Evaluate Vantage

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Amyloid testing reaches a limited market

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Never let it be said that the FDA does not have a sense of timing. Two days after Biogen pretty much gave up on its anti-amyloid drug Aduhelm, the US regulator has granted de novo clearance to the first in vitro diagnostic for amyloid plaques. The Lumipulse G β-Amyloid Ratio (1-42/1-40) test, made by Fujirebio, may now be used for patients aged 55 and older who have cognitive impairment and are being evaluated for Alzheimer's disease. The Lumipulse test measures the ratio of two different β-amyloid fragments, 1-42 and 1-40, in cerebral spinal fluid. β-amyloid 1-42 is generally recognised as one of the major constituents of amyloid plaques. While the commercial failure of Aduhelm means that short-term uptake of Lumipulse might not be as good as it could have been, the test could still find a niche. Amyloid is used as a diagnostic criterion for Alzheimer's, and this test might take the place of more expensive and hazardous PET scans. That said, a lumbar puncture is still fairly invasive. Perhaps Lumipulse's best chance of ramping sales will come if another β-amyloid MAb gains approval; Lilly's donanemab and Eisai/Biogen's lecanemab face regulatory decisions this year.

β-amyloid MAbs to the rescue?

Company	Project	Event
Eisai & Biogen	Lecanemab (BAN2401)	Rolling AA submission to complete Q2 2022
Lilly	Donanemab	Rolling AA submission to complete Q2 2022
Lilly	Donanemab	Topline data from Trailblazer-Alz 4, H2H vs Aduhelm, due H2 2022
Eisai & Biogen	Lecanemab (BAN2401)	Topline readout from phase 3 Clarity-AD due Q3 2022
Roche	Gantenerumab	Topline results from phase 3 Graduate 1 and 2 due Q4 2022
Lilly	LY3372993 (N3pG 4)	Pivotal trials to start 2022; project is said to work similarly to donanemab but with better dosing & administration
Lilly	Donanemab	Topline data from phase 3 Trailblazer-Alz 2 due mid-2023

AA: accelerated approval. Source: company statements.