Evaluate Vantage

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Durect pushes Posimir to get on the Nash bandwagon

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Durect's perseverance with its non-opioid painkiller, Posimir, looks puzzling, especially with the group recently cutting development costs for its new hope, DUR-928. The company plans to reply to a 2014 US FDA complete response letter for Posimir, despite the failure of a subsequent phase III trial, Persist. Pressing on looks like throwing good money after bad, especially as Durect is not exactly rolling in cash: it had $41.5m in cash and $20m debt at the end of September. In January the group cut back its DUR-928 programme, winding down efforts in primary sclerosing cholangitis and alcoholic hepatitis to focus on psoriasis and Nash; a phase I trial in the latter is due to start dosing this quarter. In lodging a response to Posimir's CRL the company might have a chance of approval, however slim, without shelling out for another trial. And if approved, Durect could seek another partner for Posimir, Stifel analysts noted. Posimir, an extended-release formulation of bupivacaine, had previously been partnered with Novartis's Sandoz division, but that group recently returned rights to Durect. Still, getting the go-ahead for Posimir looks like a long shot, so Durect might soon be looking for another source of funds.

Development of Durect's DUR-928

Setting	Status	Trial	Data due
Psoriasis (topical)	Phase IIa	NCT03837743	H2 2019
Alcoholic hepatitis (IV)	Phase IIa	NCT03432260*	Primary completion Mar 2019
Nash (oral)	Phase I to begin Q1 2019	-	H2 2019
Primary sclerosing cholangitis (oral)	Phase II discontinued	NCT03394781	N/A

**Tranferring to University of Louisville. Source: Clinicaltrials.gov.*