Evaluate Vantage

October 05, 2018

Non-inhibitor Hemlibra approval means Roche now has to deliver

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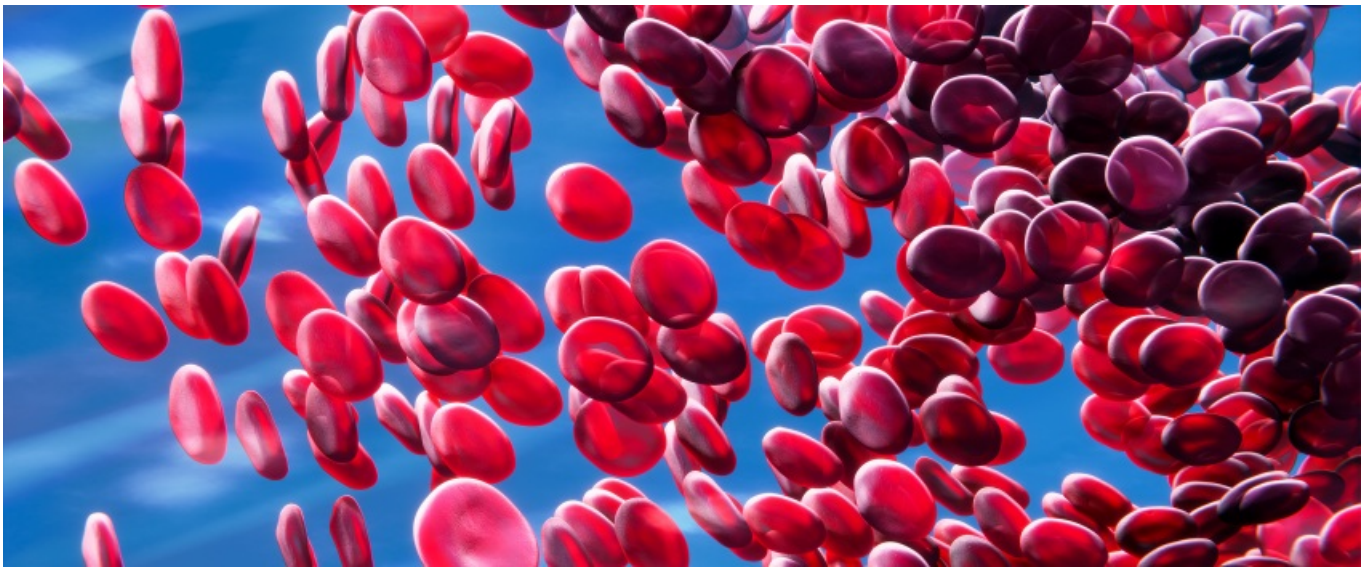

As the Roche drug secures its second, most valuable, green light the pressure is on the Swiss group to execute.

Yesterday's extended US approval of Hemlibra in haemophilia A positions the Roche drug to seize what analysts believe to be its most lucrative population – patients without inhibitors. The drug is off to a strong start in the inhibitor population, and the Swiss group must now negotiate several stumbling blocks.

Chief among these might be payer acceptance in a notoriously conservative haemophilia market. It did not go unnoticed that when launching Hemlibra for inhibitor patients Roche priced the drug in line with current factor VIII replacement therapies, gaining the blessing of the US pricing watchdog Icer in the process.

How the situation plays out in non-inhibitors patients will be interesting to watch. Icer has yet to give its verdict on the cost-effectiveness of Hemlibra's sub-$500,000-a-year price in this patient population (*Reasons to be cautious about new haemophilia therapies, May 30, 2018*).

Another issue is safety. Thrombotic events have been a problem in haemophilia A patients with inhibitors, but most doctors put these down to the concomitant use of bypassing agents like Shire's Feiba; notably, such agents are not used in patients without inhibitors, and Roche's pivotal Haven 3 non-inhibitor study raised no special issues regarding Hemlibra's safety profile.

Deaths have occurred in people taking the drug, and recently the reported tally rose from six to seven, including two in clinical trials, according to analysts at ABG Sundal, who cover Roche's competitor Swedish Orphan Biovitrum.

Importantly, however, no deaths have been deemed related to Hemlibra. But in a conservative market Roche will find unwelcome any uncertainty among doctors who are considering switching well-controlled patients to Hemlibra.

Battleground

Still, the initial battleground for Roche will likely be semi-controlled patients and those who are not well controlled, respectively accounting for some 40% and 30% of the non-inhibitor population, according to Barclays analysts.

The sellside tends not to split this out the market specifically, but Andy Chen, an analyst at Bernstein, reckons

that around 90% of all haemophilia A patients have not developed inhibitors. Overall consensus is for total 2024 Hemlibra sales to hit $3.8bn in 2024, slightly off the $4bn that was being forecast a few months ago.

All that said, it cannot be denied that Hemlibra is a threat to established haemophilia players like Shire, and once Takeda completes this company's takeover the problem will be the Japanese group's. Bernstein cites the threat of Hemlibra as well as that of upcoming gene therapies, though given the pricing dynamics achieving broad uptake of the latter will be tough.

Hemlibra was launched in patients with inhibitors last November, and recorded 2018 half-year sales of SFr57m ($57m). This, Bernstein says, is at the high end of expectations, and Roche will now be keen to repeat the trick in non-inhibitor patients.

This story has been updated to add comments from Bernstein about the split of the haemophilia A market.