

NEWS RELEASE

## Brain+ confirms imminent commercial launch of *Ayla – your CST Assistant* as a medical device in the UK

Copenhagen, Denmark, 25 September 2024 – Brain+ A/S (Nasdaq First North: BRAINP)

**Summary:** Brain+ A/S (“Brain+” or the “Company”) has to date in 2024 achieved all planned development and go-to-market milestones and is now ready for launch of *Ayla – your CST Assistant* in the UK. The product will launch as a UK Class I medical device software, which is a validation of the product’s clinical efficacy and safety and key to opening the doors to the dementia care market. Regulatory certification will position *Ayla – your CST Assistant* as the only medical device software in the UK to deliver Cognitive Stimulation Therapy (CST) - the one non-pharmacological dementia therapy, which is recommended in the country’s national health guidelines. Brain+ has established a UK presence and started executing a sales plan that shall lead to the first NHS evaluation track sales contracts in Q4 2024. Building from the first contracts and with three additional *Ayla* product launches in 2025, the Company retains earlier communicated expectations of annual recurring revenue (ARR) of DKK 7-8 million by end 2025 and ARR of DKK 25-27 million by end 2027.

Brain+ has advanced significantly in line with its UK focused go-to-market strategy and continuously through Q3 2024 delivered on the remaining outstanding milestones before being ready to launch *Ayla – your CST Assistant* into the UK dementia market (See Brain+ news release from 23 August 2024: [‘Fully on track towards market entry and first sales in the United Kingdom in H2 2024’](#)). The UK is the most attractive European market for Brain+’ suite of digital dementia care products to deliver and support Cognitive Stimulation Therapy (CST), recently rebranded under the name of *Ayla*. *Ayla – your CST Assistant* will be launched in the UK in week 30 September – 4 October 2024 and Brain+ is on track towards reaching the next important milestones of first UK sales in Q4 2024 and commercial scaling.

### **Launch of *Ayla – your CST Assistant* as certified Medical Device secures a strong competitive position**

Certification in accordance with UK Medical Device Regulations puts *Ayla - your CST Assistant* in the ‘medical’ category, making the product stand out from non-medical dementia products *and* giving it a unique position on the UK market. The Medical Device status validates the product’s clinical benefits and software quality and is perceived by the UK National Health Service (NHS) as a key stamp of product quality and relevance, thus supporting clinicians’ and other key dementia care stakeholders’ adoption and willingness to pay for the product. With the certification Brain+ can make medical claims on the clinical efficacy, user relevance and safety of *Ayla – your CST Assistant*, documenting its product value and supporting higher price and reimbursement levels.

**Simon Nielsen, Chief Innovation & Strategy Officer, Brain+** commented:

*“I am very pleased that years of diligent work is now paying off with our product being ready for commercial launch in the UK as a medical device software with documented benefits for people with dementia and healthcare providers. The UK regulatory*

*certification is also a key step in securing our competitive position, as we start embarking on our 2025 product roadmap to broaden our Ayla suite of digital dementia products and extend our offerings to the UK dementia care system. I feel convinced that we stand on the brink of starting to realize our ambitions of building a leading dementia care and management platform for the benefit of people with dementia in the UK and beyond."*

### **Progressing according to plan towards first UK sales in Q4 2024**

Brain+ has diligently delivered on its UK focused commercial strategy and market access plan for 2024 and achieved several important milestones year to date.

#### Milestones achieved by Brain+ to date in 2024

- √ Build UK Market Access and Commercial Scaling plan
- √ Submitted application for *Ayla - your CST Assistant* to be included on the G-Cloud-based procurement platform used by the NHS
- √ Conducted the first UK usability study of *Ayla - your CST Assistant* in partnership with Age UK
- √ Established a UK subsidiary, Brain+ UK Ltd, to enable NHS sales and open access to UK-based funding
- √ Significantly strengthened its in-house commercial competencies with the hire of Devika Wood as new UK-based Chief Commercial Officer and the subsequent hire of UK-based Fiona Castello as SVP Partnerships
- √ Completed the development of both the technological platform and the UK content of *Ayla - your CST Assistant* – and advanced the product to final Quality Assurance phase
- √ Finalized the Clinical Evaluation Report (CER) for *Ayla - your CST Assistant*
- √ Obtained validation of the CER and the clinical relevance of *Ayla – your CST Assistant* from Professor Aimee Spector, University College of London (UCL), the developer of CST
- √ Launched Ayla, as the new overarching brand name for full suite of digital CST-based dementia products, included *Ayla – your CST Assistant* as the UK brand name for the CST-Assistant
- √ Developed a product roadmap, adding three new Ayla dementia care and management products to the pipeline, all targeted for release in 2025
- √ Obtained positive results of the Age UK usability study documenting cost benefits and product market fit of *Ayla – your CST Assistant*

With a UK dementia market ripe for scalable CST adoption, *Ayla - your CST Assistant* validated and ready for launch as a Medical Device Software, and a targeted commercial plan in place to be executed by an experienced commercial team, scalable sales and proof-of-business are within reach. For further information on Brain+' commercial plan and sales revenue targets for 2025-2027, see news release from 13 September 2024: ['Brain+ is set to deliver on an ambitious UK commercial plan to reach recurring revenue of DKK 7-8 million by 2025 and DKK 25-27 million by 2027'](#)

## UK market access and commercial milestones for the rest of 2024

- **September – Launch new Brain+ branding and awareness campaign**  
Build a strong and recognizable brand to support the commercial introduction of the Ayla suite of products as unique and valuable CST offerings to support dementia care and management.
- **September – Launch *Ayla - your CST Assistant* as a Medical Device Software to offer scalable CST**
- **October – Initiate targeted outreach to identified key CST stakeholders and dementia decision makers in selected NHS trusts**
- **October - Publish White Paper on *Ayla - your CST Assistant***  
The White Paper will highlighting the documented clinical benefits of our product as a new and innovative approach to high-quality and scalable CST delivery that actively addresses the current barriers to scaled adoption of this highly relevant therapy in the UK.
- **October – Host webinar with key partners and CST advocates**  
The webinar will introduce key dementia care stakeholders to the benefits and potential of CST and to *Ayla - your CST Assistant* as a valuable tool for scalable delivery of CST, thus bringing the white paper and its core messaging to life.
- **November/December – Build pipeline of active customer leads among NHS Trusts**
- **November/December – Close the first ‘Evaluation Track’ sales contracts with the NHS**  
NHS ‘Evaluation Track’ contracts typically range values of £10,000-30,000. Such early contracts are expected to set the basis for the transition into larger, recurring SaaS contracts with the NHS from 2025.

### **Contact Information**

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**Brain+ mission:** Become the preferred provider of certified healthtech solutions for better dementia care and management, servicing one million people affected by dementia by 2030.