Biogen calls criticism of Alzheimer's drug 'misinformation'

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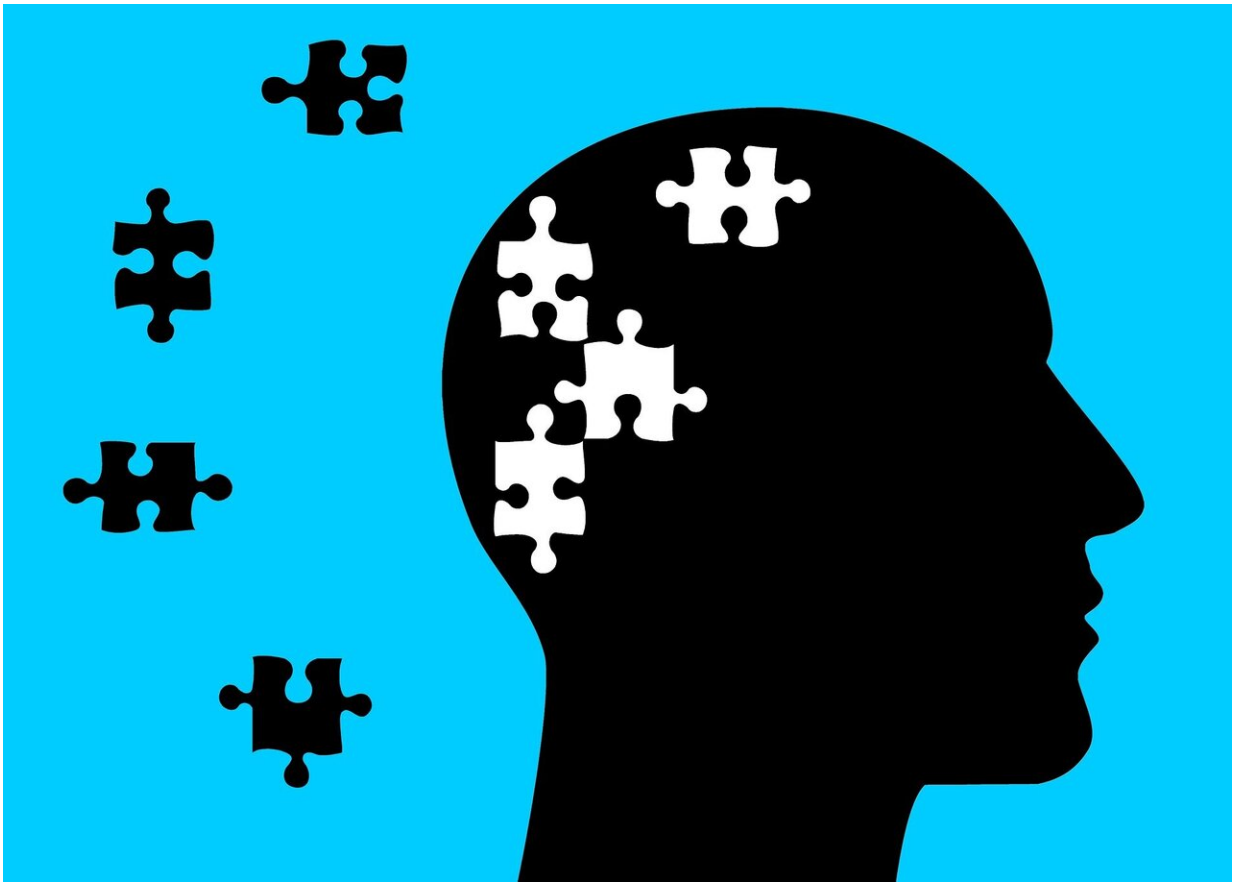

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Biogen Inc. fought back against criticism of the unusual circumstances that led to the U.S. approval of its Alzheimer's drug Aduhelm, saying in

an open letter it has been the subject of "extensive misinformation and misunderstanding."

Aduhelm, approved in June, is controversial because it hasn't been shown to slow cognitive decline. Two big tests were stopped early by Biogen and ended up producing contradictory results. But the Food and Drug Administration still gave it an accelerated clearance on the basis of its ability to remove an abnormal protein called amyloid from the brain.

Since then, the approval has been heavily criticized because of the murky relationship between amyloid and Alzheimer's symptoms, and the close collaboration between Biogen and FDA in analyzing the data. After the approval, three members of an advisory panel that evaluated the drug quit in protest.

"Biogen stands behind the integrity of the review process," Biogen CEO Michel Vounatsos said on a conference call with investors.

Of 900 infusion sites for Aduhelm that were expected to be ready to use the drug shortly after approval, Vounatsos said, roughly 35% had already successfully completed an internal pharmacy coverage review or said the drug would not need an internal review.

Biogen is moving quickly to complete design of the required trial to confirm that Aduhelm actually slows cognitive decline, research head Al Sandrock said on the call. The company expects to complete the study "well ahead" of the regulatory deadline of nine years.

Biogen fell 0.2% at 9:46 a.m. in New York. The shares had risen 32% this year through Wednesday, mainly on Aduhelm's perceived prospects.

In Biogen's open letter, Sandrock said critics of Aduhelm have gone too far.

"There has been a turn outside the boundaries of legitimate scientific deliberation," he said in the letter. In particular, Sandrock said it was unfair to compare Biogen's drugs to many earlier failed anti-amyloid drugs. Those work differently than Aduhelm and weren't able to clear amyloid in the same way, he said.

"The review process that led to accelerated approval was extensive and thorough," he concluded, saying the company recognizes that the process "did not follow a conventional path."

The company raised its revenue guidance for the year and said its Aduhelm gained $2 million in its first partial quarter of sales. Sales will be in a range of $10.65 billion to $10.85 billion, Biogen said, an increase from an earlier forecast that topped out at $10.75 billion.

Quarterly adjusted earnings were $5.68 a share, compared to analysts' expectations for $4.48. Revenues were $2.78, beating analysts' expectations of $2.62 billion

The company needs Aduhelm to counteract declining revenue from its portfolio of multiple sclerosis drugs. Quarterly sales of Tecfidera, which faces generic competition, were $488 million, compared to Wall Street's expectation for $400 million. Meanwhile, sales of Spinraza for spinal muscular atrophy were $500 million, beating estimates.