



Lundbeck



# Maintaining profitable, sustainable growth

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# The Neuroscience market is on a growth trajectory as new areas of unmet medical need are being served

## Rapidly growing knowledge

Scientific articles for  
**“Neuroscience” grew 4x**  
from 2010-2020\*

## Many exciting new advances

**Rapidly evolving science,**  
technologies and methodologies

## Expanded drugability

Multiple drug modalities such as  
**small molecules, antibodies**  
**and SMiRNAs**

## Increased regulatory approvals

FDA neuroscience approvals  
**grew 12% annually**  
from 2012-2021\*\*

## Escalating investments

Investments in neuroscience  
**grew 23% annually\***  
from 2012-2021

## CNS is delivering in the 2020s

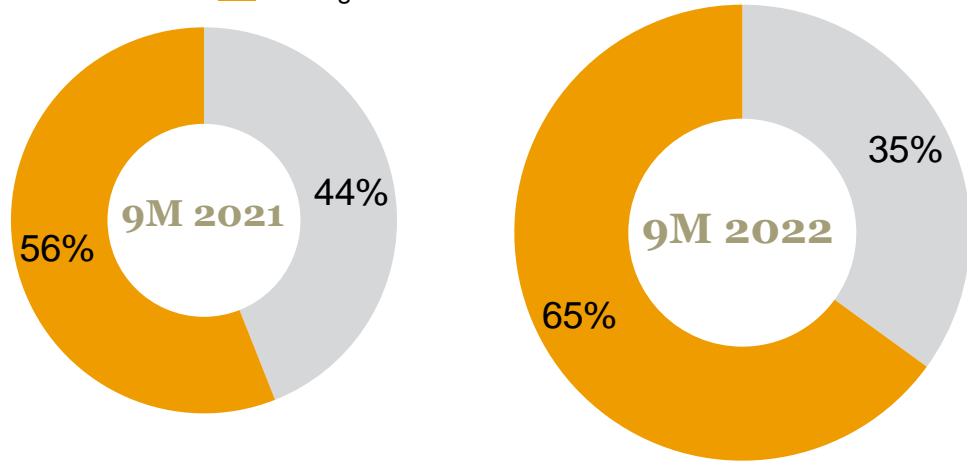
The neuroscience market is  
forecasted to  
**grow 11% annually**

**Lundbeck’s neuroscience heritage and global footprint enables us to capitalize on these shifts**

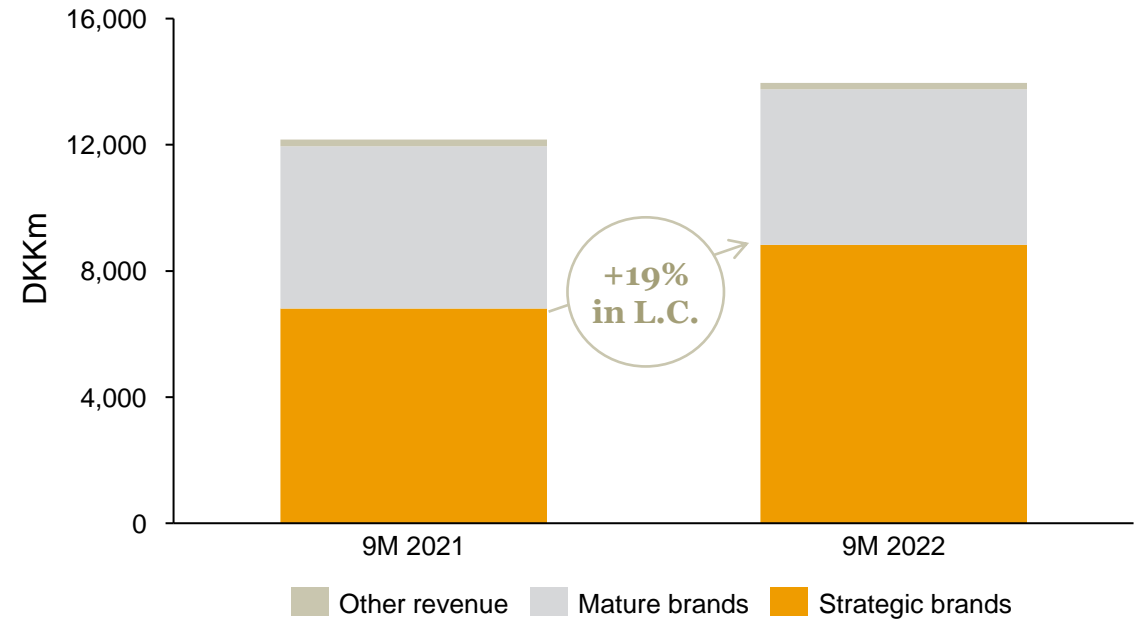
# Strategic brands powering growth across the portfolio

## % Revenue contribution

■ Mature brands incl. Other revenue and hedging  
■ Strategic brands



## Strong growth from strategic brands



Key drivers of revenue in period



### Strategic

Continued double digit growth across all regions



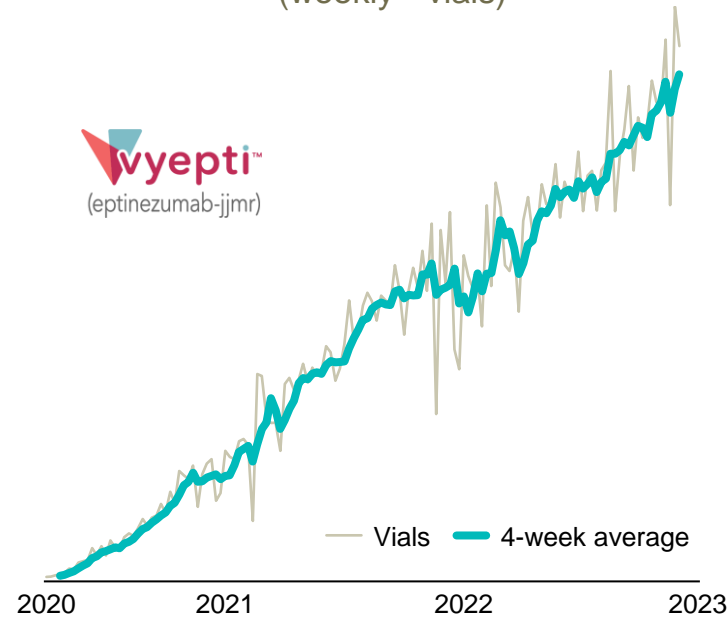
### Mature

- CipraleX/Lexapro continues to be very stable

# Vyepti: Strong growth in the U.S.



## U.S. Vyepti demand\* (weekly - vials)



Vyepti was approved by FDA in February 2020 and by the EU Commission in January 2022. \*) Weekly data view through December 9, 2022. \*\*) Thru October 2022

## U.S. growth advances

- Prevention market share continues to grow in the U.S.: 5.0%\*\*
- Patient persistency on Vyepti exceeds competition



# Vyepti: Global rollout progressing as planned



## Strong adoption across new markets

- Launched in nine markets in 2022, namely Australia, Canada, Denmark, Estonia, Finland, Germany, Singapore, Sweden and Switzerland
- Volume share of prevention market:
  - 13% market share in U.A.E.
  - 4% in Switzerland (5<sup>th</sup> month)
  - 0.4% in Germany (1<sup>st</sup> month)
- Several launches planned for 2023, including launch in the UK

# Strong Brintellix/Trintellix growth underpinned by excellent efficacy profile

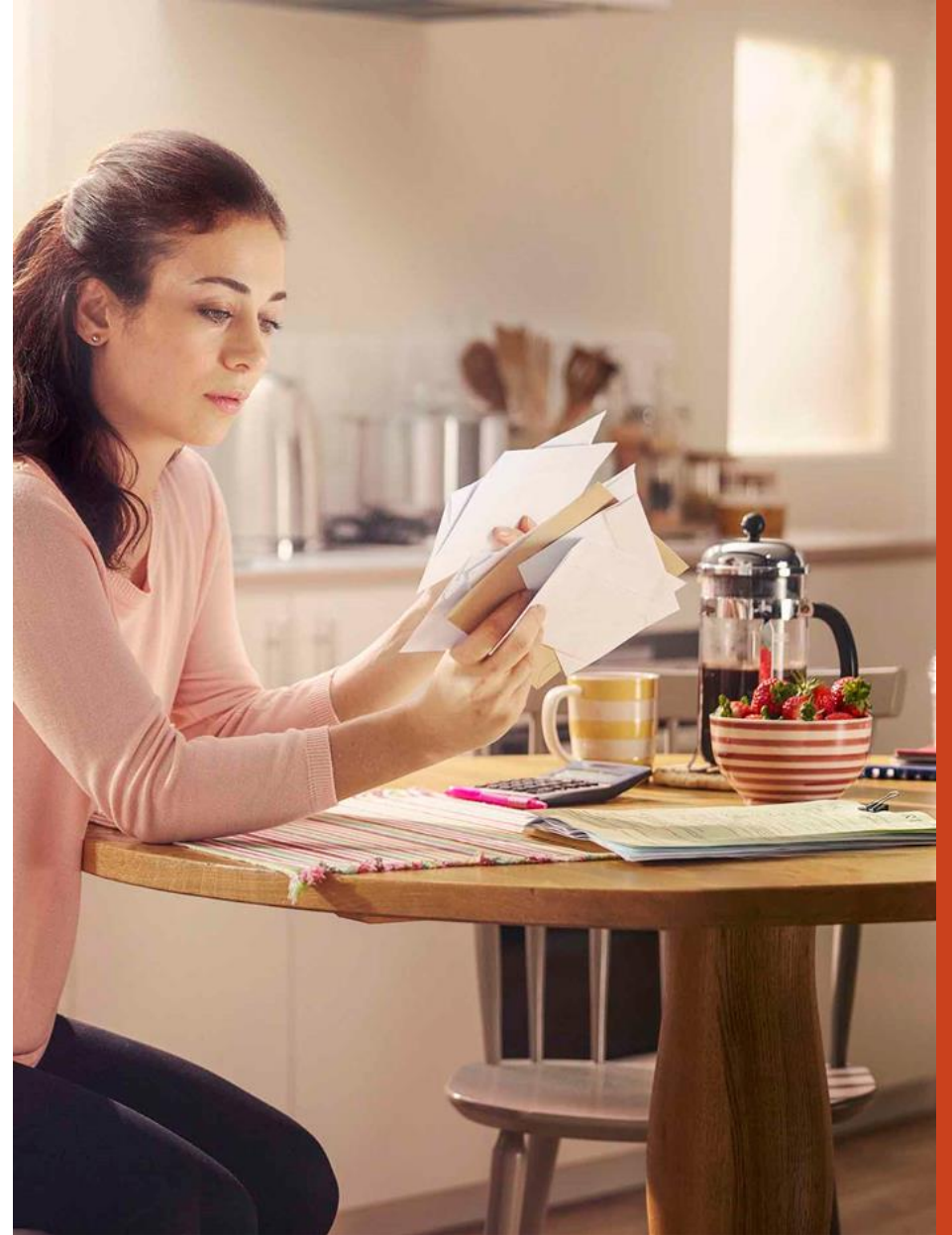
## Continued strong growth in Japan

- 9.1% value market share (up 3.3ppt in 2022)
- Benefitting from stronger positioning due to increased adoption by psychiatrists as a first-line of treatment

## Strong growth continues in Europe and International Markets

- Canada, Spain, China and Italy are growth leaders
- Strong growth in prescribing GPs, e.g. in Spain
- Positive momentum across multiple other markets

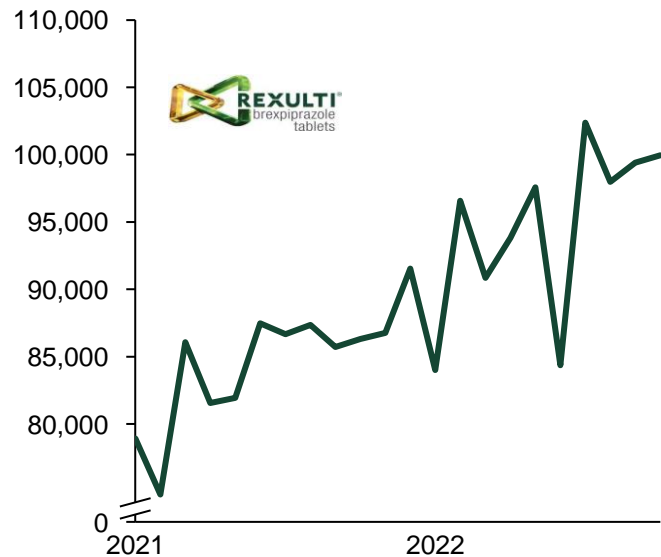
*Trintellix was approved by FDA September 2013 and Brintellix by EMA December 2013*



# Rexulti continues to show strong volume growth



**U.S. Rexulti demand\***  
(Monthly - TRx)



Rexulti was approved by the FDA July 2015 and by the EU Commission July 2018.. \*) Bloomberg, data ending November 2022.. \*) AAD: Agitation in Alzheimer's Disease

Continued strong growth momentum in the U.S...

- Share at all time high
- Number of R<sub>x</sub> increased with strong in person promotion and DTC offering
- AAD\*\* launch preparations underway

...and in countries such as Brazil and Canada

- Dynamic growth in Canada of close to 30% y/y with volume share now at ~3.2%
- Brazil more than doubled sales with volume share now at ~1.8%



# Brexpiprazole offers an exciting treatment option for patients with Agitation in Alzheimer’s Dementia (AAD)



An estimated **6.5 million** patients with AD in the U.S. increasing with at least 100,000 patients per year\*



## Blockbuster potential

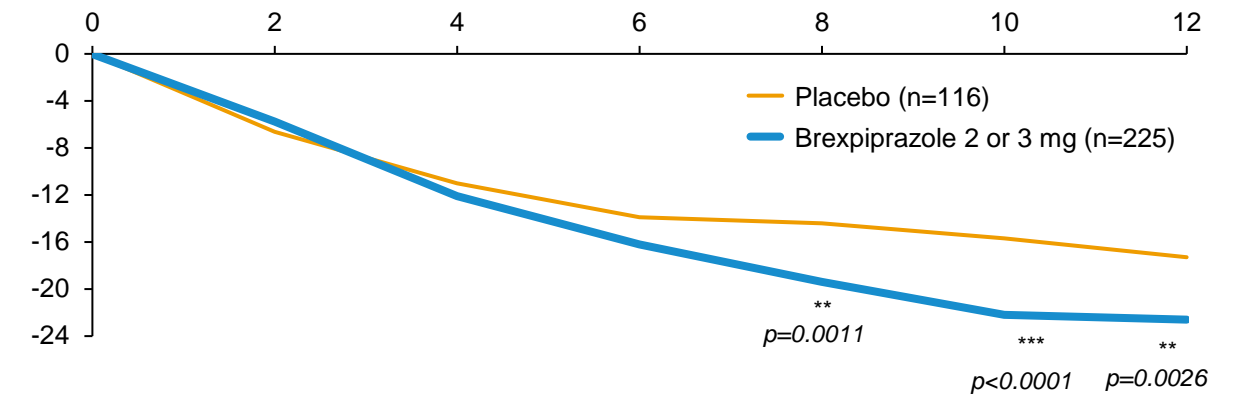
AAD has blockbuster potential for the Lundbeck/Otsuka alliance



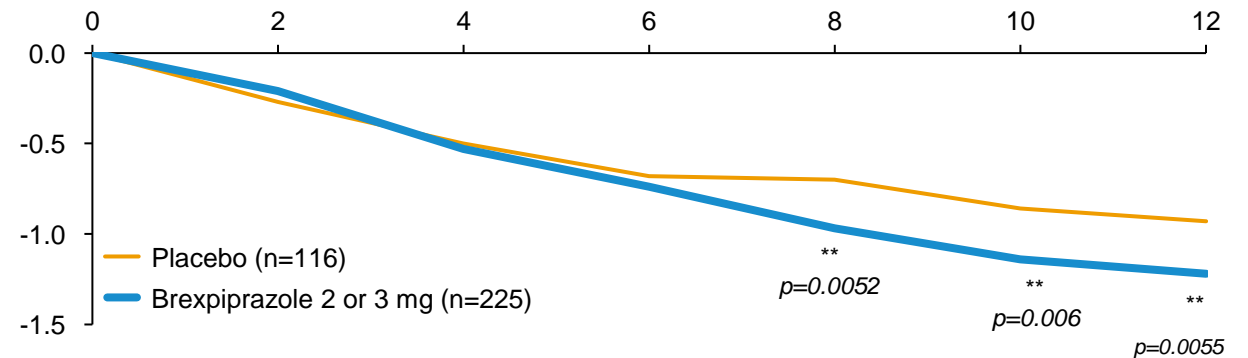
## No approved treatments for AAD

- >30% of patients with dementia are prescribed antipsychotics
- Antipsychotics prescribed for AAD patients are limited by their tolerability profile, e.g. heavily sedating and EPS\*\*\*

Primary Endpoint: Change from Baseline in CMAI Total (MMRM) (Study 213)



Key Secondary Endpoint: Change from Baseline in CGI-S score (MMRM) (Study 213)



\*) 2022 Alzheimer’s Disease Facts and Figures, *Alz & Dem.*, 2022, 18: 700-789. \*\*) Halpern R. et al. *Int. J. Geriatr. Psychiatry* 2019; 34: 420-431. \*\*\*) EPS: Extrapyramidal Symptoms. MMRM: Mixed Model Repeated Measures. CMAI: Cohen-Mansfield Agitation Inventory. CGI-S: The Clinical Global Impressions Scale



# Getting ready to launch aripiprazole 2M RTU

## Abilify Maintena continues to show solid growth -13% in L.C

- Growth mainly driven by the U.S., Spain and Canada

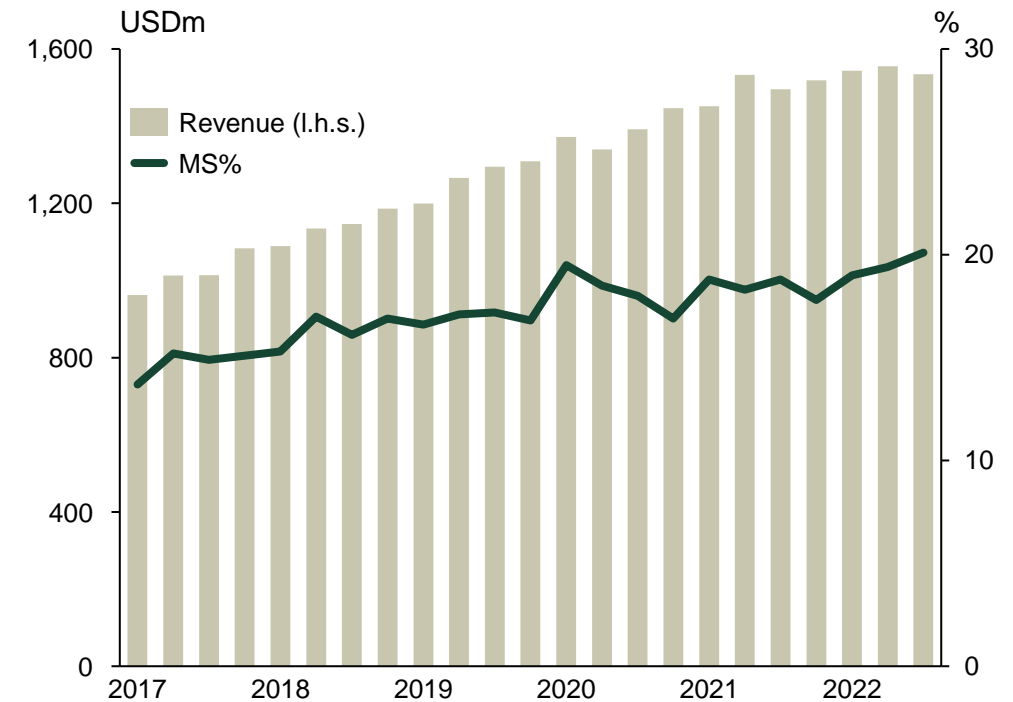
## Strong market share gains in Europe

- Exceeding 30% market share in countries such as Italy, Switzerland and U.K.
- In key markets, Abilify Maintena is growing faster than the aLAI market

## Regulatory process for 2-month formulation initiated

- The FDA target date (PDUFA date) for completion of the review is April 27, 2023
- Also submitted in Canada and Europe

**Global LAI sales and Abilify Maintena MS%**  
(Quarterly – USD and %)



RTU: Ready To Use formulation. aLAI: Atypical Long-Acting Injectable Antipsychotics

# Lundbeck's strategic journey to expand while focusing

We stay true to our neuroscience heritage

## 2021 and beyond

Specialist neurology (incl. pain)
Rare disease neurology
Specialist psychiatry

## 2019



We are targeting specialist treated indications with impactful medicines

- Well-defined patient segments
- Severe diseases with clear unmet medical needs

We execute in alignment with our strategy

- Work on programs with strong biological rationale
- Early de-risking through biomarker driven experimental medicine
- A well-defined and actionable path towards chosen specialist indications



# Streamlined R&D platform with strong progress in developing the product pipeline

Biology	Project	Area	Phase I	Phase II	Phase III	Filing/launch
Hormonal / neuropeptide signaling	Eptinezumab (anti-CGRP mAb) <sup>1)</sup>	Migraine prevention	SUN-studies			PROMISE 1 & 2
	Eptinezumab (anti-CGRP mAb) <sup>1)</sup>	Episodic cluster headache	ALLEVIATE			
	Eptinezumab (anti-CGRP mAb) <sup>1)</sup>	Chronic cluster headache	CHRONICLE			
	Lu AG09222 (anti-PACAP mAb) <sup>2)</sup>	Migraine prevention	HOPE			
	Lu AG13909 (anti-ACTH mAb) <sup>3)</sup>	Neuro-hormonal dysfunctions				
Circuitry / neuronal biology	Brexiprazole <sup>4)</sup>	Agitation in Alzheimer's disease				
	Brexiprazole <sup>4)</sup>	PTSD				
	Aripiprazole 2-month injectable formulation <sup>5)</sup>	Schizophrenia & bipolar I disorder				
	Lu AF28996 (D1/D2 agonist)	Parkinson's disease				
	Lu AG06466 (MAGL inhibitor) <sup>6)</sup>	MS spasticity, PTSD, ect.				
Protein aggregation, folding and clearance	Lu AF82422 (anti alpha-synuclein mAb)	Synucleinopathies (MSA)	AMULET			
	Lu AF87908 (anti-Tau mAb)	Tauopathies				
Neuroinflammation / neuroimmunology	Lu AG22515 (CD40L inhibitor)	Neurology				

**Streamlined R&D organization in place focused on four biological clusters for innovation**

**Biomarker driven development with active portfolio management: "Up or out"**

**Strong progress in both late-stage LCM as well as the early and mid-stage pipeline**

**Potential to improve longer-term pipeline through BD (in-licensing, M&A)**

1) CGRP: Calcitonin gene-related peptide. 2) PACAP: Pituitary adenylate cyclase-activating polypeptide. 3) Adrenocorticotrophic hormone. 4) Acts as a partial agonist at 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors at similar potency, and an antagonist at 5-HT<sub>2A</sub> and noradrenaline alpha<sub>1B/2C</sub> receptors. 5) Life cycle management in partnership with Otsuka Pharmaceuticals. 6) MAGL: Monoacylglycerol lipase



# Strong progress in the pipeline

- Vyepti approved in EU and continued global regulatory roll-out
- Brexpiprazole **positive phase III data** in Agitation in Alzheimer's Disease
  - Submitted for regulatory approval in the U.S. and Canada
- Aripiprazole 2-month formulation (ready-to-use long-term injectable) **submitted for regulatory approval** in the U.S., EU and Canada
- Brintellix/Trintellix **LCM program concluded successfully** with strong support for its unique profile
- Two phase II/PoC programs **completed enrollment**, awaiting results in 2023/2024
- First **neuroimmunology** and **neurohormonal** programs entered into clinical development
- Rich innovative Research pipeline established, including **SMiRNA** modality class

SMiRNA: *Small molecules interacting with RNA*



# Lu AG09222 holds the potential to be first-in-class with a differentiated approach to migraine prevention



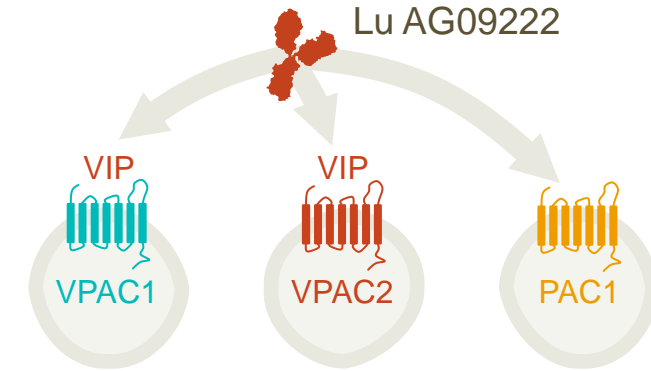
**Medical condition**  
Migraine (prevention)



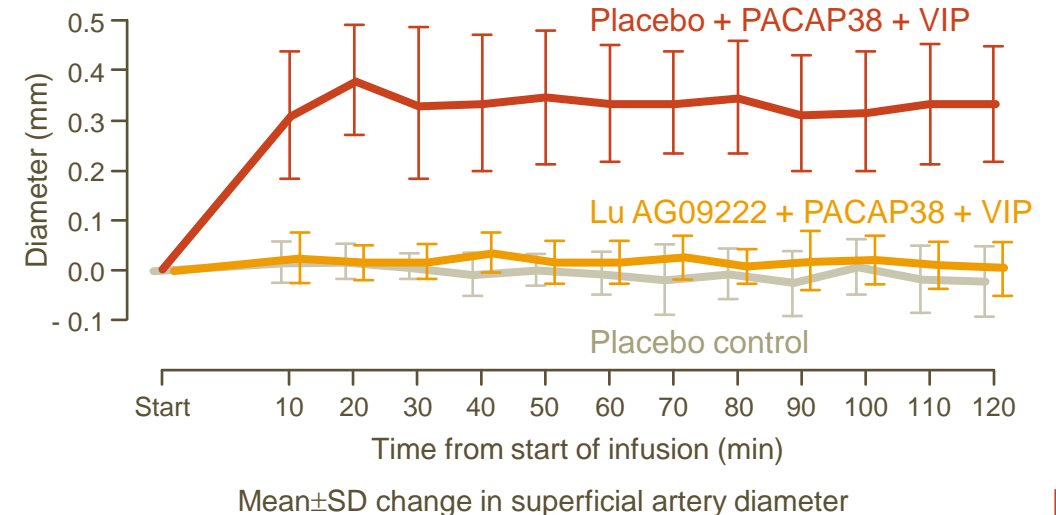
**Molecule**  
Anti-PACAP\* humanized IgG1 antibody



**Highest phase for lead asset**  
Phase IIa: Prevention of migraine in adults not helped by prior treatments



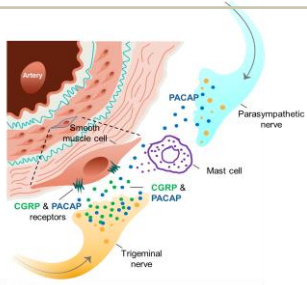
## Robust clinical data supporting MoA



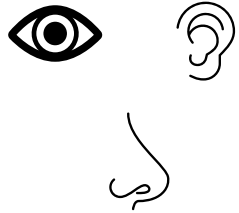
Notes: \*PACAP: Anti-pituitary adenylate cyclase activating peptide. VIP: Vasoactive intestinal peptide



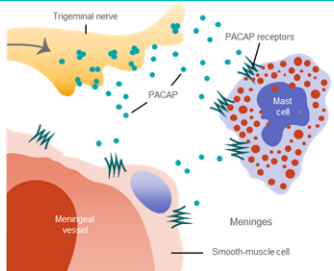
# The potential of PACAP inhibition provides opportunities beyond migraine



PACAP relaxes smooth muscle cells leading to **vasodilation**, and **activates** key components of the **trigeminovascular system**



PACAP is involved in **parasympathetic activation** and thereby the presentation of **cranial autonomic symptoms**



PACAP stimulates **mast cell degranulation** and **neurogenic inflammation**

These effects all contribute to **migraine** and in other **pain conditions** and can potentially be prevented by an **anti-PACAP treatment**



# Lu AF82422 in phase II - Potential first therapy delaying disease progression in Multiple System Atrophy



## Medical condition

Alpha-synucleinopathies: Multiple System Atrophy  
– A rare, aggressive, disease with a high unmet medical need



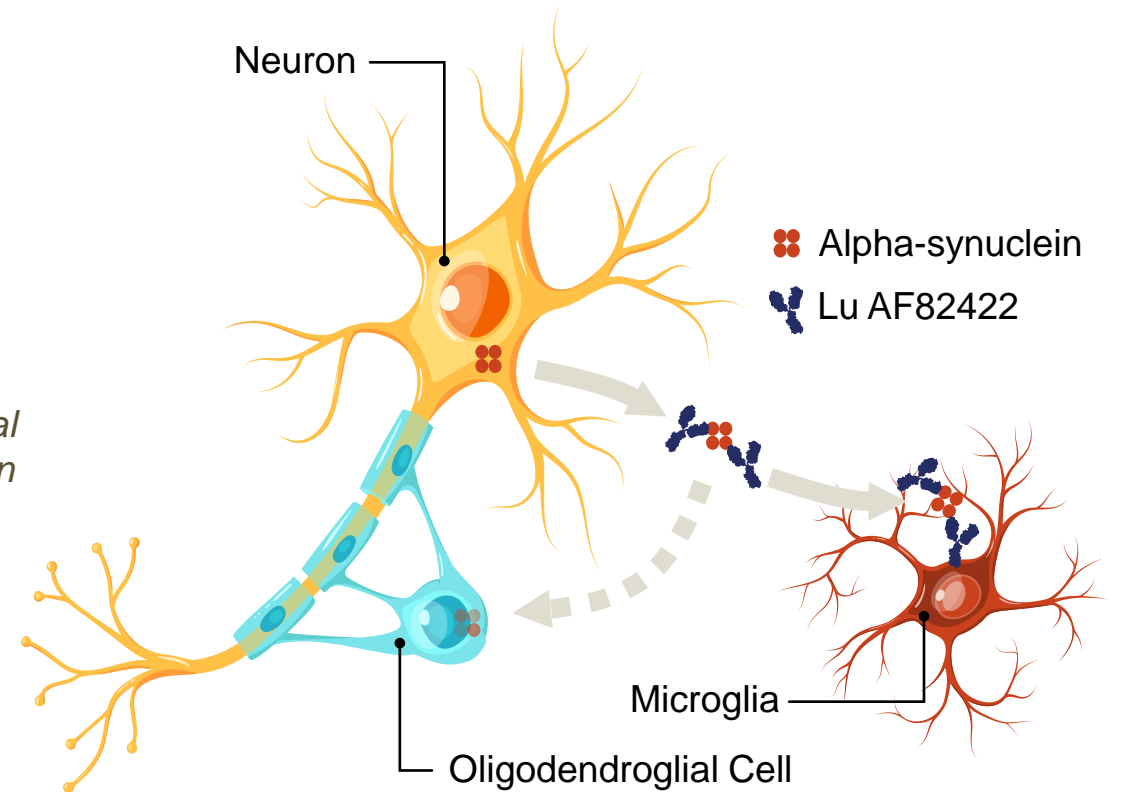
## Molecule

Anti alpha-synuclein IgG1 antibody  
– Binds to multiple species of alpha-synuclein, including C-terminal truncated forms, and shows target engagement on the monomer in CSF



## Highest phase for lead asset

Phase II: Innovative and adaptive, supported by biomarkers



# Lu AG22515 – first neuroimmunology program progressing in phase I



## Medical condition

Immune-mediated nervous system disorders



## Molecule

Differentiated anti-CD40L antibody-like drug candidate

- Recombinant bispecific scFv-Fab fusion protein, which binds to human serum albumin
- Longer half-life expected due to SAFA technology and possibly better safety profile than competitors



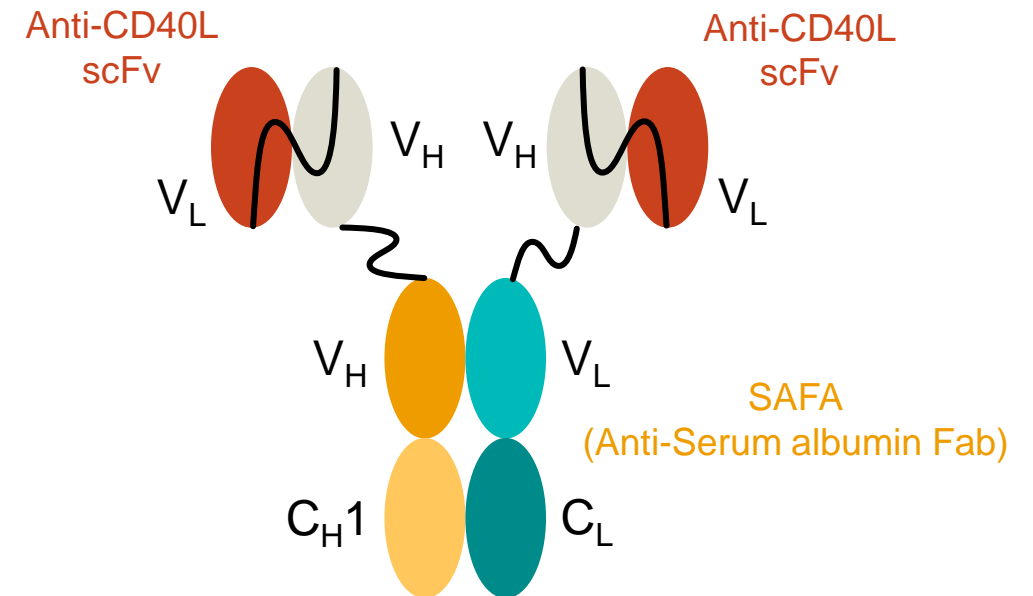
## Highest phase for lead asset

Phase I: Selecting the most promising indications

- Clinical development program initiated March 2022
- Pipeline in a product – Several potential indications

## Molecular structure of Lu AG22515

(scFv)<sub>2</sub>-Fab fusion  
Molecular weight ~ 100 kDA



Notes: scFv: single-chain Variable Fragment; Fab: Fragment antigen binding region; SAFA: Anti-Serum Albumin Fab;

# Lu AG13909 – first neurohormonal program started clinical development



## Medical condition

Neurohormonal dysfunctions related to HPA axis



## Molecule

Anti-ACTH humanized IgG1 antibody

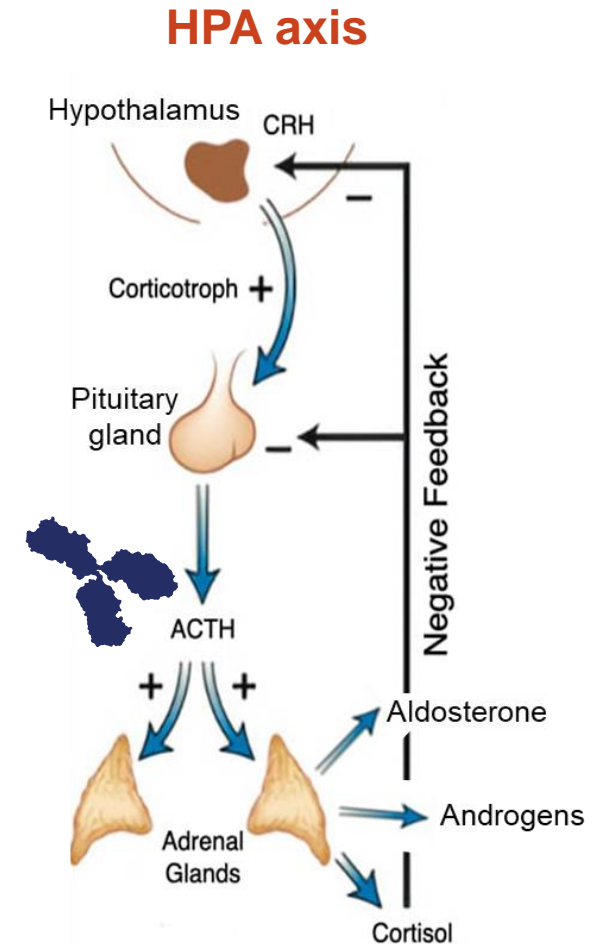
– *First in class mAb with potential to offer a safe and efficacious treatment alternative to patients suffering from conditions with increased ACTH*



## Highest phase for lead asset

Clinical development program was initiated December 2022

ACTH: Adrenocorticotrophic hormone. HPA axis: Hypothalamic-pituitary-adrenal axis



# Selected deliverables 2023

- Vyepti: Continue global roll-out through 2023
- Aripiprazole 2M RTU: FDA, Health Canada and EMA approvals  
*(Expected Q2 and Q3 2023)*
- Brexpiprazole AAD: FDA approval  
*(The FDA target date (PDUFA date) for completion of the review is May 10, 2023 following priority review)*
- Lu AG09222 (PACAP): Phase II HLR in migraine prevention  
*(Expected mid-2023)*
- Brexpiprazole PTSD: HLR from two phase III trials  
*(Expected H2 2023)*



HLR: Headline results



# Strong heritage in transformative medicines for brain diseases: A foundation serving enormous unmet medical needs in neuroscience



Substantial unmet and growing medical needs in CNS

Lundbeck's strategic brands provide strong, predictable growth

Major launch activity continues with continued global roll-out of Vyepti and with expected launches of brexpiprazole AAD and aripiprazole 2M RTU

Maturing pipeline with promising science for future growth – several data read-outs the next 12-15 months

Highly efficient global footprint

Solid, stable cash generative base business and strong balance sheet

**Guided by Lundbeck's Purpose:**  
*“Tirelessly dedicated to restoring brain health,  
so every person can be their best”*



# Q&A

# Strong heritage in transformative medicines for brain diseases: A platform to serve enormous unmet medical needs in neuroscience

- 1 Exposure to the resilient, growing and attractive global CNS market with supportive fundamentals
- 2 Attractive portfolio of highly-growing strategic brands constituting majority of the business
- 3 Truly global and diversified sales, distribution and production footprint
- 4 Streamlined R&D platform with strong progress in developing the product pipeline
- 5 Well-defined strategy of '*expand and invest to grow*' currently being executed
- 6 Recognized ESG leader dedicated to restoring brain health among patients
- 7 Strong business momentum supporting short term financial guidance
- 8 Attractive mid- and long-term financial outlook



# Focus on promising biology

## Selected four biology clusters feeding into our strategy

Scientifically well-described areas still rich in targets with untapped potential  
High feasibility for early de-risking and maintaining a competitive edge

