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Nektar’s clearing event clears away $500m

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As a US adcom gives the strongest possible indication that oxycodegol won’t be approved, Nektar’s valuation loses 11%.

Significant doubts had swirled around Nektar Therapeutics’ abuse-proof painkiller oxycodegol long before yesterday’s unequivocal 27-0 US advisory panel vote against approval. Analysts had not expected the product to yield significant revenues, and the company had distanced itself from it.

Why Nektar’s stock fell 11% this morning is therefore something of a mystery. That there had still been hope before the adcom might be a sign of the sorts of unrealistic expectations that exist in the current market, but perhaps the share price fall suggests broad fears about Nektar’s technology.

Evercore ISI’s Josh Schimmer suggested in a note to clients yesterday that Nektar was “bouncing across” scientific application of its pegylation tech. This, he wrote, showed the company to be a jack of all trades but master of none – including oxycodegol, previous Nektar projects and possibly current ones too.

Filing pulled

However lenient the US FDA is being of late it will not have the opportunity to go against its advisors, as Nektar quickly scrapped oxycodegol and pulled its filing. This, it said, would save it $75-125m in 2020; developing the project had cost the group around $250m in total, *EvaluatePharma Vision* estimates.

Oxycodegol, earlier known under the lab code NKTR-181, was a mu-opioid receptor agonist designed to give severe chronic low back pain relief without resulting in CNS-mediated side effects like euphoria that can lead to abuse and addiction.

This was achieved through pegylation, altering the project’s kinetics to reduce its entry into the CNS. However, yesterday’s adcom decided that its potential for abuse had not been adequately addressed: there were resulting concerns over a product that would have been marketed as a “safer opioid” but whose full safety profile had apparently not been characterised.

The shortcuts Nektar had taken to develop oxycodegol had already been highlighted in the panel’s briefing documents – another factor that should have made a negative outcome foreseeable. Against the FDA’s advice the group had run a single efficacy trial, yielding no data beyond 12 weeks, and was thought to be trying to get around this shortcoming by seeking a relatively narrow label.

Distance

The advisory panel had been postponed from last August, but even before that Nektar had sought to separate itself from oxycodegol. Three months earlier it had transferred the project to a legally separate though wholly owned entity, Inheris Biopharma (*Nektar hopes to attract fresh valuation, May 23, 2019*).

If that had been an attempt to minimise any association with the US opioid crisis, and be seen as more of an oncology company, then the adcom result should be seen as a "clearing event" that allows Nektar formally to discontinue oxycodegol. The project carried a consensus 2024 sales forecast of $192m, according to *EvaluatePharma*.

Its efforts will also have been helped by Bristol-Myers Squibb's decision last week to double down on the IL-2 project bempegaldesleukin. Despite the bubble under this asset deflating fast, Bristol moved to add two registrational Opdivo combo studies to bempegaldesleukin's existing three trials.

That had rightly caused Nektar's stock to pop, so today's reaction might simply be a return to normality. But oxycodegol's death should really have surprised no one.

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