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Indivior gets new injection of life

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The US healthcare system should soon have two new weapons as it fights the opioid crisis: Indivior's RBP-6000 and Camurus and Braeburn's CAM2038 both got the thumbs-up from FDA advisory committees this week.

Of the two projects, Indivior's monthly depot buprenorphine formulation looks likely to come out on top – the panellists had reservations about CAM2038's studies, and its approval could be limited to the lower doses proposed. Still, the ongoing crisis, now designated a public health emergency, has left the US desperate for options, which should give both products a shot at decent sales.

Indivior's shares, now trading at around £4, are almost back at levels seen before they crashed in September on the threat of a generic version of the company's Suboxone film from Dr Reddy's (*Snippet Roundup: PI3Ks not dead, but PD(L)-1 multiple myeloma hopes falter, September 8, 2017*).

Premium pricing

However, there is still the issue of who will pay for RBP-6000 and CAM2038 if they are approved. Despite the recent actions of the US government it is unclear if extra cash will be committed to the fight against opioid abuse. President Trump stopped short of announcing a national emergency under the Stafford Act, which would have released federal funds.

This could be a problem, with RBP-6000 set to be much more expensive than its predecessor. Indivior's chief executive, Shaun Thaxter, today put the new product's price in the range of $1,000-2,000 per month, versus a list price of around $5,000 per year for Suboxone film, according to *EvaluatePharma*.

Mr Thaxter, speaking on a conference call to discuss Indivior's third-quarter results, seemed confident that payers would be willing to shell out for RBP-6000, insisting that this was not just a me-too product and that it would bring value to the healthcare system, which the company hopes to demonstrate through health economic studies.

He added that the group was getting positive feedback from payers, who have "a high degree of comfort in this range". Indivior will announce the exact price of RBP-6000 once it is approved and its label finalised.

A decision on approval is due by November 30, but this seems like a foregone conclusion after Tuesday's adcom vote came down 18-1 in favour of RBP-6000. The project is expected to bring in nearly $800m by 2022, according to *EvaluatePharma* sellside consensus – providing much-needed replacement sales as Suboxone film faces generic erosion.

The changing fortunes of Indivior

		Annual sales ($m)			
Product	**First launch**	**2016**	**2018e**	**2020e**	**2022e**
Suboxone film	2010	933	738	397	209
RBP-6000	Due Q1 2018	--	144	582	782

Source: EvaluatePharma.

Anyone expecting Indivior to launch quickly and make the most of its first-mover advantage will be disappointed, however. Mr Thaxter said the company would stick to its plan to begin marketing RBP-6000 in the first quarter of 2018, saying he wanted to focus on getting the launch right.

Indivior is seeking the go-ahead for two dosing regimens: 300mg once-monthly for six months; or two months of 300mg followed by four months of 100mg. Briefing documents had suggested that there might be concerns with the 300mg/300mg regimen, but in the event the panel backed both regimens by 13 to six.

Lower doses?

Camurus and Braeburn did not fare so well with their candidate, CAM2038. The companies have filed for approval of once-weekly formulations of 8mg, 16mg, 24mg and 32mg and once-monthly formulations of 64mg, 96m, 128mg and 160mg – but it looks like approval will be denied to at least some of these.

Panellists were asked to vote on whether to approve all doses, only some doses, or no doses of CAM2038: 17 said some doses should get the go-ahead, while three were against approval altogether.

Stifel analysts believe that the best-case scenario for CAM2038 would be approval of all doses except once-monthly 160mg, “for which major reservations on lack of data were raised by several panel members”. The worst outcome, meanwhile, would be approval for just the once-weekly 24mg and 32mg doses, which were used in the phase II blockade study.

Camurus and Braeburn’s project does have potential advantages over RBP-6000, including its administration via a narrower-gauge needle and the fact that it does not require cold chain distribution. If a wide range of doses of CAM2038 are approved this could give it another edge. The outlook should become clearer early next year: CAM2038 has a PDUFA date of January 19.

Barring any surprises Stifel expects RBP-6000 to capture 30% of the buprenorphine market, versus 20% for CAM2038. With this segment set to grow as the opioid crisis continues, this would be a result for all the companies involved.

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