on docs' decisions to prescribe sotatercept given the unmet needs.

Exhibit 1: PAH checks with physicians
Docs believe black box warnings

	Questions	Yes	No
1	Are you concerned about sotatercept's bleeding risks (spider vein, nose bleeds, GI bleeds)?	9	7
2	Does sotatercept have more serious bleeding risks than Remodulin (Treprostinil) or other standard of care PAH drugs?	7	9
3	Do you expect sotatercept to receive black box warnings, REMS, and/or monitoring requirement?	11	5
4	Do you think sotatercept should be administered at home?	15	1

Source: BofA Global Research, Guidepoint

BofA GLOBAL RESEARCH

Abbreviation:
AEs: adverse events
CRL: complete response letter
EMA: European Medical Agency
FDA: Food and Drug administration
GI: gastrointestinal
KOL: key opinion leader
PVRI (Pulmonary Vascular Research Institute)
REMS: Risk Evaluation and Mitigation Strategies
PDUFA: The Prescription Drug User Fee Act

Price objective basis & risk

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Risks to our PO are 1) impressive competitor readouts results in key immuno-oncology (I/O) indications, 2) more rapid declines across the diabetes franchise than expected, 3) negative outcomes from the company's later-stage assets in ongoing development, and 4) pressures from headline risks facing the sector (including drug pricing reform).

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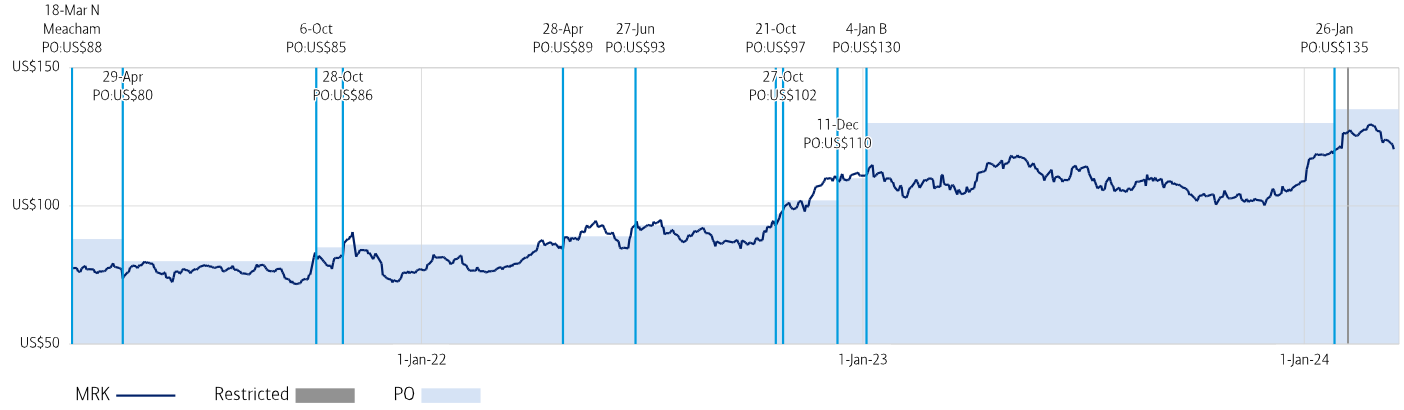
Merck & Co. (MRK) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

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