

Roche dents the amyloid hypothesis again



[Madeleine Armstrong](#)

With some big late-stage readouts due in Alzheimer’s disease in the coming year, Roche and AC Immune have reminded investors of the perils of this space. True, hopes were not high for the anti-amyloid MAb crenezumab, which had [already flunked the pivotal Cread studies](#) several years ago. But the latest failure, of a [mid-stage trial in presymptomatic patients with a specific mutation](#), could make the likes of Lilly, Biogen – and indeed Roche – nervous. Roche and AC Immune are not saying much about the data, although the partners appear to disagree about whether numerical differences favouring crenezumab were “small” or not. More details are due at the AAIC meeting on August 2. The latest flop hits the theory that intervening early could halt Alzheimer’s, though the amyloid debate will rumble on, particularly as [crenezumab has not been shown to reduce amyloid plaques](#). This has been seen with Roche’s gantenerumab, Lilly’s donanemab and Biogen/Eisai’s lecanemab. Whether plaque reduction has an impact on Alzheimer’s symptoms remains to be proven, something that pivotal data with these projects will hopefully help clarify.

Upcoming big readouts of amyloid-targeting projects in Alzheimer's

Project	Company/ies	Clinical trial details	Note
Lecanemab (BAN2401)	Biogen/Eisai	Topline readout from ph 3 Clarity-AD due Q3 2022	Rolling BLA for AA submitted May 2022; filing for full approval slated for Q1 2023
Donanemab	Lilly	Topline data from Trailblazer-Alz 4 , H2H vs Aduhelm, due H2 2022; Topline data from pivotal Trailblazer-Alz 2 due mid-2023	Rolling BLA for AA to be completed Q2 2022
Gantenerumab	Roche	Topline data from Graduate 1 & Graduate 2 due Q4 2022	Roche not pursuing AA

AA=accelerated approval; BLA=biologics licence application. Source: company releases & [clinicaltrials.gov](#).

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