Breakthrough Alzheimer's drug approval seen to renew dementia drug investments and increase the potential for digital dementia therapies – good news for Brain+

Copenhagen, Denmark, July 10, 2023 – Brain+ A/S (Nasdaq First North: BRAINP)

- The US FDA has granted full approval to Lecanemab, the first ever disease modifying treatment for early Alzheimer's disease, invented by BioArctic AB of Sweden and developed by Eisai and Biogen

- Lecanemab has shown to slow brain destruction in Alzheimer's, and after decades of drug failures in the field, experts now see a turning point to renewed investments in dementia drug research and the start of a new era of treatment

- Dementia represents an immense unmet need - and there is growing acknowledgement of the role of digital approaches to compliment pharmaceutical treatments in building a more effective dementia ecosystem

- Brain+ is a pioneer in the development of evidence-based digital dementia therapeutics to improve cognition in people with early Alzheimer's dementia, and the recent industry news is seen to increase the company's potential to attract co-development partnerships

Kim Baden-Kristensen, CEO of Brain+ comments on the implications for Brain+ of the recent industry news and the growing interest for new dementia treatment approaches:

"*Dementia represents a heavy burden on people and societies on a global scale, but for many years, the pharmaceutical industry's multi-billion investments and eager attempts to develop new and more effective medical treatments of mainly Alzheimer's dementia have been a graveyard of failures. With positive trial results and the approval of Lecanemab, we now witness a clear renewal of interest and investments in new dementia treatment approaches– which includes a more holistic view on better disease management with support from digital therapeutics. Increasing pharma interest in digital therapeutics also stems from clear regulatory and reimbursement pathways being established these years, which is key for the clinical adoption of digital products. All this is good news for a company like Brain+, as we are well positioned with several digital therapeutic products, all building on an already well established, evidence-based and clinically relevant analogue dementia therapy, Cognitive Stimulation Therapy (CST), which has consistently shown to enhance the effect of Alzheimer's drugs*."

FDA approval of the first ever disease modifying drug for early Alzheimer's disease

On 6 July 2023, Lecanemab was granted full approval from the US FDA with an indication to slow disease progression in people with early Alzheimer's Disease. The approval is based on a unanimous recommendation by an FDA advisory panel and follows an accelerated FDA approval of the drug in early January. This means that for the first time ever a disease modifying treatment has become broadly available for people with early Alzheimer's. Lecanemab (US brand name: Leqembi™) was invented by Swedish BioArctic AB (Nasdaq Stockholm: BIOA B) and is the result of a development collaboration between Japanese Eisai Co. and Biogen of the US.

Huge unmet needs in dementia – and Lecanemab approval expected to spur new era of treatment

WHO estimates that more than 55 million people are living with dementia. This number is estimated to rise to 78 million by 2030 and to 139 million by 2050. Alzheimer's is the most common cause of dementia, accounting for around 60% of cases.

The pharmaceutical industry has invested billions of dollars in the development of effective drugs to meet the needs for better treatment of dementia. However, for decades these investments have resulted mainly in failures. With the breakthrough clinical effects shown with Lecanemab and the subsequent approval of this new drug, experts foresee a strong increase in pharma pipeline investments and a whole new class of effective drugs being available forAlzheimer's dementia after a long period of very limited new treatment options.

Non-pharmaceutical Cognitive Stimulation Therapy (CST) can enhance the effects of dementia drugs

Renewed interest and investments in the global dementia drug pipeline bode well also for the potential in new combination approaches, combining new clinically meaningful dementia drugs with non-pharmaceutical treatment offerings, in particular digitally delivered therapies.

In a systematic Cochrane review from January 2023 based on results from 37 randomized controlled clinical trials, it was concluded that combining non-pharmaceutical Cognitive Stimulation Therapy (CST) with drug treatments provides enhanced cognitive benefits compared to drug treatment alone for people with mild to moderate dementia (2nd systematic Cochrane review (Woods et al., Jan 2023)). Further, clinically relevant improvements were found in communication and social interaction as well as slight benefits in a range of outcomes including Quality of Life, mood and behavior that challenges.

Brain+ digital CST products well positioned to complement the Alzheimer's drug pipeline

The potential for drug-digital stimulation combination treatments to better manage Alzheimer's dementia represents a major opportunity for Brain+. While there are 140+ potential drug candidates, currently Brain+ is the only known company to focus on digital delivery of Cognitive Stimulation Therapy (CST), which is the non-pharmaceutical therapy with the strongest evidence base worldwide. CST was in 2022 recommended for global implementation by the major policy prescribing NGOs Alzheimer's Disease International and highlighted by WHO as part of the dementia solution.

The focus of Brain+ is to deliver digital dementia products, backed by clinical evidence, to attain status as medical devices for prescription and payer reimbursement, like a drug. This places Brain+ in a unique position to bring value to the Alzheimer's space and to developers of new dementia drugs via co-development and/or licensing agreement covering its digital therapies for combination treatments.

Growing acknowledgement of the potential in digital solutions from both policy makers and pharma

In their '*Global status report on the public health response to dementia'* from 2021, WHO highlights the urgent need to strengthen dementia support at national level, both in terms of care for people with dementia, and in support for the people who provide that care, in both formal and informal settings.

During recent years, both the EU and US have established regulatory pathways for digital healthcare products, and large countries like the UK, Germany and France have established reimbursement pathways to further support the development and implementation of digital solutions in healthcare. In response, the pharma industry is starting to realize the attractive potential in combining drugs with digital therapeutics for enhanced treatment benefits. As an example, Eisai's has in its business plan, EWAY2025 announced an intension to build up or collaborate on digital solutions for early diagnosis and early treatment. Subsequently, the Japanese pharma company has announced two collaborations around digital tools in the dementia field: one with Cogstate on the company's digital test for self-assessment of cognitive function (Eisai-doubles-down-cogstate-digital-cognitive-tool-pact) and another broader research collaboration for the development of digital tools for dementia diagnosis and treatment (Eisai launches Gates-backed research collab to develop digital tools for dementia diagnosis, treatment).

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About Lecanemab

Lecanemab is a new treatment approach based on monoclonal antibodies against the amyloid beta (Aβ) protein which is accumulating in the brain of people with Alzheimer's disease, affecting and disabling normal brain function. The accumulation of Aβ results in brain plaques and is the main course of Alzheimer's dementia.

Lecanemab received accelerated FDA approval on January 6, 2023, and was launched in the U.S. on January 18, 2023. The accelerated approval was based on results from a Phase 2b study demonstrating that lecanemab reduced the accumulation of Aβ plaques in the brain. In June, an FDA advisory committee evaluated results from a confirmatory Phase III Clarity AD trial. The advisory committee agreed that Clarity AD verified the clinical benefits of lecanemab and unanimously recommended the new drug for traditional approval. On July 6, 2023, FDA granted full approval of lecanemab.