



Insight: Have we reached a turning point in the advancement for treatments against dementia?

#clsinsights



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Introduction

The recent clinical trials results announcement around the success of both donanemab, and lecanemab, used to treat dementia, has been met with rapturous enthusiasm – and for good reason: this is the first instance in more than 20 years where new Alzheimer’s medicines have shown real signs of triumph.

The results showed that Eli Lilly’s donanemab slowed cognitive decline in Alzheimer’s patients by 35%, whilst Eisai and Biogen’s lecanemab – having published their results in late 2022 – also showed promise by reducing decline by 27%. Regulatory approval is being sought for donanemab in both the US and UK, as well as a number of other global regulators; whilst lecanemab had confirmation for US regulators in July 2023 that the product can be used as a form of treatment in the United States.

Understanding the scale of the issue

The number of people living with dementia globally is forecast to more than triple to 153 million by 2050, demonstrating the scale of the disease, and the opportunity these medical treatment options present.

In the UK, it would potentially benefit 720,000 diagnosed with emerging Alzheimer's disease, with the Alzheimer's Society CEO – Kate Lee – observing that at present, only 2% of people in England and Wales receive their diagnosis through the specialist investigations needed to be eligible for these treatments.



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A case for optimism

Whilst not a cure, the introduction of medicines like donanemab or lecanemab to dementia sufferers enables the management of treatment for the condition, much like insulin for diabetes is used on patients.

Donanemab removes a protein called amyloid which builds-up inside the brain of those with dementia. The clinical trial – known as Trailblazer ALZ-2 – involved 1,736 participants aged between 60 to 85, with early-stage Alzheimer's, half of whom half were given the Eli Lilly drug, the others receiving a placebo, across the course of an eighteen-month period.

Half of patients on donanemab were able to stop the treatment after a year – only two thirds into the trial – because it had cleared sufficient brain deposits, whilst an average 84% of amyloid plaque was removed at the eighteen-month mark, compared to only 1% removal for those taking the placebo.



Areas of concern

The results of the study are also limited to treating cognitive decline, and not other types of dementia such as vascular dementia. During the course of the study, three deaths were recorded in the donanemab group, with side effects including swelling of the brain – which will no doubt be a concern for regulators.

A further Alzheimer's drug – aducanumab – was rejected by European regulators owing to safety concerns and effectiveness.

NICE (National Institute for Health and Care Excellence) is currently assessing whether it can be used in the NHS. In the US, approval for lecanemab was granted earlier this month (July 2023), where the drug is licensed at \$27,500 – whilst awaiting approval for donanemab. The disparity for dementia treatment either side of the Atlantic will be interesting to observe these coming months.

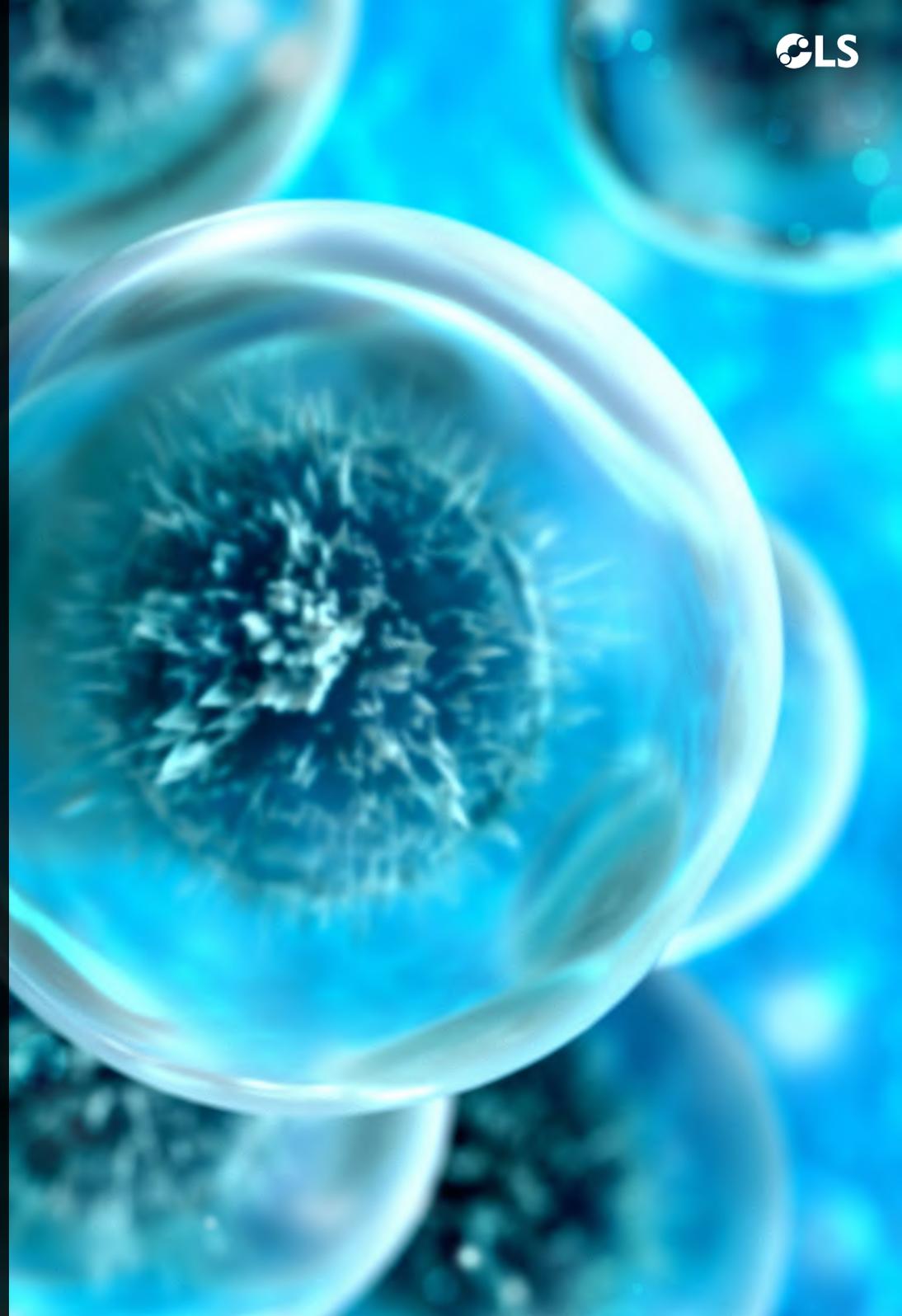
What the future holds

After more than two decades of limited medical success in the fields of Alzheimer's treatment, the two successfully will no doubt accelerate investment and interest from an M&A perspective within the neuro therapeutic area.

Neurogene and Neoleukin completed their merger to operate under the brand, Neurogene Inc., in what their press release has outlined as “a transformative step forward in our mission to bring life-changing genetic medicines to the patients and families impacted by devastating neurological diseases”.

Beckman Coulter announced it has partnered with Fujirebio, focussing on developing and marketing blood tests for Alzheimer's, with the objective of combining the latter's neurological biomarker and assay experience with the former's globally installed base of lab hardware.

Both instances demonstrate pharmaceutical businesses renewed appetite to enter the neurological space, particularly addressing Alzheimer's disease and the treatments thereof.



References

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