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Biogen hints at jobs cuts unless government pays up

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An analyst call over the Aduhelm coverage debacle sees Biogen threaten more cost cutting.

Biogen had already gone on the offensive against Tuesday's proposal by the US Centers for Medicare & Medicaid Services to curtail Aduhelm coverage, and today it directed more venom against what it called an "incomplete and sometimes inaccurate assessment".

An analyst call did lay out some of the company's plans, but perhaps its most extraordinary moment came when Biogen effectively threatened to cut more jobs unless the national coverage determination (NCD) was changed. "We need to be incentivised and rewarded," said the company's chief executive, Michel Vounatsos.

Biogen had already announced $500m of cost-cutting measures last month, alongside halving Aduhelm's annual cost to $28,000. The NCD is still at the draft stage, but "should we be in such a position in April [when the final guidance is due] there will be additional waves. We have to protect the bottom line," Mr Vounatsos said.

He called for interested parties to make their voices heard during the 30-day public comment period now starting. The draft NCD, proposing coverage with evidence development, means that Medicare would only cover patients given Aduhelm in randomised, controlled trials that are approved by the CMS, and in those backed by the NIH.

"I cannot believe that the final NCD position will be the same as the draft," Mr Vounatsos, who is seen by many as fighting for his job in light of the debacle, told analysts. "We don't want unfair treatment for the pioneer [of amyloid-beta research]."

Withdraw?

Asked whether Biogen would consider pulling Aduhelm from the market if the final NCD was unchanged, he said the company would "follow the data and the science. But everything is on the table."

It is clear, therefore, what Biogen does not want to see. As for what it does want, the dream scenario would be open access, but it says coverage with restrictions, to reflect Aduhelm's clinical data, would be a more realistic outcome.

Alisha Alaimo, president of Biogen US, said that even a less onerous coverage with evidence development,

involving a patient registry or more inclusive clinical trials, for example, would limit the number of patients on Aduhelm.

Another thread to Mr Vounatsos's argument was the stick and carrot. He claimed that since 1995 the industry had spent $40bn on Alzheimer's drug development "with the expectation that this would be rewarded", adding that the draft NCD, if implemented, could have a "chilling effect on future innovation".

CMS vs FDA

In a separate statement Eisai, Biogen's amyloid-beta partner, today expressed concern that the guidance called into question the FDA's autonomy and undermined the accelerated approval pathway. But both companies largely avoided commenting on Aduhelm's questionable supporting dataset, which is at the root of a problem that has pitched the CMS against the FDA.

With Aduhelm famously selling just $300,000 in its first full quarter on the market, analyst attention has understandably turned to Biogen's next big Alzheimer's readout, that of lecanemab's phase 3 trial, due in the second half. An obvious question is what Biogen would do should this readout be positive.

It would seem logical then to pivot away from Aduhelm and switch to lecanemab, but on this point the company basically said it would wait and see.