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Novartis Makes An Ideal Match For MorphoSys

by Kevin Grogan

The Swiss major looks to have bagged a bargain in buying MorphoSys and its potential game-changer myelofibrosis candidate pelabresib.

Having turned the company's fortunes around in the past year, *MorphoSys AG* CEO Jean-Paul Kress can reflect on a job well done now that *Novartis AG* is acquiring the German biotech.

The Swiss major has made a €68 per share cash offer, which values MorphoSys at €2.7bn, that has been approved by both boards, with the Munich-based group noting that it represents a 94% premium over the average price during the last month. Investors like the look of the deal and MorphoSys's stock had climbed 14% at 12.20pm UK time to €65.50.

At the heart of the transaction is the myelofibrosis candidate pelabresib, which has been touted as one of the sector's most valuable late-stage assets. At the end of last year, MorphoSys presented results from the Phase III MANIFEST-2 trial of pelabresib, an investigational BET inhibitor, in combination with current standard of care, *Incyte Corporation*'s JAK inhibitor Jakavi/Jakafi (ruxolitinib), in patients with myelofibrosis who have not previously been treated with a JAK. The 430-patient trial met its primary endpoint, with the combination therapy demonstrated a significant and clinically meaningful improvement in the proportion of patients achieving at least a 35% reduction in spleen volume (SVR35) at week 24. (Also see "*MorphoSys Keeps The Faith Despite Mixed Data For Myelofibrosis Combo*" - Scrip, 21 Nov, 2023.)

Specifically, 65.9% of patients receiving pelabresib in combination with ruxolitinib achieved SVR35 at week 24, the primary endpoint, versus 35.2% of those receiving placebo and ruxolitinib, nearly doubling response rates. Less convincing, however, were the data for the key secondary endpoints assessing symptom improvement which missed statistical significance. MorphoSys noted that 52.3% of patients taking pelabresib and ruxolitinib had at least a 50% reduction in total symptom score (TSS50), compared with 46.3% for those on placebo combined with the JAK

inhibitor.

MorphoSys believes that the entirety of the data will be enough to bag approval. Filings of pelabresib in combination with ruxolitinib with the US Food and Drug Administration and the European Medicines Agency are expected by mid-2024. Novartis would appear to think the same, describing the drug as a "potentially practice changing treatment option with a well-tolerated safety profile."

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By Kevin Grogan

14 Dec 2023
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Novartis is already a major player in the myelofibrosis space given that it holds the ex-US rights to Jakavi. The drug, which is also approved for polycythemia vera, contributed $444m to the Basel-headquartered group's coffers in 2023, a rise of 14% on the previous year.

When asked on a 6 February conference call about the timing of the deal, CEO Kress said that it was not a decision that was taken lightly but "after a thorough review of all the strategic options, we firmly believe it's the best interest of the company [and] its shareholders." For the latter, "it provides attractive and certain cash value now" ahead of a regulatory decision, he said, pointing out that Novartis had "ample resources which are actually currently unavailable to MorphoSys as a standalone biotech for accelerating and maximizing pelabresib potential on a global scale."

Kress would not be drawn on rumors that Incyte had also been a potential suitor, saying that MorphoSys couldn't comment on the process "at this time." However, Incyte is getting exclusive worldwide rights to Monjuvi (tafasitamab), the MorphoSys lymphoma drug the firms have been co-marketing in the US, for just $25m. Kress said Incyte was "best positioned to drive tafasitamab's future growth opportunities far more successfully and more efficiently on its own at this time."

The proposed transaction has gone down well with the investment community. Analysts at Wells Fargo said that while the price tag "does seem a bit low to us, as we expected a deal value in the $3bn-$4bn range, it's a solid outcome." They added that Novartis made sense as an acquirer, given it already has a sales force in place for myelofibrosis with the co-promotion of Jakavi and saw think lots of synergies for Novartis in the deal.

Antitrust Issues?

However the Jakavi tie-up Novartis has with Incyte may mean the MorphoSys acquisition "could

have more antitrust risks than are apparent at first blush," claimed Leerink Swann analyst Andrew Berens. He noted that "given the size of the deal and its geographic diversification, it would seem that this acquisition would be unlikely to receive significant regulatory scrutiny, however, given the therapeutic area overlap in myelofibrosis, we think it is possible that both the Federal Trade Commission and the European Commission may raise antitrust concerns."

In particular, Berens said the FTC could be interested in the royalties Novartis receives from US sales of Jakafi, which for the first nine months of 2023 amounted to $88m. Kress said on the conference call that the takeover offer was subject to clearances by several regulatory authorities but he did not expect any antitrust difficulties.

For Novartis, the deal is another example of its bolt-on M&A strategy around deals worth up to $5bn, reiterated last week by chief financial officer Harry Kirsch. Besides pelabresib, it is also getting hold of the EZH2 inhibitor tulmimetostat and a portfolio of assets of which some are already partnered with Novartis, including ianalumab which targets B-cell lysis and BAFF-R blockade and is being evaluated in various autoimmune disorders including lupus, Sjogren's disease and immune thrombocytopenia. (Also see "*MorphoSys Teams Up Again With Novartis For Preclinical Cancer Program*" - Scrip, 7 Dec, 2022.) (Also see "*Novartis Keen On Cardio Deals But Obesity Ship Has Sailed*" - Scrip, 31 Jan, 2024.)