

COPENHAGEN, 19 NOVEMBER 2019



Lundbeck R&D Event

2019

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Agenda

Time (approx.)	Min.	Topic	Speaker
13:00-13:30	-	Coffee, registration	-
13:30-13:40	10	Welcome and introduction + Expand and Invest to Grow strategy	Dr. Deborah Dunsire
13:40-14:40	60	Lundbeck's expanding R&D pipeline	Johan Luthman Morten Grunnet Gary O'Neill
14:40-15:05	25	Eptinezumab profile	Bjørn Aaris Grønning
15:05-15:35	30	Break	-
15:35-16:00	25	Preparing to launch eptinezumab	Peter Anastasiou
16:00-16:50	50	What makes migraine unique?	Dr. Messoud Ashina
16:50-17:20	30	Final remarks and Q&A	Dr. Deborah Dunsire

Presenters

Presenter

Deborah Dunsire

Peter Anastasiou

Morten Grunnet

Bjørn Aaris Grønning

Johan Luthman

Gary O'Neill

External speakers

Messoud Ashina, MD, PhD, DMSc

Title

President & CEO

Executive Vice President, North America

Director, R&D Leadership Office

VP, Clinical Research Neurology

Executive Vice President, R&D

CSO, Lundbeck La Jolla Research Center

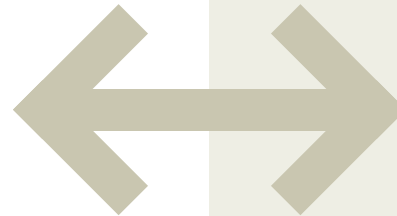
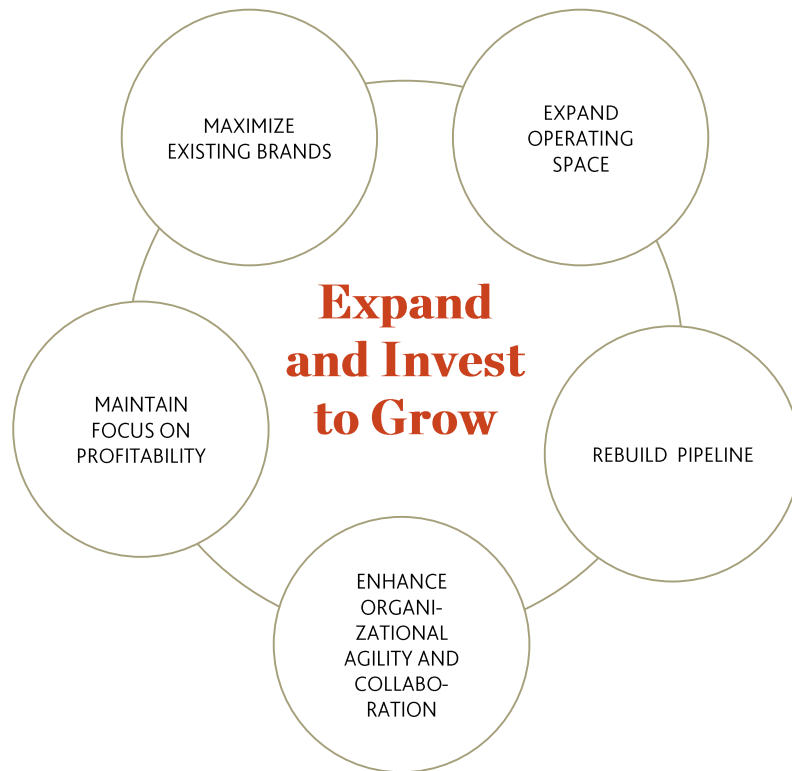
Title

Professor of Neurology – Faculty of Health and Medical Sciences; Rigshospitalet Glostrup

Speaker: Dr. Deborah Dunsire

Expand and Invest to Grow

The *Expand and Invest to Grow* strategy plan



We maximize growth opportunities in our current business and maintain a disciplined approach to cost

We maximize the performance of existing brands

We enhance organizational agility and collaboration

We expand our global footprint

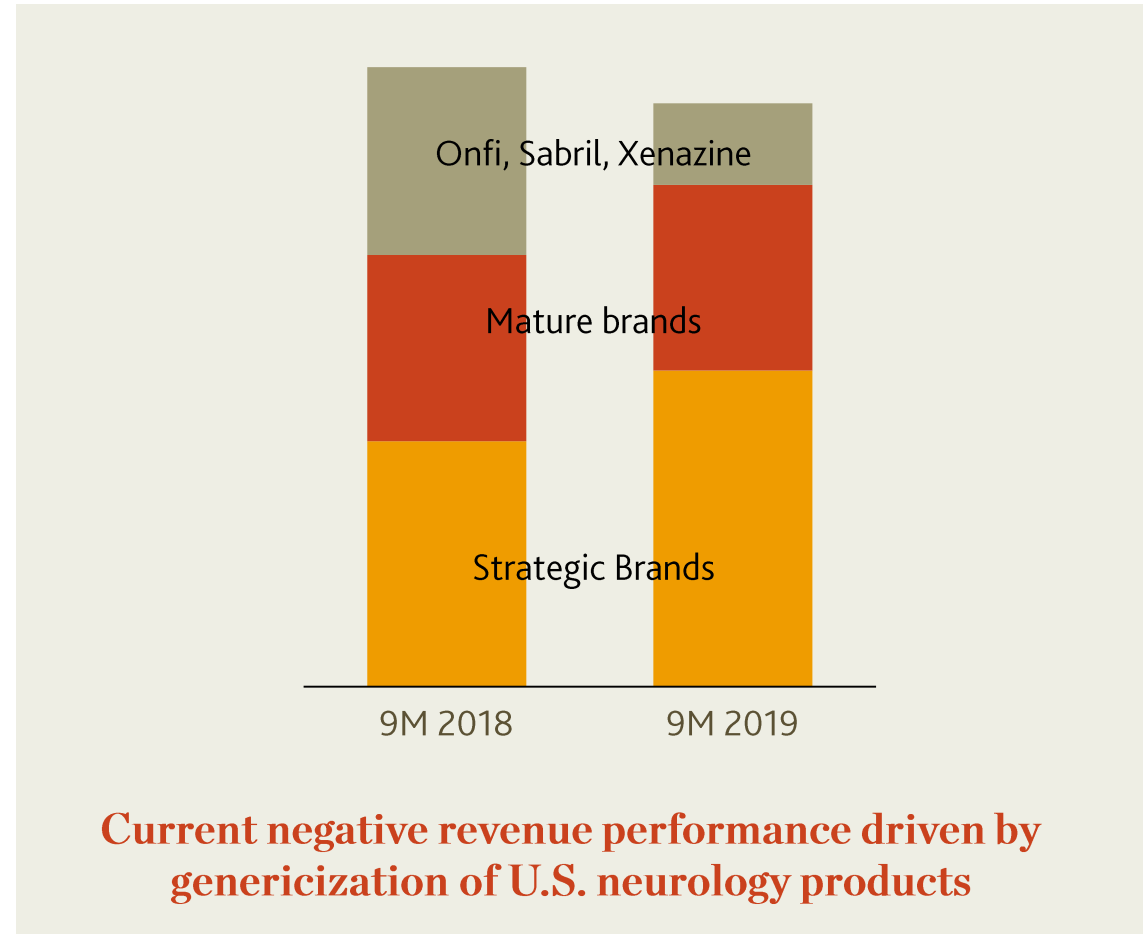
We continue to maintain high profitability, but allow flexibility to invest in growing the top-line and profits

We launch new indications and improved formulations



Through excellent execution, together with targeted acceleration projects, we maximize our existing brands

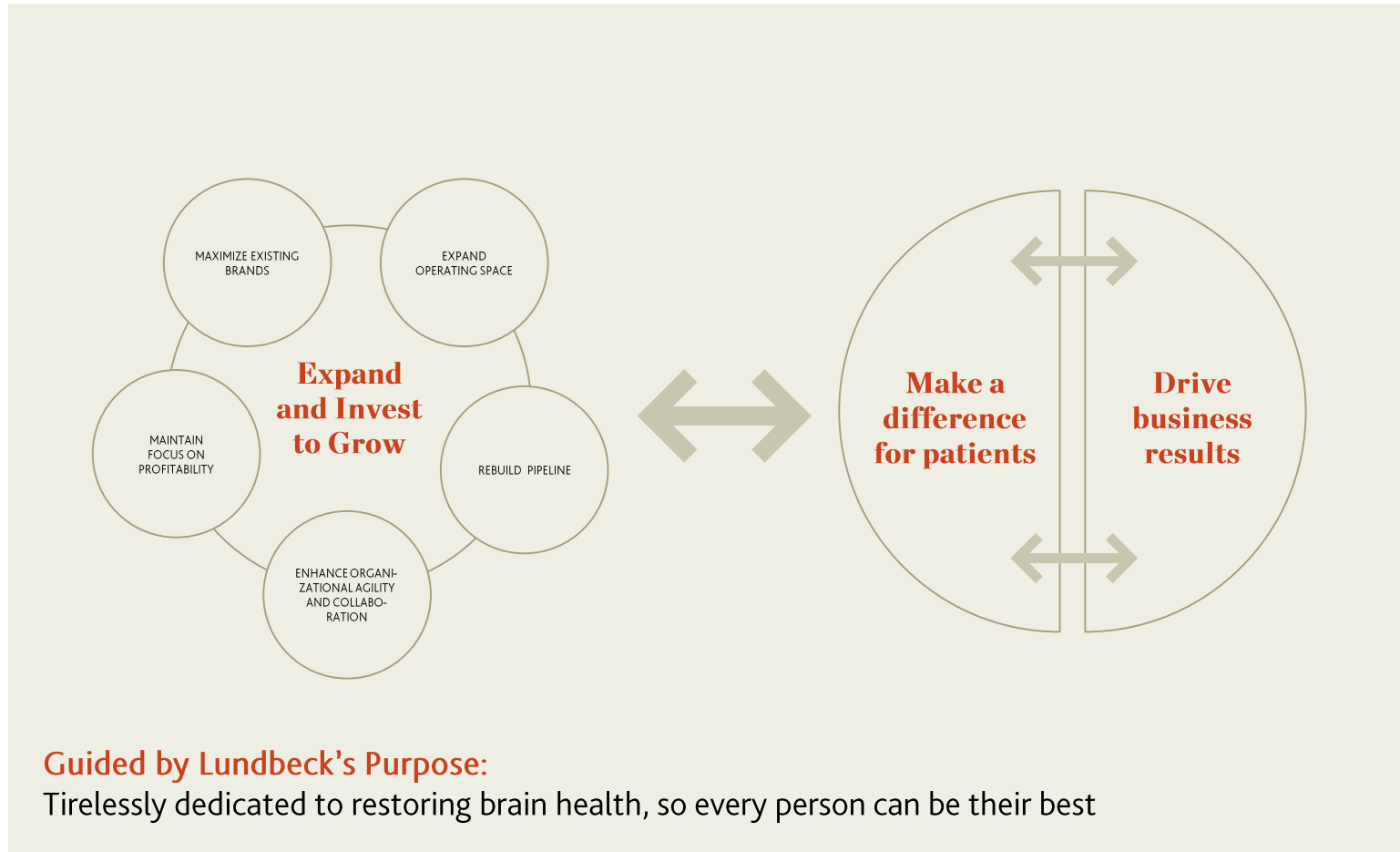
Strategic Brands +29%



Mature Brands Unchanged



Expand and Invest to Grow has expanded our operational space



Expand and Invest to Grow - 11 projects included in our R&D pipeline in February 2019

Project	Indication	Phase I	Phase II (PoC)	Phase III	Filing
Brexiprazole	Bipolar mania				2019
Brexiprazole	Agitation in Alzheimer's disease				~2021
Brexiprazole	PTSD				≥2023
Foliglurax (mGluR4 PAM)	Parkinson's disease				~2025
Lu AF11167 (PDE 10 inhibitor)	Schizophrenia				≥2025
Abilify Maintena 2-mth	Schizophrenia				~2020
Lu AF76432 (PDE 1 inhibitor)	Schizophrenia (CIAS)				≥2025
Lu AF20513 (active immunotherapy)	Alzheimer's disease				≥2025
Lu AF82422 (alpha-synuclein mAb)	Parkinson's disease				≥2025
Lu AF28996 (D ₁ /D ₂ agonist)	Parkinson's disease				≥2025
Lu AF35700	--		Project under review		-

Expand and Invest to Grow - 15 projects included in our R&D pipeline in November 2019

Project	Indication/label expansion	Phase I	Phase II (PoC)	Phase III	Filing
Eptinezumab (anti-CGRP mAb)	Migraine prevention				
Eptinezumab (anti-CGRP mAb)	"Treat and Prevent", migraine				-
Brexpirazole	Agitation in Alzheimer's disease				~2021
Brexpirazole	PTSD				≥2023
Brexpirazole	Borderline Personality Disorder				≥2025
Foliglurax (mGluR4 PAM)	Parkinson's disease				~2025
Lu AF11167 (PDE 10 inhibitor)	Schizophrenia				≥2025
Lu AG06466 (MGLLi)	Tourette Syndrome				≥2025
Abilify Maintena 2-mth	Schizophrenia				~2021
Lu AF82422 (alpha-synuclein mAb)	Parkinson's disease				>2025
Lu AF28996 (D ₁ /D ₂ agonist)	Parkinson's disease				>2025
Lu AG06466 (MGLLi)	Neuropathic pain				>2025
Lu AF88434 (PDE1b inhibitor)	Cognitive impairment				>2025
Lu AG09222 (PACAP mAb)	Migraine				>2025
Lu AF87908 (Tau mAb)	Alzheimer's				>2025

Speaker: Dr. Johan Luthman

Expanding the R&D pipeline

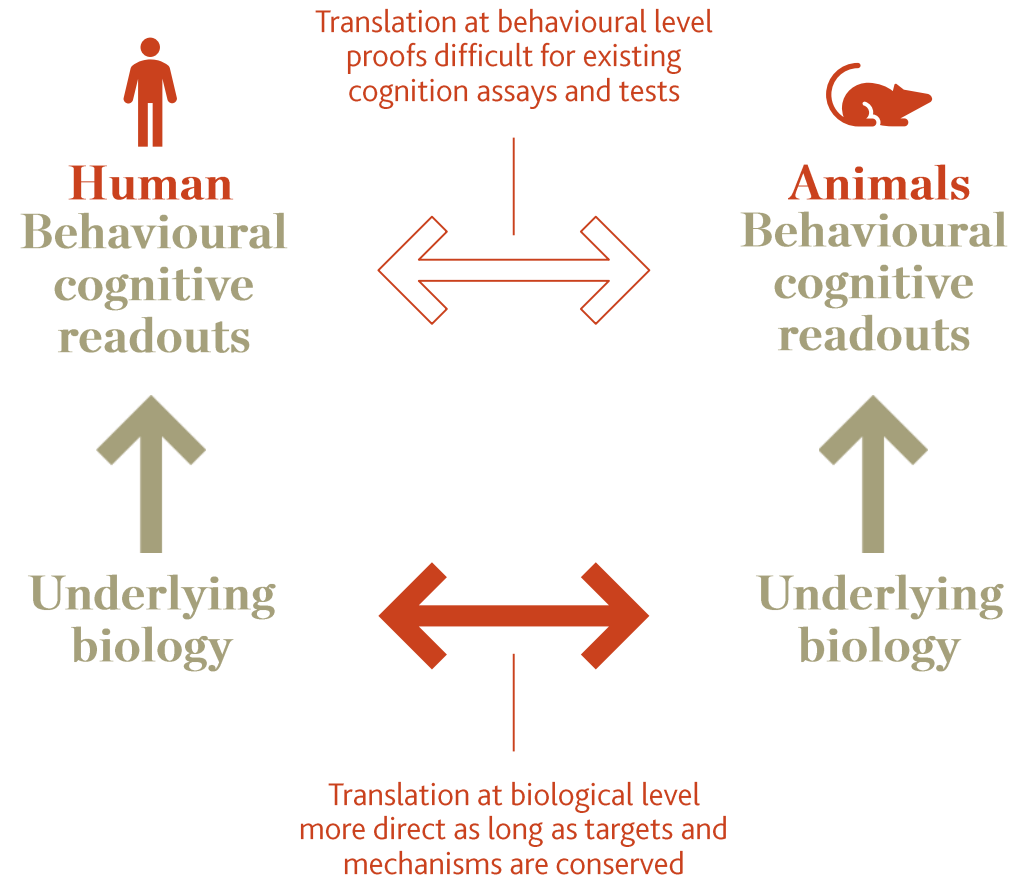
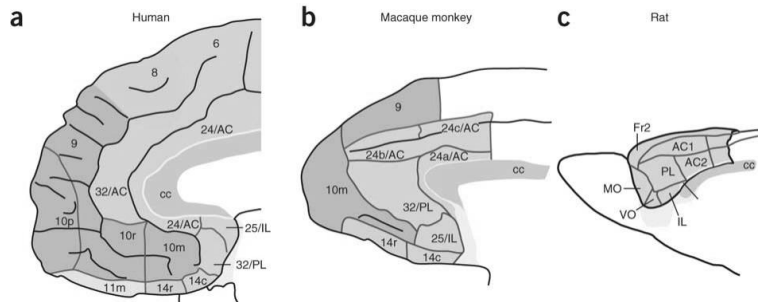
Expand and Invest to Grow has significantly strengthened the pipeline

Project	Indication/label expansion	Phase I	Phase II (PoC)	Phase III	Filing
Eptinezumab (anti-CGRP mAb)	Migraine prevention				
Eptinezumab (anti-CGRP mAb)	"Treat and Prevent", migraine				-
Brexpirazole	Agitation in Alzheimer's disease				~2021
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Brexpirazole	Borderline Personality Disorder				≥2025
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Lu AF28996 (D ₁ /D ₂ agonist)	Parkinson's disease				>2025
Lu AG06466 (MGLLi)	Neuropatic pain				>2025
Lu AF88434 (PDE1b inhibitor)	Alzheimer's, schizophrenia (CIAS)				>2025
Lu AG09222 (PACAP mAb)	Migraine				>2025
Lu AF87908 (Tau mAb)	Alzheimer's				>2025

CGRP: Calcitonin gene-related peptide. mGluR4 PAM: Positive Allosteric Modulator of metabotropic glutamate receptor 4. PDE: Phosphodiesterases. MGLLi: Monoacylglycerol lipase inhibitor ("MAGlipase). PACAP: Pituitary adenylate cyclase-activating peptide.

We focus on translational research to bridge the gap between pre-clinical and clinical research

The human brain has complexity and executive functions that are not represented in other mammals (translational research is difficult)



Long-term vision: Transformative neuroscience

**Reduce attrition
rates in R&D by...**

**Focus on biomarkers and
experimental medicine**

**Projects enter development
only with clear biomarker
strategy**

**Projects enter clinical phase
III only after solid supportive
Proof of Concept**

*”Let the
molecule
guide us”*

We are simplifying the organization to drive operational excellence

Simplified Global R&D Organization

Special emphasis on...

Establishing Experimental Medicine

Establishing Patient Insight Function

Strengthened Regulatory Affairs

Cross-functional Decision Making

Portfolio Management Board established to increase research, development and commercial alignment on all programs



Speaker: Dr. Johan Luthman

Pivotal programmes Phase III

Restoring brain health

Brexpiprazole – Agitation in Alzheimer's

Brexpiprazole in pivotal programme for the treatment of agitation in Alzheimer's disease

Alzheimer's Disease (AD)

50 million people worldwide have dementia (Alzheimer's is the most common cause of dementia contributing 60-70% of cases)

It is predicted that the number of people affected by dementia will almost double every 20 years

People with Alzheimer's live an average of 8 years after their symptoms become noticeable to others

The total global societal costs of dementia are estimated to be USD 600 billion

Agitation in Alzheimer's disease (AAD)

>20% of individuals in a community setting and >50% of nursing home residents with dementia have agitation

1.5-2m dementia patients in the U.S. with agitation / aggression

No FDA approved medication

Associated with:

Increased caregiver burden leading to increased cost to the healthcare system

Decreased functioning

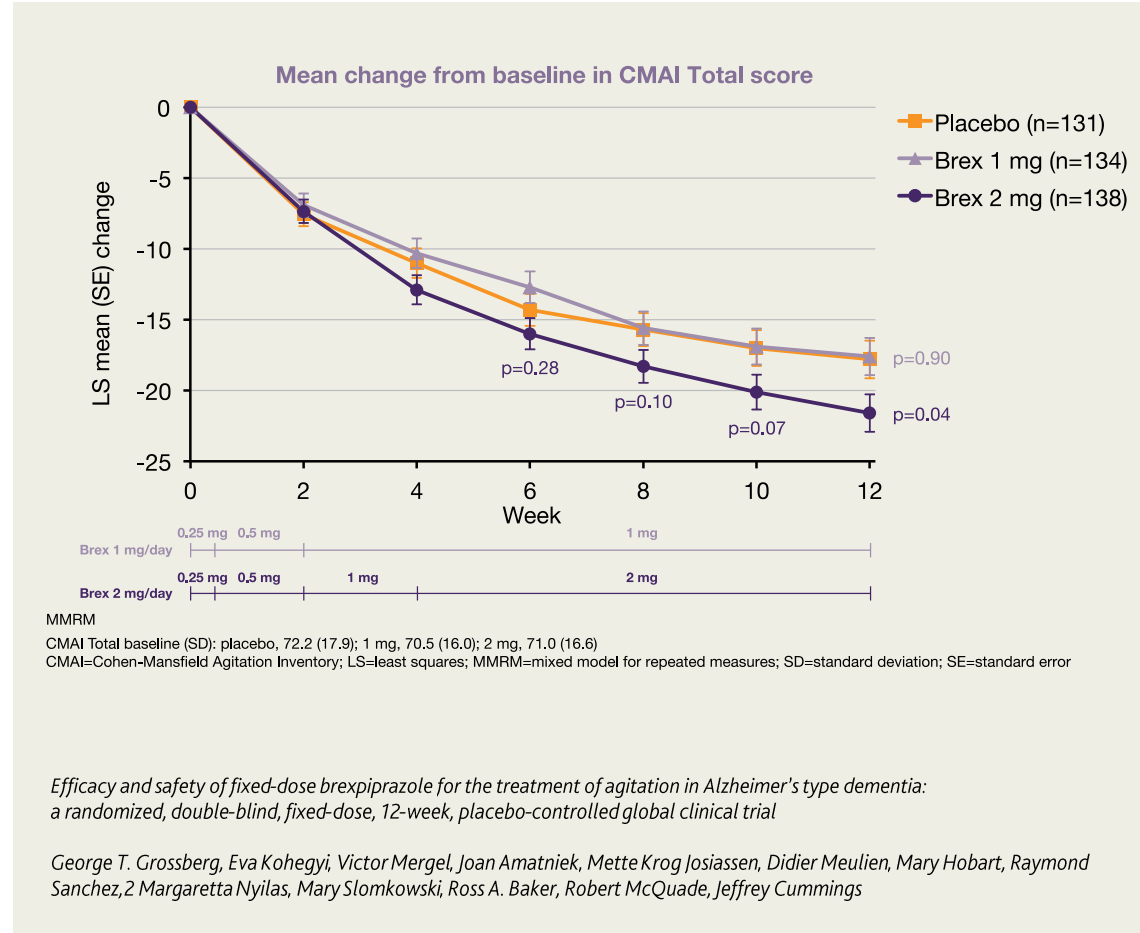
Earlier nursing home placement

Grossberg: “Efficacy and safety of fixed-dose brexpiprazole for the treatment of agitation in Alzheimer’s type dementia” (AAGP2018)

CMAI¹⁾: Brexpiprazole 2mg/day statistically significant improvement over placebo

CGI-S score²⁾: Numerical improvement was observed for brexpiprazole 2 mg/day from Week 6 - 12

No new safety signals were observed



Study I (NCT01862640)

N = 433 patients

Male or female, aged 55-90 years

1 mg, 2 mg and placebo

12 weeks' treatment duration

CMAI¹⁾: 2 mg statistically superior to placebo

CGI-S²⁾: 2 mg not statistically superior to placebo

Cummings: “Efficacy and safety of flexibly-dosed brexpiprazole for the treatment of agitation in Alzheimer’s type dementia” (AAGP2018)

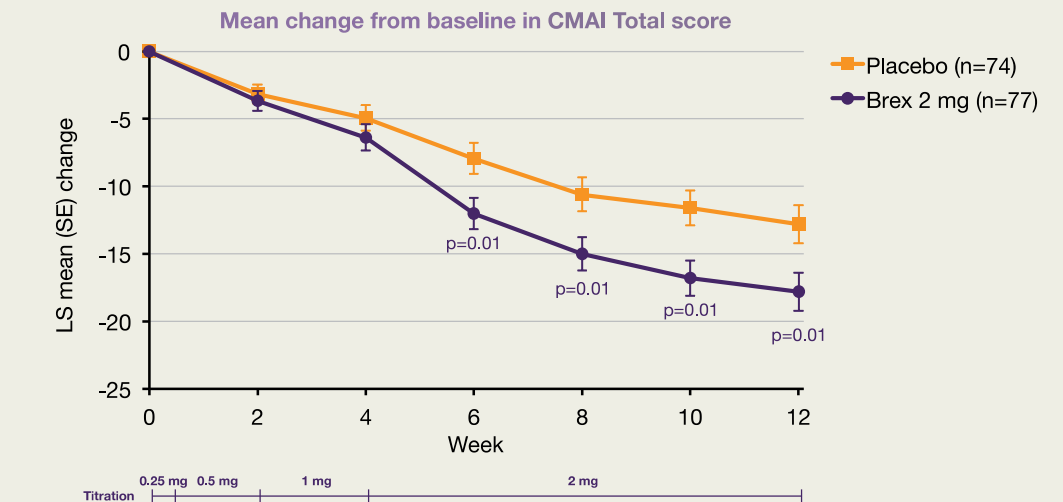
CMAI: Numerically favourable for flexibly-dosed brexpiprazole (0.5–2 mg/day) over placebo, but not statistically significant

Brexpiprazole 2 mg/day showed improvement for both the primary and key secondary efficacy endpoints (post-hoc analyses, $p \leq 0.01$)

Brexpiprazole 2 mg/day may be an effective and well-tolerated new treatment for agitation in Alzheimer’s dementia

Post-hoc analysis

– subgroup of patients titrated to 2 mg



MMRM

CMAI Total baseline (SD), dose increase at Week 4: placebo, 68.3 (16.2); 0.5–2 mg, 69.2 (15.4)

Efficacy and safety of flexibly-dosed brexpiprazole for the treatment of agitation in Alzheimer’s type dementia: a randomized, double-blind, flexibly-dosed, 12-week, placebo-controlled global clinical trial

Jeffrey Cummings, Eva Kohegyi, Victor Mergel, Joan Amatniek, Mette Krog Josiassen,3 Didier Meulien,3 Mary Hobart, Raymond Sanchez, Margaretta Nyilas,2 Mary Slomkowski, Ross A. Baker, Robert McQuade, George T. Grossberg

Study II (NCT01922258)

N = 270 patients

Male or female, aged 55-90 years

Flexible dose: 0.5-2 mg

12 weeks’ treatment duration

CMAI¹⁾: 0.5-2 mg not superior to placebo

CGI-S²⁾: 0.5-2 mg superior to placebo

Third study in brexpiprazole pivotal programme in Agitation in Alzheimer's progresses as planned

Study objective¹

To compare the efficacy of 2 doses of brexpiprazole with placebo in subjects with agitation associated with dementia of the Alzheimer's type (n = ~225)

Third study out of three in the pivotal programme (phase III):

Brexpiprazole (fixed dose 2mg and 3mg) and placebo

Primary endpoint: Cohen-Mansfield Agitation Inventory (CMAI) total score (Week 12)

Secondary endpoint: Clinical Global Impression Severity of Illness (CGI-S) score

Study started in May 2018 - headline results due early 2021

Fast Track designation granted February 2016

Restoring brain health

Brexpiprazole – Post-Traumatic Stress Disorder (PTSD)

PTSD offers an exciting opportunity for brexpiprazole

PTSD epidemiology

>8m – U.S. prevalence
(2.5%-3.6%)^{1, 2}

~3m – Severe
(36.6%)²

~1.8m – pharmacological
treatment rate
(~60%)²

Post-traumatic Stress Disorder (PTSD)

~8.6m U.S. adults affected, but ~80% estimated to be undiagnosed

Growing economic and social burden of care

Inadequate response with approved SSRIs - polypharmacy the norm

PoC study⁴ showed...

Combination of brexpiprazole and sertraline demonstrated improvement in symptoms of PTSD versus placebo ($p < 0.01$) on the primary endpoint (CAPS-5 total score³)

The efficacy supported by multiple secondary endpoints

The overall safety and tolerability of brexpiprazole were good

Both studies in brexpiprazole pivotal programme in PTSD commenced

Study objective¹

To evaluate the efficacy, safety, and tolerability of 12-week brexpiprazole + sertraline combination treatment in adult subjects with PTSD (n = ~600)

Two studies initiated in the pivotal programme (phase III)

Brexpiprazole (fixed 2 , 3mg and flexible dose up to 3mg) in combination with sertraline

Primary endpoint: Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total score

Secondary endpoints: Change in Clinical Global Impression - Severity (CGI-S) score; Change in Brief Inventory or Psychosocial Functions (B-IPF) score

First study started in October 2019 and the second in November 2019 - headline results due 2022

U.S. dedicated study

Speaker: Dr. Johan Luthman

Proof of Concept Phase II

Restoring brain health

Brexpiprazole – Borderline Personality Disorder (BPD)

Borderline Personality Disorder (BPD) offers an exciting opportunity for brexpiprazole

BPD epidemiology

~5m – U.S. prevalence
(1.6%, but likely higher)¹⁾

~2.4m – diagnosis rate
(45%)

~1.7m – pharmacological
treatment rate
(~70%)²⁾

Borderline Personality Disorder (BPD)

Dysfunctions in the serotonergic and dopaminergic systems is considered as possible causes for symptoms associated with BPD³⁾

Pharmacotherapy focuses on key symptoms (aggression, irritability, depressed mood, behavioural dys-control and affective dysregulation, anxiety, psychoticism and hostility) which brexpiprazole is hypothesized to address

No drugs approved for BPD

1. Grant BF, Chou SP, Goldstein RB, et al. Prevalence, correlates, disability, and comorbidity of DSM-IV borderline personality disorder: results from the Wave 2 National Epidemiologic Survey on Alcohol and Related Conditions. *J Clin Psychiatry* 2008; 69:533. | 2. Bridler et al (2015) and Zaanarini et al. (2004 and 2015) | 3. Friedel RO: Dopamine dysfunction in borderline personality disorder: a hypothesis. *Neuropsychopharmacology* 2004; 29:1029–1039 and Hansenne M et al: 5-HT1A dysfunction in borderline personality disorder. *Psychol Med* 2002; 32:935–941

Brexpiprazole PoC study in Borderline Personality Disorder (BPD) commenced

Study objective¹

To evaluate the efficacy and safety of 12-week brexpiprazole for the treatment of subjects diagnosed with BPD (n = ~240) to provide a pharmacological treatment for BPD

PoC study (phase II)

Brexpiprazole (flexible dose 2-3mg) and placebo

Primary endpoint: Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD) total score (Week 12)

Secondary endpoints: Clinical Global Impression - Severity of Illness (CGI-S); Patient's Global Impression of Severity (PGI-S); Patient's Global Impression of Change (PGI-C) Scale; Clinical Global Impression - Improvement (CGI-I) Scale

Headline results due in 2021 - Fast Track designation granted October 2019

PHASE II



Restoring brain health

Lu AF11167

Negative symptoms represent a major unmet medical need

Schizophrenia has three core symptoms: Positive, cognitive and negative symptoms

Negative symptoms together with impaired cognition are the major cause of the marked functional disability

Negative symptoms are thus a key contributor to the enormous costs of schizophrenia

No pharmacological treatment

40 - 50% of patients with schizophrenia are clinically stable outpatients; of those 40% experience at least two prominent negative symptoms (~ 20% of the total schizophrenia population)

Prevalence (major countries)

4.7m

Prevalence of schizophrenia (G7)

3.5m

Treatment prevalence (75%)

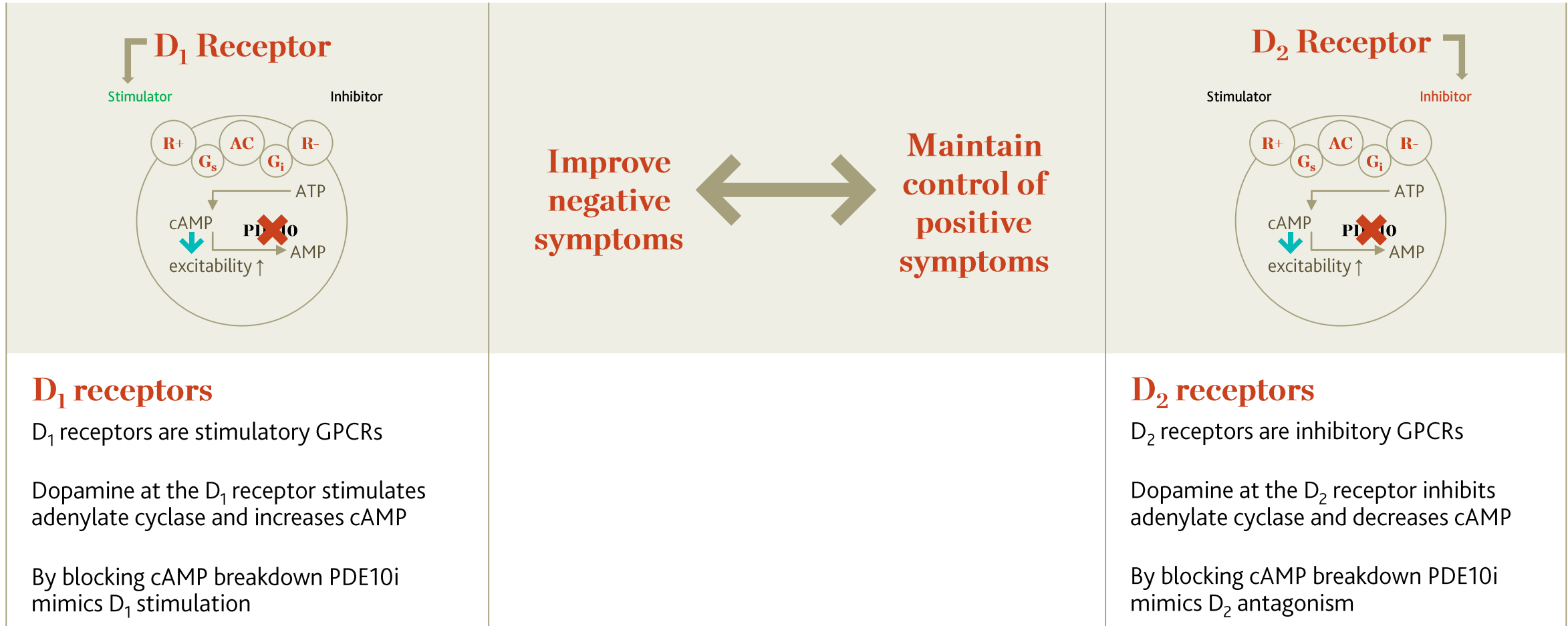
1.7m

Clinical stable outpatients (50%)

0.8m

Negative symptoms (40%)

PDE10 inhibition: A new approach to obtain a combined D₁ agonist-like effect and D₂ antagonist-like effect



Proof-of-concept study commenced in December 2018

Monotherapy*

Two fixed-flexible doses, once daily

1-2mg/day

3-4mg/day

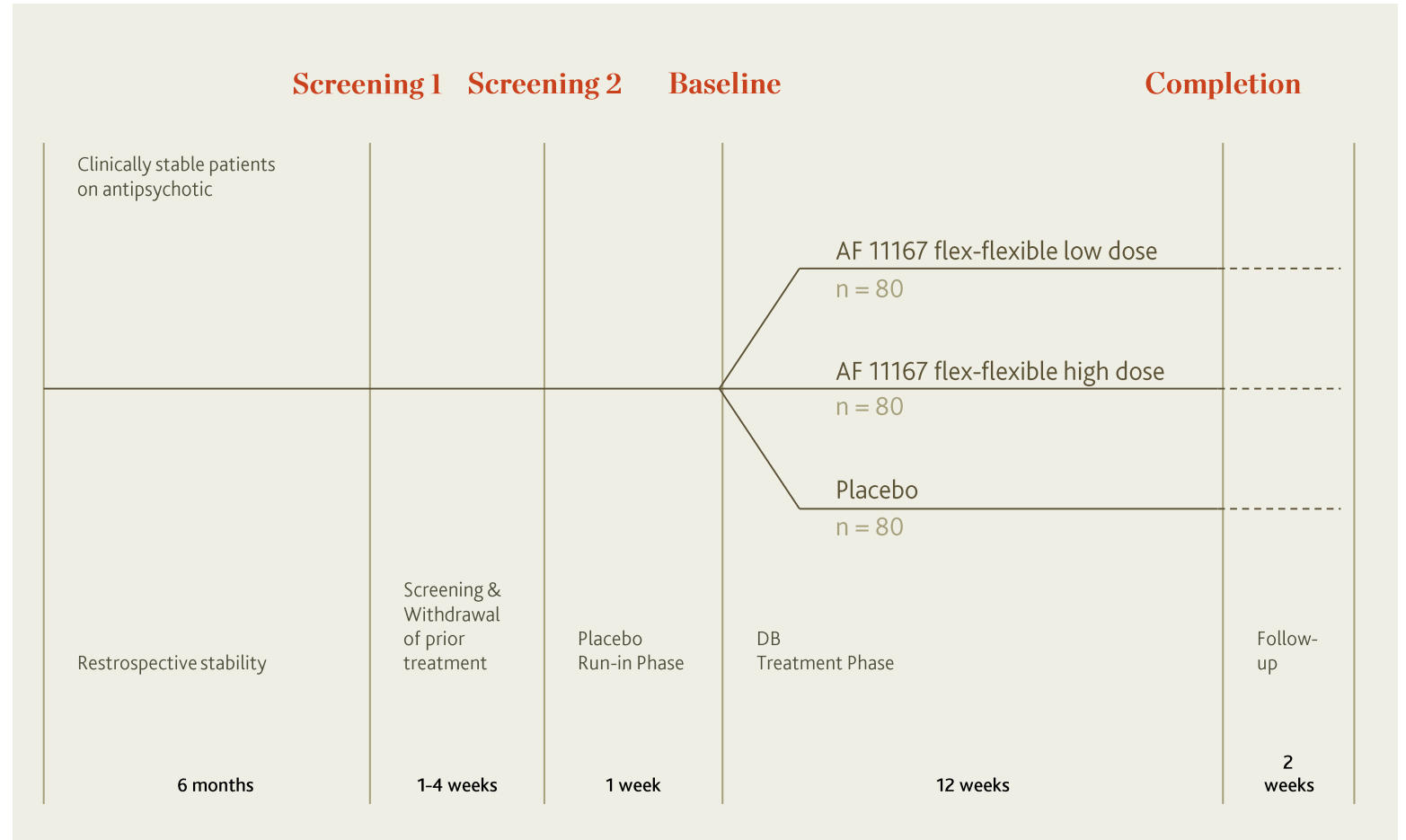
placebo

N = ~250 patients

Primary endpoint: Change from baseline to Week 12 in BNSS total score**

Several secondary endpoints

Expected completion: 2021



* NCT03793712. | ** BNSS: Brief Negative Symptoms Scale

PHASE II



Restoring brain health

Foliglurax

Foliglurax is a potential new treatment for Parkinson's disease

PD-LID is the most important unmet medical need after disease modification in Parkinson's¹⁾

PD-LID affects ~50% after 5-10 years increasing to ~90% after 10-15 years of L-DOPA therapy

170-200,000 patients in the U.S. with PD-LID²⁾

Once established, PD-LID is difficult to treat

Foliglurax increases the sensitivity of the mGlu4 receptor towards glutamate and hence reduces, in a physiologically relevant manner, the abnormal glutamate stimulation that is believed to develop during levodopa dosing

Levodopa-induced dyskinesia³⁾

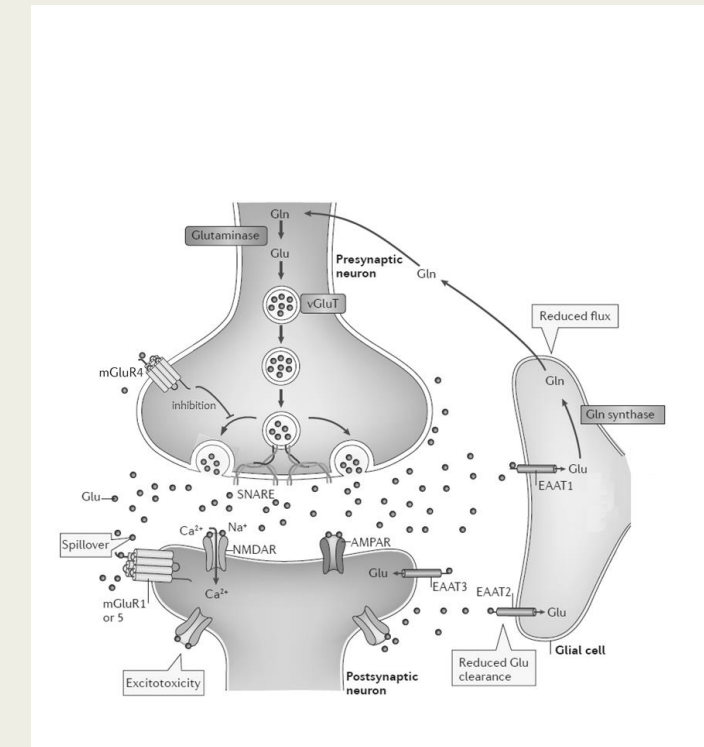


Disease progression in patients with motor fluctuations



With addition of foliglurax (illustrative)

mGluR4 PAM



Phase IIa study (*AMBLED*) investigating foliglurax near final recruitment

Study objective¹

Evaluate the efficacy, safety and tolerability of 28-Day oral treatment with foliglurax in reducing motor complications of levodopa therapy in subjects with Parkinson's disease experiencing end-of-dose wearing off and levodopa-induced dyskinesia (*AMBLED*)

Phase IIa (PoC)

Two active arms (10mg and 30mg) + placebo

~165 patients (Europe)

Primary endpoint: Change from baseline to end of Treatment Period in the daily awake *OFF* time based on subject Hauser diary entries

Phase IIa started in July 2017; headline results due in H1 2020



Speaker: Morten Grunnet

Early projects

Lu AF82422: Potential disease modifying antibody for Parkinson's disease

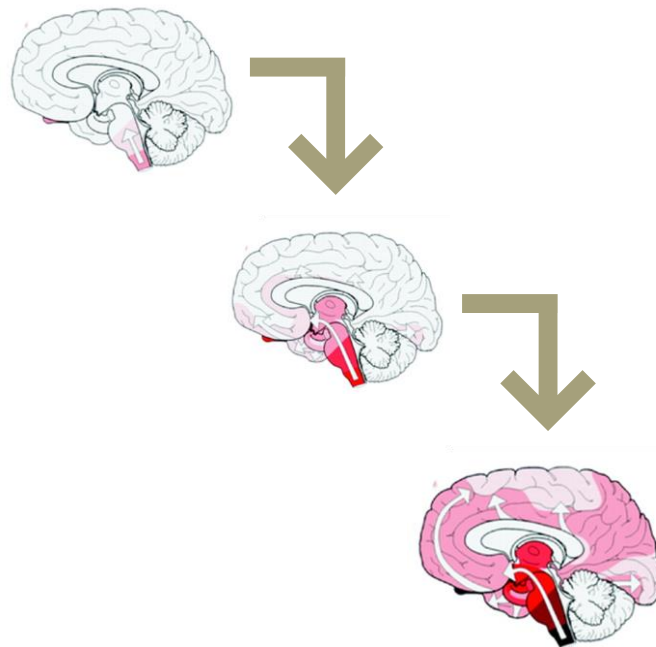
Pathological alpha-synuclein is released to extracellular space upon cell death and can mediate seeding and aggregation of alpha-synuclein in healthy neurons¹

This process is considered to be central in the disease progression of Parkinson's, Multiple System Atrophy and other synucleopathies²

Lu AF82422 is able to inhibit seeding of pathological form(s) of alpha-synuclein in in vitro and in vivo models

Has the potential to induce immune-mediated clearance of alpha-synuclein/mAb complexes

Pathogenesis of Parkinson's



Ongoing phase I study³:

- Healthy non-Japanese and Japanese subjects and in patients with Parkinson's
- ~45 participants
- Primary endpoint: Number of patients with incidence of Treatment-Emergent Adverse Events (safety and tolerability) from dosing to Day 84
- Study initiated in July 2018 with expected completion H2 2020

Lu AF28996: A potentially new oral treatment for Parkinson's patients experiencing motor fluctuations

D₁/D₂-type agonists

Known to be highly efficacious even in the later stages of Parkinson's, but the currently available agonist (apomorphine) cannot be delivered by oral route

Improving the treatment of fluctuating Parkinson's patients answers a strong unmet need and is an attractive commercial target

Lu AF28996

A highly potent agonist at the D₁- and D₂-type dopamine receptors

Designed to solve a long-standing challenge of oral delivery of D₁/D₂-type agonists such as apomorphine

Parkinson's disease (moderate to advanced) as adjunct to L-DOPA (or monotherapy pending data)

Further expansion of patient population and symptoms (including non-motor symptoms) are being considered

Phase I studies¹:

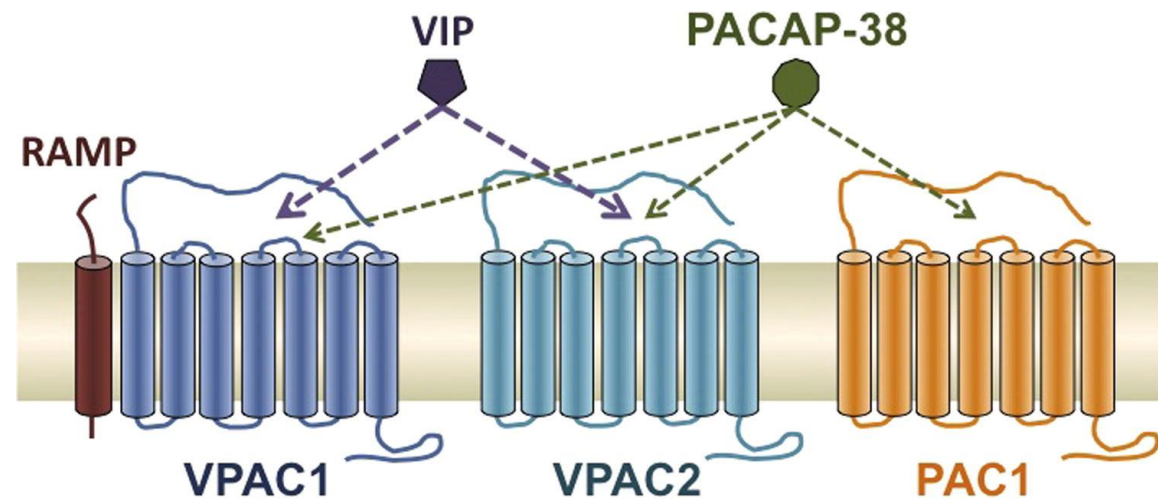
- Single- and sequential-ascending-dose of Lu AF28996 to healthy young men
- ~38 participants
- Open-label study investigating the safety, tolerability and pharmacokinetic profile of Lu AF28996
- Phase Ia initiated in May 2018, completed in August 2019
- Phase Ib to be initiated Q1 2020

1) NCT03565094

Lu AG09222: Potential to build a migraine franchise in the future with early-stage PACAP² inhibitor mAb

A differentiated approach to migraine prevention

- Highly potent and selective humanized PACAP binding antibody
- Preclinical data¹ indicate that PACAP² and CGRP³ have differentiated pharmacology with respect to migraine-associated symptoms
- Potential for mono-therapy in non-CGRP³ induced migraine or combination therapy with eptinezumab



Lu AF88434: Potential to improve cognition

Phosphodiesterase 1 (PDE1)

PDE1 is an intracellular enzyme responsible for the degradation of cGMP and cAMP

cGMP is a critical intracellular signalling molecule that regulates neuronal functions like synaptic plasticity, cognitive function, neuronal survival and axonal regeneration

Inhibition of PDE1 increases the intracellular messenger cGMP and cAMP (cGMP > cAMP)

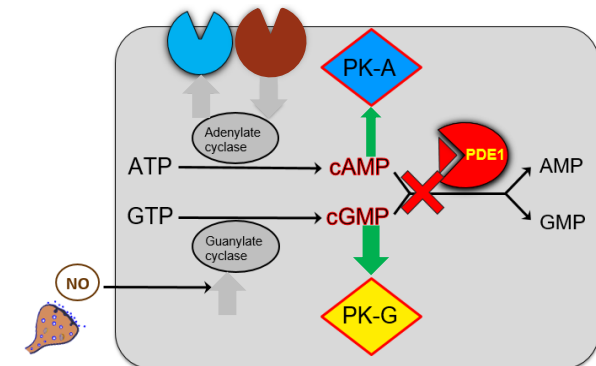
Lu AF88434¹⁾

Lu AF88434 is a potent and selective phosphodiesterase PDE1b inhibitor (PDE1b-i)

SAD study investigating the safety, tolerability, PK/PD properties of Lu AF88434

N = ~66 participants

Study initiated in July 2019 with expected completion during 2020



1) [Clinicaltrials.gov ID: NCT04082325](https://clinicaltrials.gov/ct2/show/study/NCT04082325)

Lu AF87908 – Potential for delaying disease progression in Alzheimer’s or other tauopathies

- Lu AF87908 is a humanized IgG1 mAb recognizing Tau

Competitive advantage by

- Binding to and inhibition of pathological seeding form of Tau
- Specific and pathology directed mAb
- Retaining the capacity to mediate active clearance of Tau

Phase I study

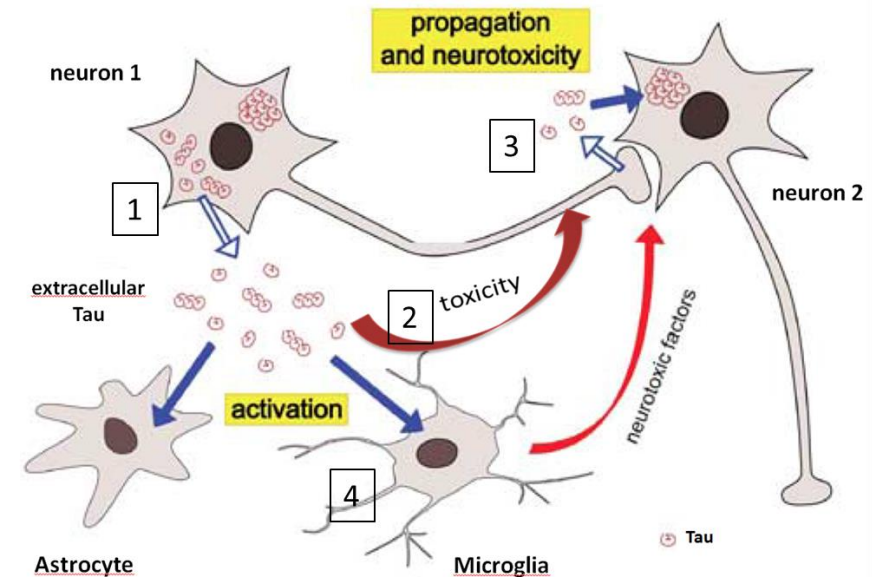
- SAD study in healthy subjects and AD patients¹⁾
- N = ~100 participants
- Study initiated in September 2019 with expected completion during 2021

Neutralization

- Inhibit seeding
- Inhibit toxicity
- Inhibit spreading

Clearance

- Mediate phagocytosis of Ab/Tau complexes



Hypothesis: Hyperphosphorylated Tau (PHF-Tau) is the pathogenic species

¹⁾ NCT04149860, Immunoglobulin G1 (Ig) is types of antibodies (Ab), Source: Nature Reviews Neuroscience 17, 22–35

PHASE II



Speaker: Gary O'Neill

Lu AG06466

former ABX-1431

Serine hydrolases: A rich source of diverse new medicines

A large enzyme family (~250)

Diverse substrates

Proteins, peptides, lipids, etc

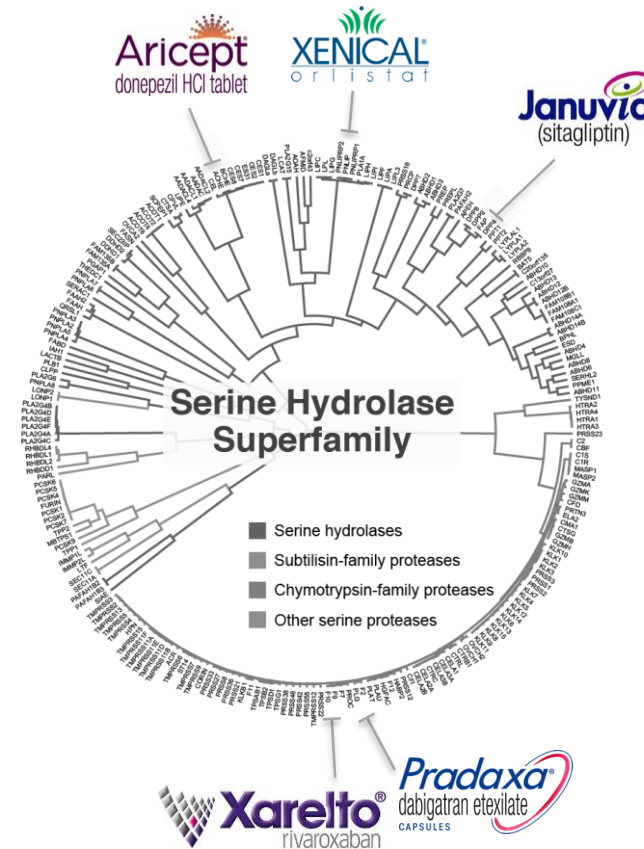
Diverse functions

CNS signalling, inflammation, metabolism

Common catalytic mechanism

Active-site serine residue for catalysis

Lundbeck La Jolla Research Center's platform unlocks the entire superfamily

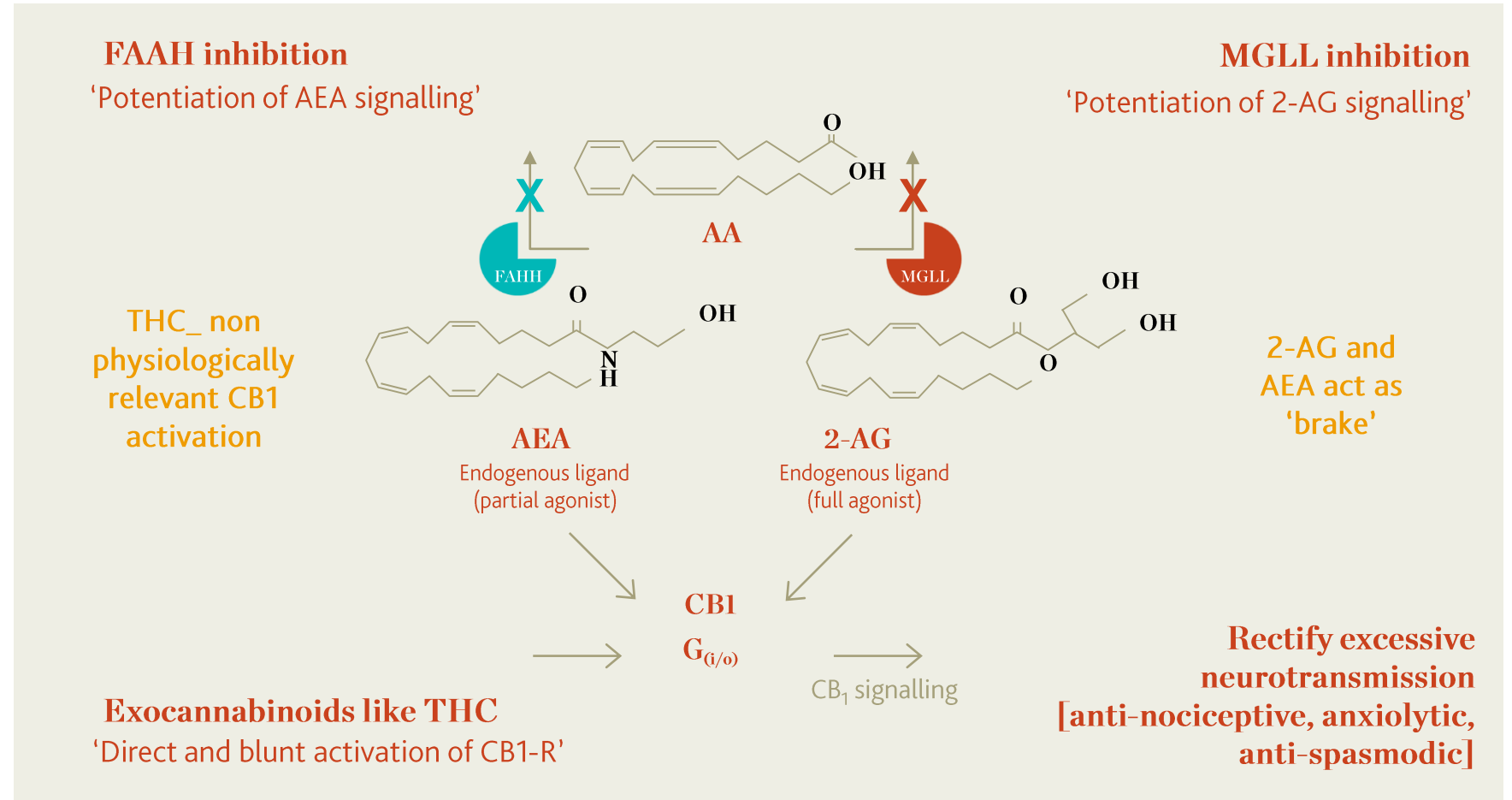


Monoacylglycerol Lipase (MGLL) Inhibitors

Endocannabinoid augmentation as a therapeutic strategy

Two main endogenous cannabinoid ligands: Anandamide (or AEA) and 2-Arachidonylglycerol (or 2-AG)

MGLL inhibition leads to a selective and spatio-temporal specific elevation of 2-AG levels



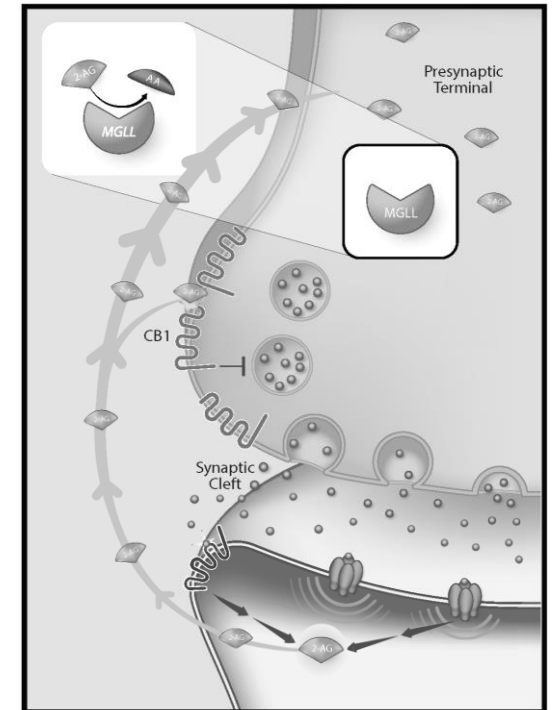
MGLL is a fundamental regulator of neurotransmission

Endocannabinoid signalling limits excessive neurotransmission

MGLL inhibition amplifies retrograde endocannabinoid signalling and rectifies overactive synapses

Restoration of balanced neurotransmission beneficial to many neurological disorders

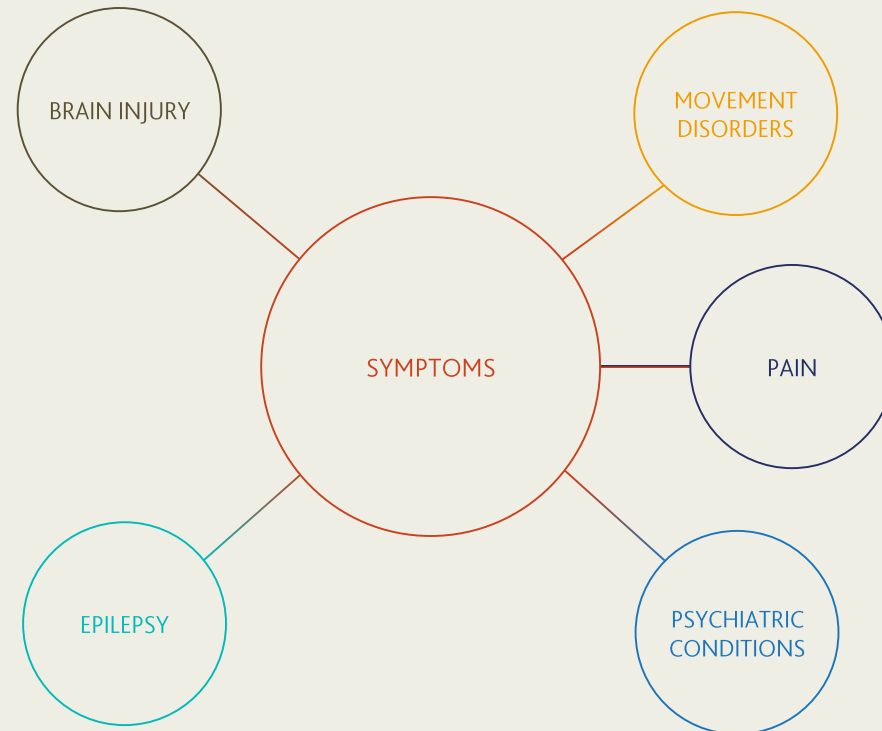
Endocannabinoids (such as 2-AG) naturally modulate neurotransmission



MGLL inhibitors may benefit many conditions

Traumatic Brain Injury
Stroke
Haemorrhagic Stroke

Treatment Resistant
Epilepsy
Epilepsy Syndromes



Tourette Syndrome
Huntington's Disease
Parkinson's Disease
MS Spasticity

Neuropathic Pain
Central Pain

OCD
ADHD
Anxiety / PTSD
Depression
Agitation in Dementia

MGLL inhibitor portfolio: Harnessing the therapeutic potential of the endocannabinoid system

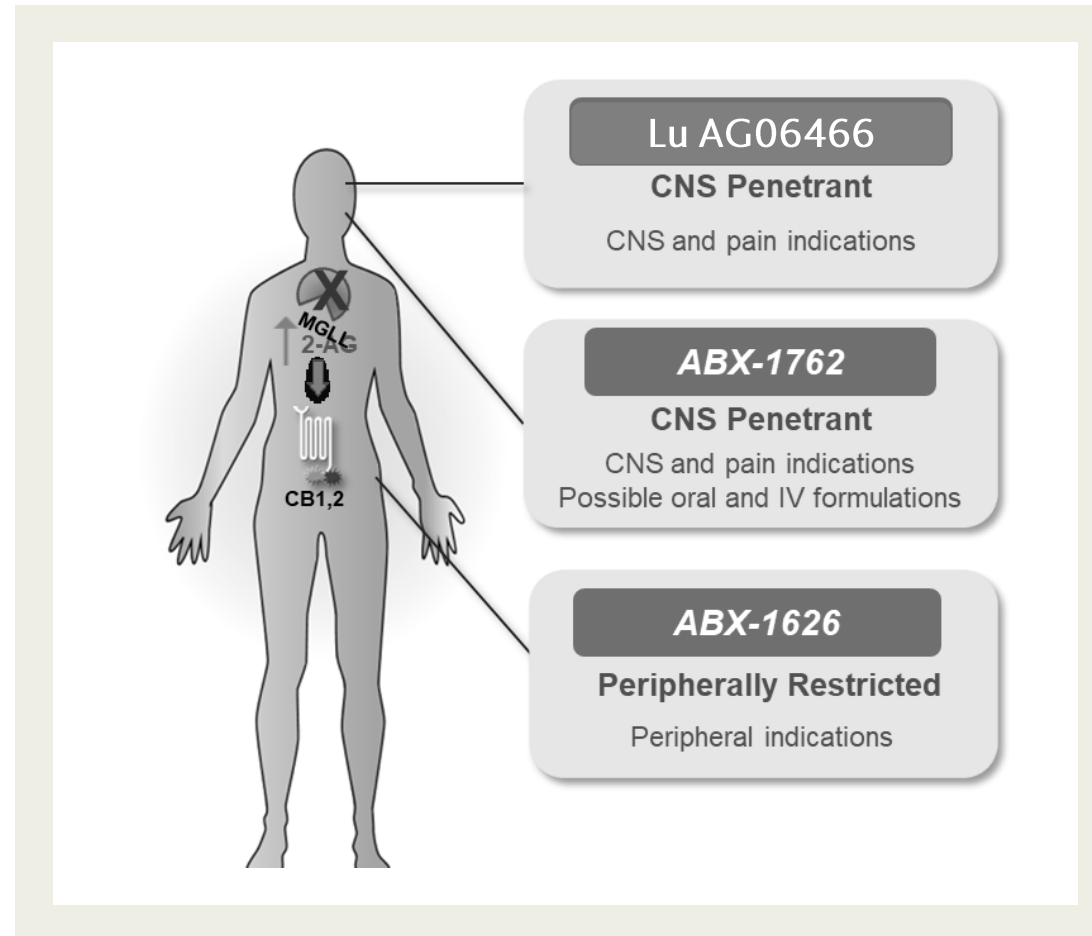
Access to world class MGLL development candidates to bolster the portfolio

Pipeline in a drug – many potential indications

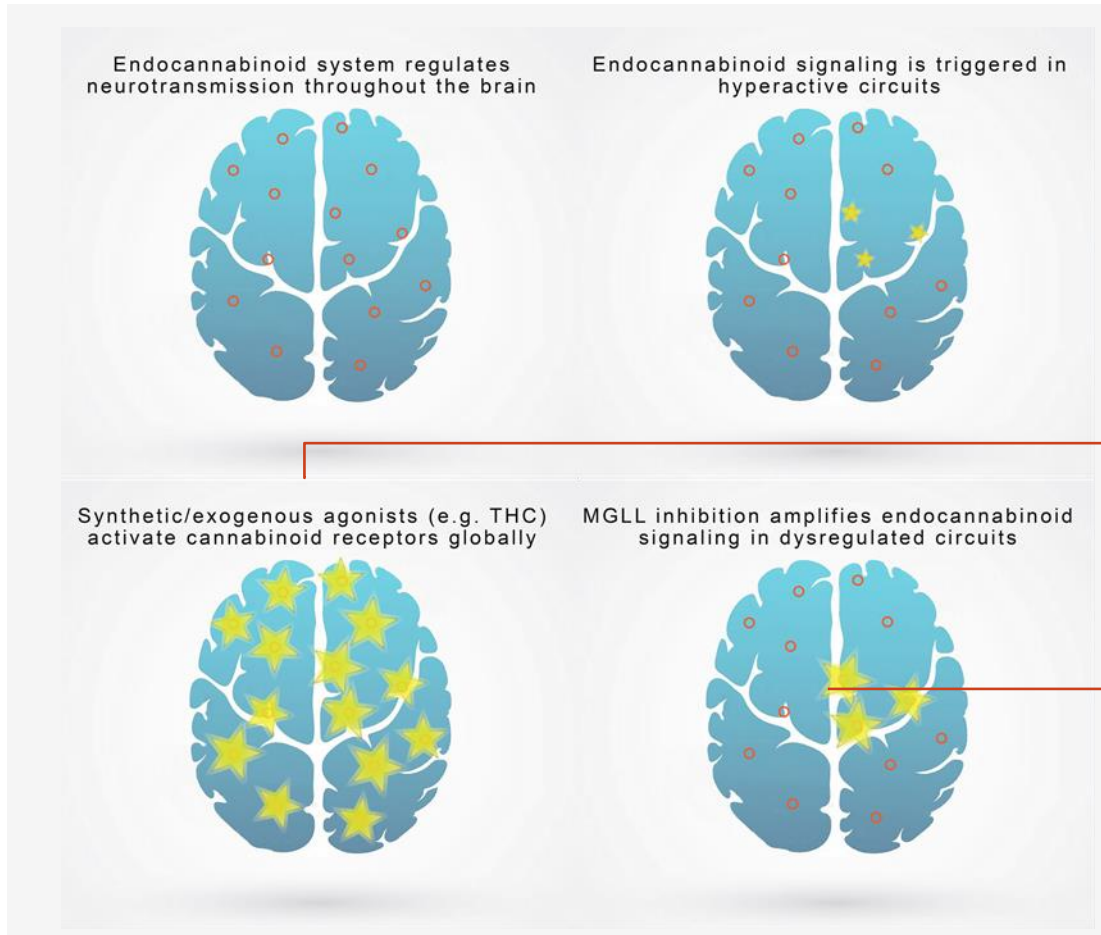
Discovery site in U.S.

World class platform to address novel biological targets

Chemical biology tool box to compliment the Lundbeck neuroscience and modality expertise

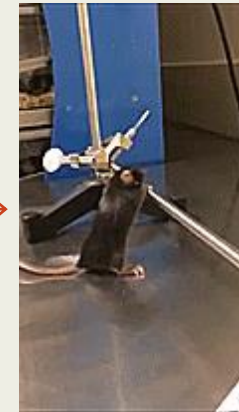


Lu AG06466 differentiation from exocannabinoids



Catalepsy Bar

Exocannabinoid
WIN 55,212-2



MGLL Inhibitor
ABD-101970



MGLL inhibitor Lu AG06466:
Potential for greater safety and efficacy than exocannabinoids

Lu AG06466: Being tested in Tourette Syndrome (TS)

Modulates the endocannabinoid system preferentially in areas where neuronal circuits are excessively activated

Initial trials ongoing in TS's and neuropathic pain

Phase Ib trial¹⁾ in adult TS patients (n = 23) demonstrated significant effects across multiple endpoints of tic reduction

Paediatric population:

0.3% – 0.6% of children (138,000 – 276,000)

Estimated 40% have moderate to severe disease needing treatment

Adult population:

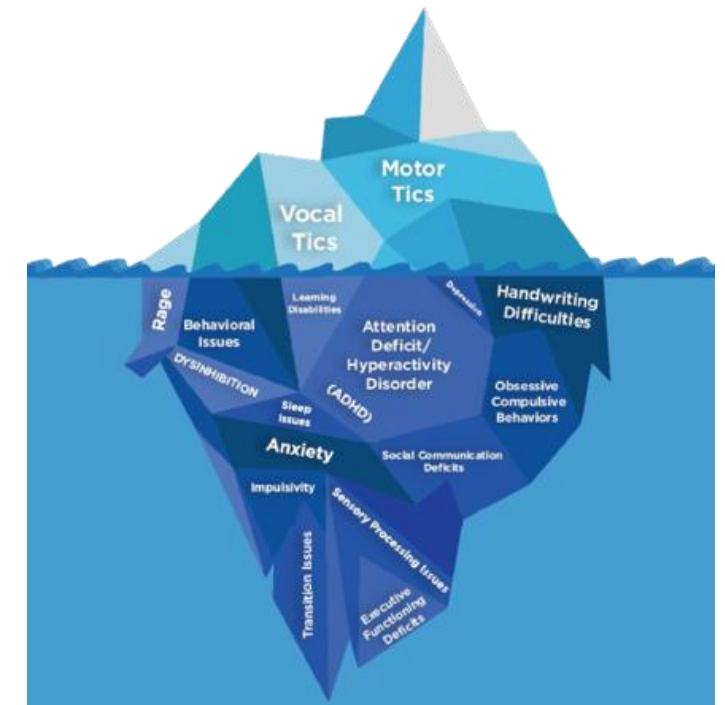
Estimated 10%-20% continue to have the disease

We estimate that adult prevalence is equal to that of paediatrics

Co-morbidities like OCD, ADHD and anxiety persist and can be impairing

Tourette syndrome

Tics are just the tip of the iceberg



1) NCT03058562

Phase IIa study investigating Lu AG06466 near finalization

Study objective¹

This study will assess the safety, tolerability, and effect on tics Lu AG06466 (previously ABX-1431) in adults with Tourette Syndrome or chronic motor tic disorder in an 8-week study. It is a two-part study

Part 1 is a double-blind, randomized, placebo-controlled study at two target dose levels

Part 2 is an optional, open-label, non-randomized study

Phase IIa (PoC):

Two active arms (10mg and 30mg) + placebo

N = ~48 patients

Primary endpoint: Change from baseline in Total Tic Score of the Yale Global Tic Severity Scale (YGTSS-TTS) compared with placebo

Secondary endpoint: Adult Tic Questionnaire (ATQ); Premonitory Urge for Tics Scale (PUTS); Clinical Global Impressions Scale for Improvement (CGII) and several AE related endpoints

Phase IIa started in October 2018; headline results due in H1 2020

Lu AG06466 in phase Ib safety and tolerability study in neuropathic pain

MGLLi have shown to reduce pain in preclinical models of inflammatory, post-surgical, and neuropathic pain

Significant scientific evidence supports the use of exocannabinoids for the treatment of pain, including controlled clinical studies in patients with NP

MGLLi may offer significant therapeutic benefits over exocannabinoids, with potential for increased efficacy and a better safety profile

Neuropathic pain (NP)

- NP results from damage to the nervous system in the brain or spinal cord or in the peripheral nerves
- NP is a common and debilitating condition that may occur in 10% of Americans
- Current approved treatments for NP include gabapentinoids and antidepressants
- Beyond the lack of effective medications, many patients chronically use opioid drugs
- There is a pressing need for efficacious non-opioid therapies for NP

Phase I study¹:

- Designed to identify a titration regimen of Lu AG06466
- ~39 adult patients with peripheral neuropathic pain
- The efficacy of Lu AG06466 in treating neuropathic pain will be assessed by the change from baseline in pain intensity scores using numerical rating scale (NRS-11)

1) NCT03447756. This study will enrol patients with peripheral neuropathic pain due to one of the four following diagnostic groups: post-herpetic neuralgia, diabetic peripheral neuropathy, small fiber neuropathy or post-traumatic neuropathic pain

Speaker: Bjørn Aaris Grønning

Eptinezumab

Migraine is one of the most debilitating diseases globally

~18m

~18m individuals are candidates for prevention

<50%

~ less than 50% are treated³

4-72 hours

Attacks usually last 4-72 hours²

Most disabling disease for people under 50 years - the most productive years of people's lives¹

Symptoms include extreme pain, nausea, vomiting, extreme sensitivities to light and sound, gastrointestinal issues

Significant unmet medical needs remain with existing preventive treatments, including speed of onset

Chronic migraine often leads to depression, anxiety, and sleep disturbances²

Migraine profoundly affects patients' lives

93%

say migraine affects their ability to work¹

86%

say migraine affects their ability to maintain relationships with children¹

89%

say migraine affects their ability to maintain relationships with a partner¹

4/10

Only 4/10 are satisfied with their current migraine treatment¹

Patients value efficacy and onset of efficacy regardless of the mode of administration

87%

rate effectiveness as important in determining whether they accept treatment (highest-rated)²

79%

rate fast acting as an important treatment feature when considering migraine prevention²



Migraine prevention represents a large and under served market

Addressable population (major countries¹)

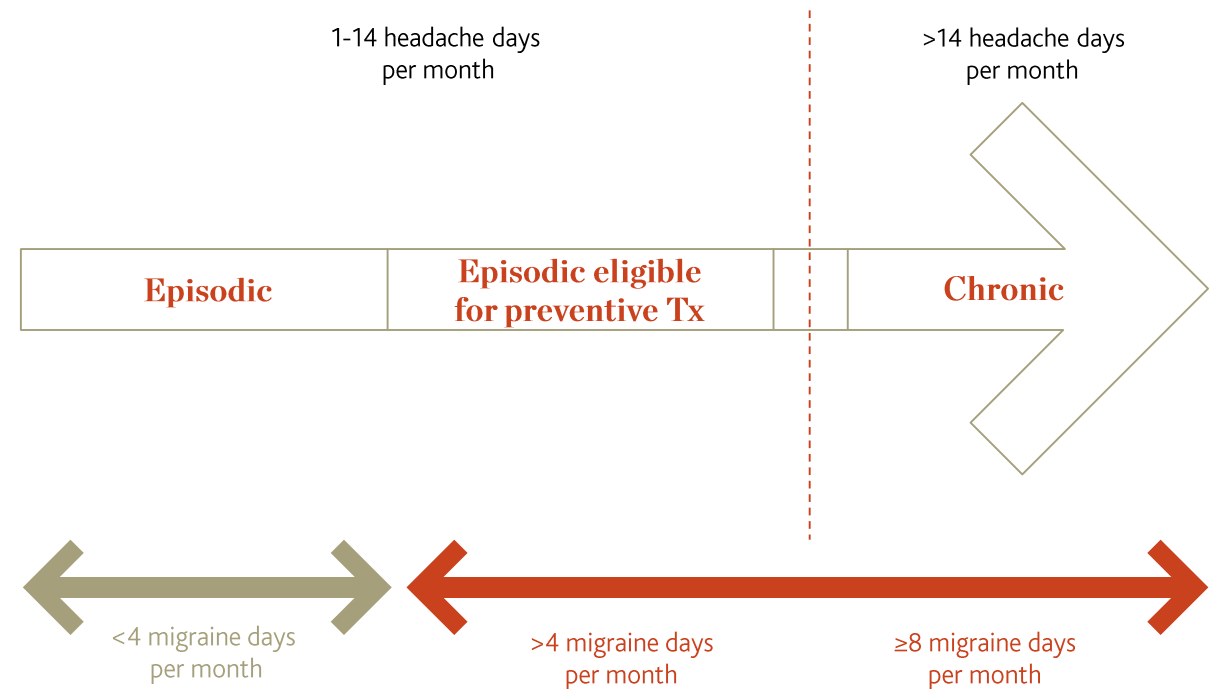
~134m – Migraine prevalence

~41m – diagnosed patients (30%)

~18m – Eligible for prevention (43%)

~9m – Currently on prophylactic treatment

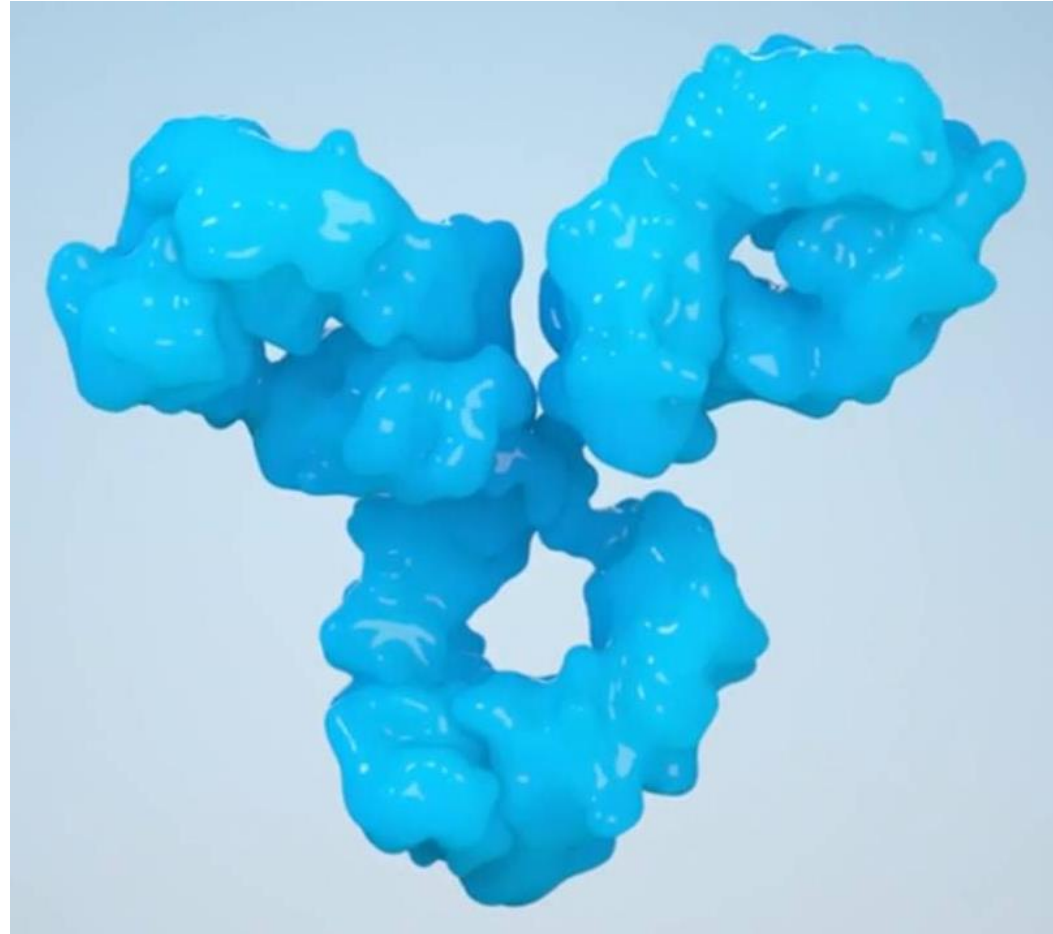
Migraine is divided into two major categories, episodic and chronic depending on the frequency of headaches



¹) Decision Resource, DRG 2018 Migraine Market report. Covers G7+China

Eptinezumab: Rapid, effective and sustained elimination of calcitonin gene-related peptide (CGRP)

- Humanized, IgG1, anti CGRP monoclonal antibody¹
- Selectively and potently inhibits CGRP biological activity
- 5 pM binding affinity for CGRP
- Persistent molecular activity (t 1/2 ~30 days)
- 100% bioavailability when administered by iv infusion
- Quarterly dosing schedule



Two large pivotal studies including ~2,000 patients demonstrated sustained efficacy and good tolerability

Promise 1

in Episodic Migraine Patients

(N=888; baseline ~9 migraine days/month)

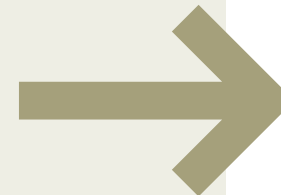
- Met primary and key secondary endpoints
- Good tolerability profile at all dosage levels

Promise 2

in Chronic Migraine Patients

(N=1,072; baseline ~16 migraine days/month)

- Met primary and all key secondary endpoints
- Good tolerability profile at both dosage levels



Powerful

≥50%, ≥75% and 100% reductions in migraine days

Fast

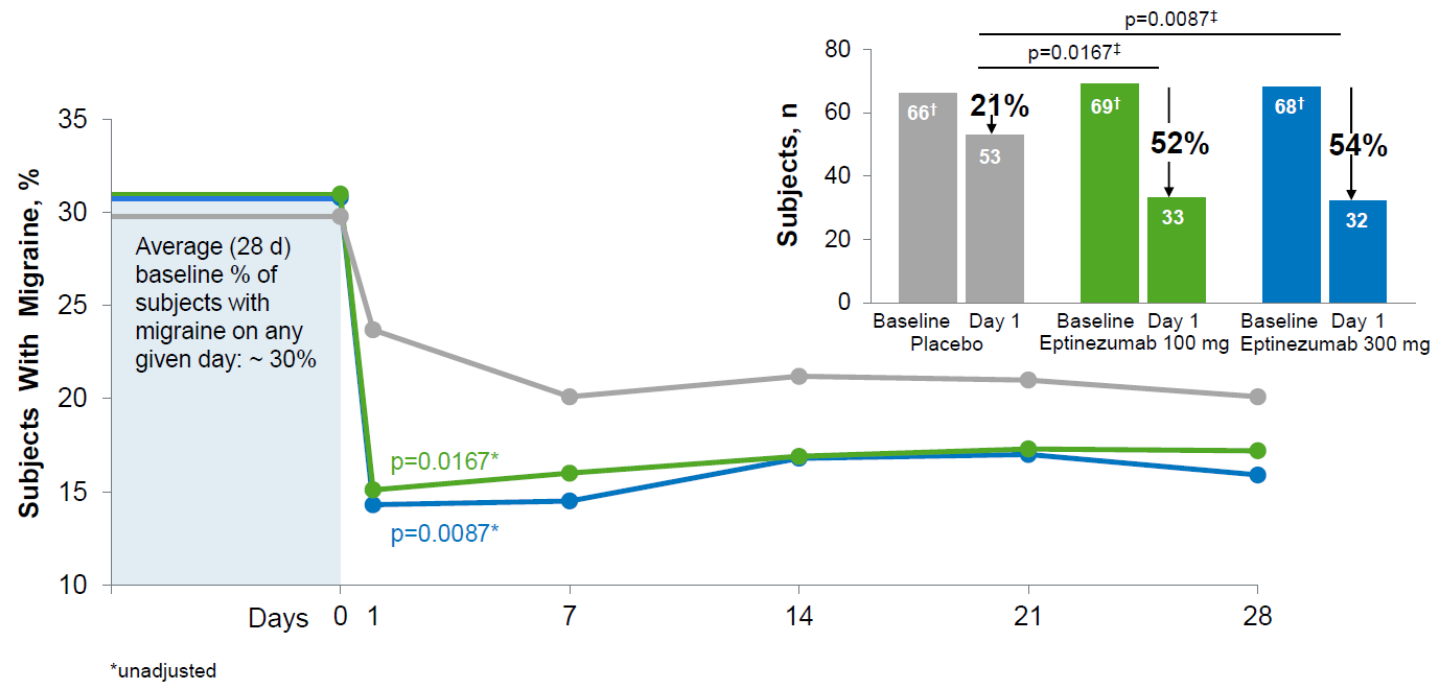
Onset of prevention
Day One post-infusion

Sustained

for 3 months following a single administration and sustained or further increased with subsequent infusions

Promise 1: A phase III study to evaluate the efficacy and safety of eptinezumab for prevention of frequent episodic migraine

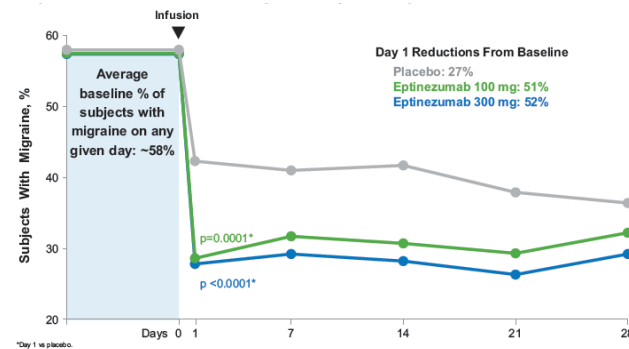
- Eptinezumab reaching statistical significance for the primary and all key secondary endpoints
- Migraine day prevalence dropped over 50% on Day 1 and reduction was sustained through Day 28
- Subjects experienced significantly fewer days with migraine
- Responder rates further improved with subsequent infusions for the 300 mg dose group



Eptinezumab achieved meaningful reductions in migraine activity as early as Day 1 that were sustained through Week 12: results from Promise-2 phase III trial in chronic migraine

- In subjects with chronic migraine beginning on the 1st day post-infusion, a single infusion of eptinezumab significantly reduced migraine activity for 3 months
- >61% of subjects' migraine days were reduced by $\geq 75\%$ and, on average, 38% experienced a $\geq 75\%$ reduction over 3 months
- The % of subjects with a migraine on Day 1 was reduced >50% following eptinezumab infusion and the reduction was sustained for 1 month

Day 1 Reductions from baseline in percentages of subjects with a migraine maintained on average through 28 Days

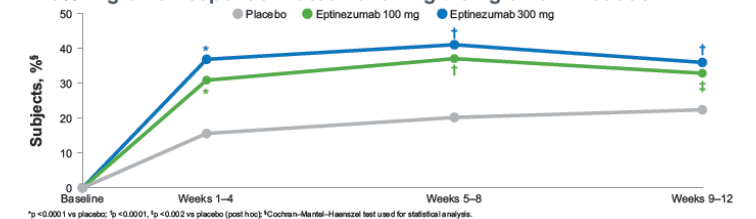


*At Day 1 following eptinezumab infusion, migraine risk was reduced by 52%

- At Day 1 following eptinezumab infusion, migraine risk was reduced by 52%

$\geq 75\%$ Migraine Responder Rates (RR) following a single administration

$\geq 75\%$ Migraine Responder Rates Following a Single Administration



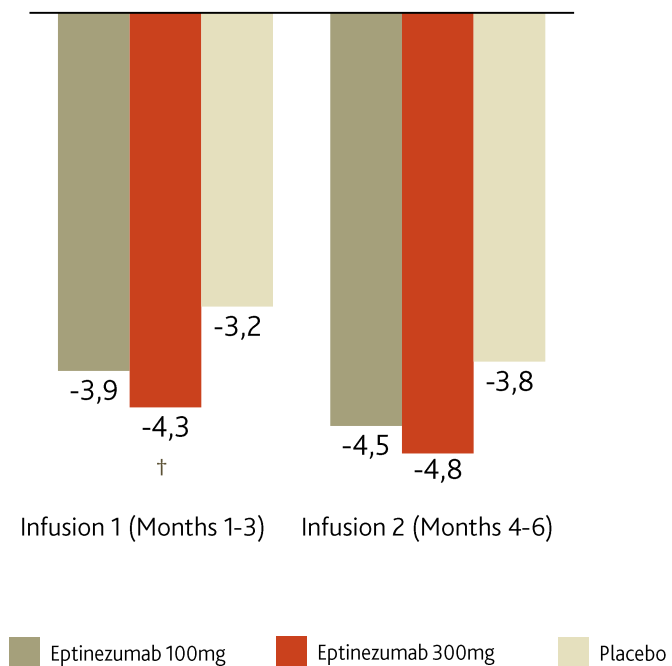
- An average of 38% of subjects treated with eptinezumab achieved a $\geq 75\%$ reduction in monthly migraine over 3 months
- This RR benefit was obtained as early as Weeks 1-4 and was maintained through Weeks 9-12

Significant reduction in monthly migraine days (MMDs) with eptinezumab at both 100mg and 300 mg

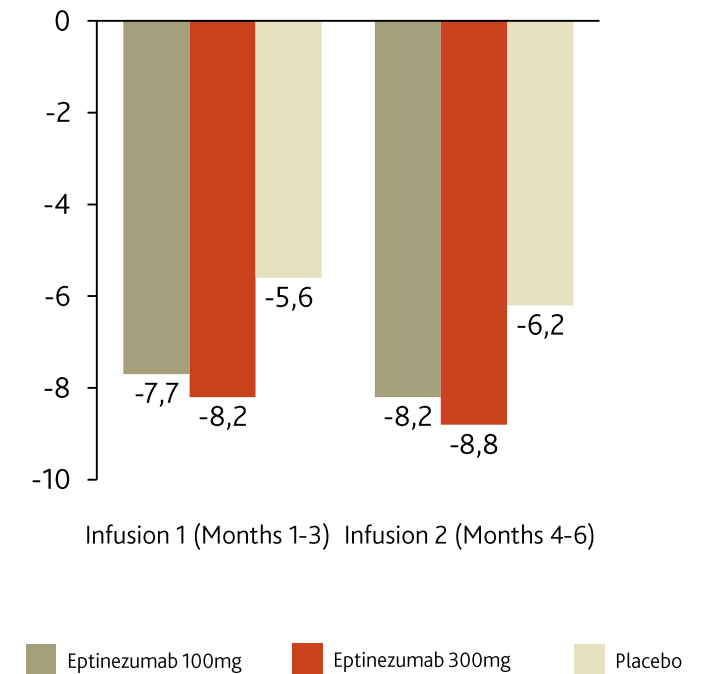
Eptinezumab has shown high response rates, especially in adult patients experiencing frequent, chronic migraine

- 60% of patients had $\geq 50\%$ reduction in migraine days
- ~40% of patients had $\geq 75\%$ reduction in migraine days
- Patients that experienced no migraines for at least half of the study period (≥ 3 mth):
 - 100mg: 14.0%
 - 300mg: 19.1%
 - Placebo: 4.9%

Promise-1
(Change from baseline in MMDs)



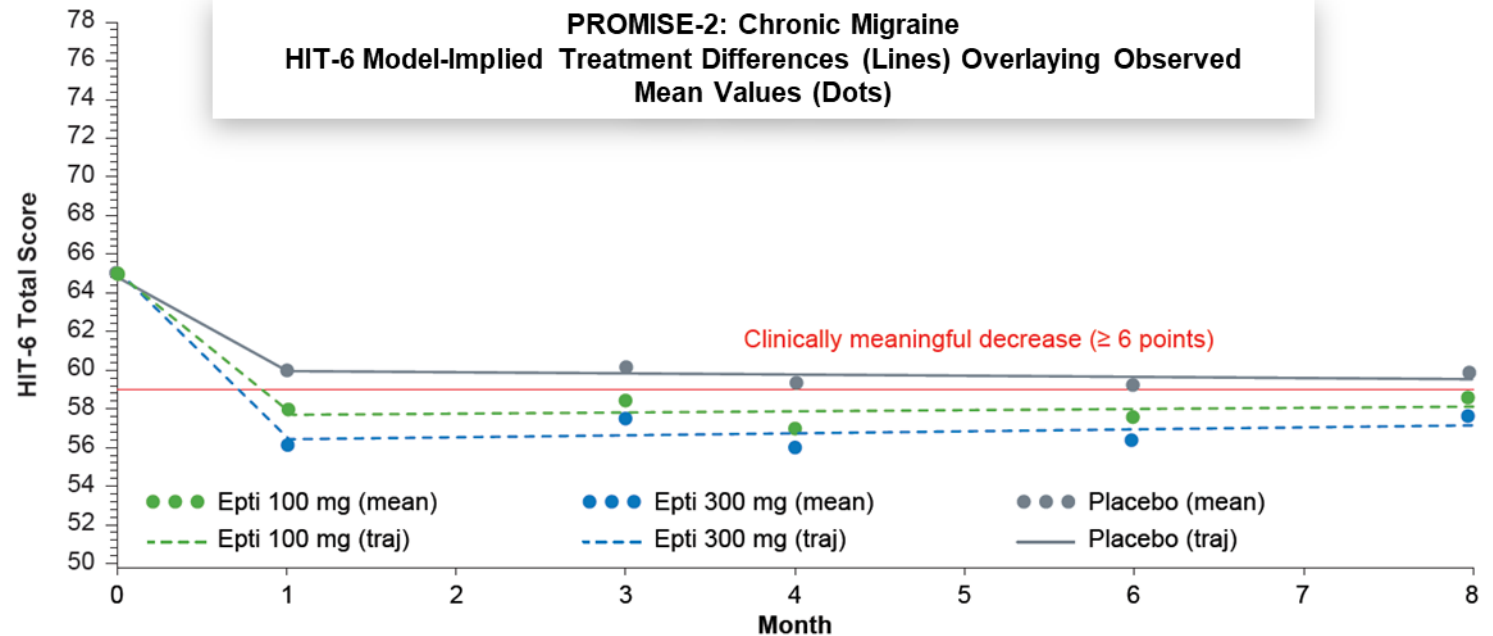
Promise-2
(Change from baseline in MMDs)



* $p=0.0182$; [†] $p=0.0001$; # $p<0.0001$ vs placebo. Months 4–6 were not included in the prespecified statistical algorithms.

HIT-6 is a widely used patient-reported outcome measure in headache and migraine research

- General measure of impact of headache on daily life¹
- Six-item scale (severe pain, limits daily activities, lie down, too tired, felt fed up or irritated, limits concentration)¹
- Scoring²:
 - ≥ 60 : severe impact
- A reduction in total HIT-6 score of ≥ 6 points has been reported to be clinically meaningful³
- 300 mg significant at $p < 0.0001$



Note: The red line demarcates an approximate 6-point decrease from baseline (clinically meaningful change threshold). Epti, eptinezumab; traj, model-implied trajectory.

Eptinezumab treatment well-tolerated across doses as compared to placebo

Safety and tolerability were evaluated in the Promise 1 and Promise 2 trials

In pooled data assessment across the two trials, nasopharyngitis (swelling of the nasal passages and the back of the throat) was the only AE occurring at an incidence of $\geq 2.0\%$ than placebo

Other AEs: Upper respiratory infection, nausea and urinary tract infection, arthralgia (joint pain), dizziness, anxiety and fatigue, which all occurred at a similar incidence to placebo (less than 2% difference vs. placebo) in the pooled data set

Adverse reaction occurring with an incidence of $\geq 2\%$ for either dose of eptinezumab and $\geq 2\%$ greater than placebo for Promise 1 and Promise 2

Adverse reactions	Eptinezumab 100 mg every 3 months N=579	Eptinezumab 300 mg every 3 months N=574	Placebo every 3 months N=588
Nasopharyngitis	6%	8%	6%

Saper J, Wilks K, Chakhava G, et al. Eptinezumab for the Prevention of Episodic Migraine Through 1 Year: Results from the Phase 3 PROMISE-1 (Prevention of Migraine via Intravenous Eptinezumab Safety and Efficacy-1) Trial. Presented at: 2019 American Academy of Neurology Annual Meeting: Philadelphia, PA; May 4-10, 2019. S38.003

Kudrow D, Lipton R, Silberstein S, et al. Eptinezumab for Prevention of Chronic Migraine: Results of 2 Infusions in the Phase 3 PROMISE-2 (Prevention of Migraine via Intravenous Eptinezumab Safety and Efficacy-2) Trial. Presented at: 2019 American Academy of Neurology Annual Meeting: Philadelphia, PA; May 4-10, 2019. P2.10-00

Eptinezumab – Powerful, Fast and Sustained action

Eptinezumab promise

- Rapid onset of prevention by Day 1 driven by IV formulation and 100% bioavailability, addressing unmet medical need
- Strong response rate data from two phase III studies
- Strong impact on patient's response on Quality of Life
- Good tolerability profile similar to placebo at all dosages
- Only prevention treatment available as an IV formulation
- Quarterly administration: Potentially increased compliance for improved outcome



Eptinezumab – Exciting upcoming newsflow with interesting LCM potential

Regulatory:

U.S. PDUFA action date: 21 February 2020

Expected submission in Canada (Q1 2020), EU (by end 2020), followed by submissions for approval in other regions around the world

Ongoing studies:

RELIEF study started in November 2019 (n = ~450)

There are several life cycle management opportunities

Indication

RELIEF study - "Treat & Prevent" (NCT04152083)

Assessing the efficacy of eptinezumab for acute migraine, defined as an active intercurrent migraine occurring in those patients who are candidates for preventive therapy.

Subjects will be randomized to receive a single dose of eptinezumab or placebo in a 1:1 ratio. The total study duration will be approximately 4 to 12 weeks, including up to an 8-week observation period, with clinic visits occurring on Screening, Day 0 (dosing day), and Week 4.

Other potential indications

- Medication overuse headache
- Cluster headache
- Post-concussion headache
- Other pain syndromes



Speaker: Peter Anastasiou - Executive Vice President, North America

Preparing to launch eptinezumab

Eptinezumab: Poised for success

1

Why Lundbeck is well positioned to successfully launch eptinezumab in the U.S.

2

Despite recent entrants, the migraine market still has substantial unmet need

3

Eptinezumab's fast, powerful and sustained control in prevention of migraine as shown in clinical trials differentiates it in the marketplace

4

Eptinezumab's profile as an infused product further differentiates it from competitors and delivers on benefits patients and physicians say they desire

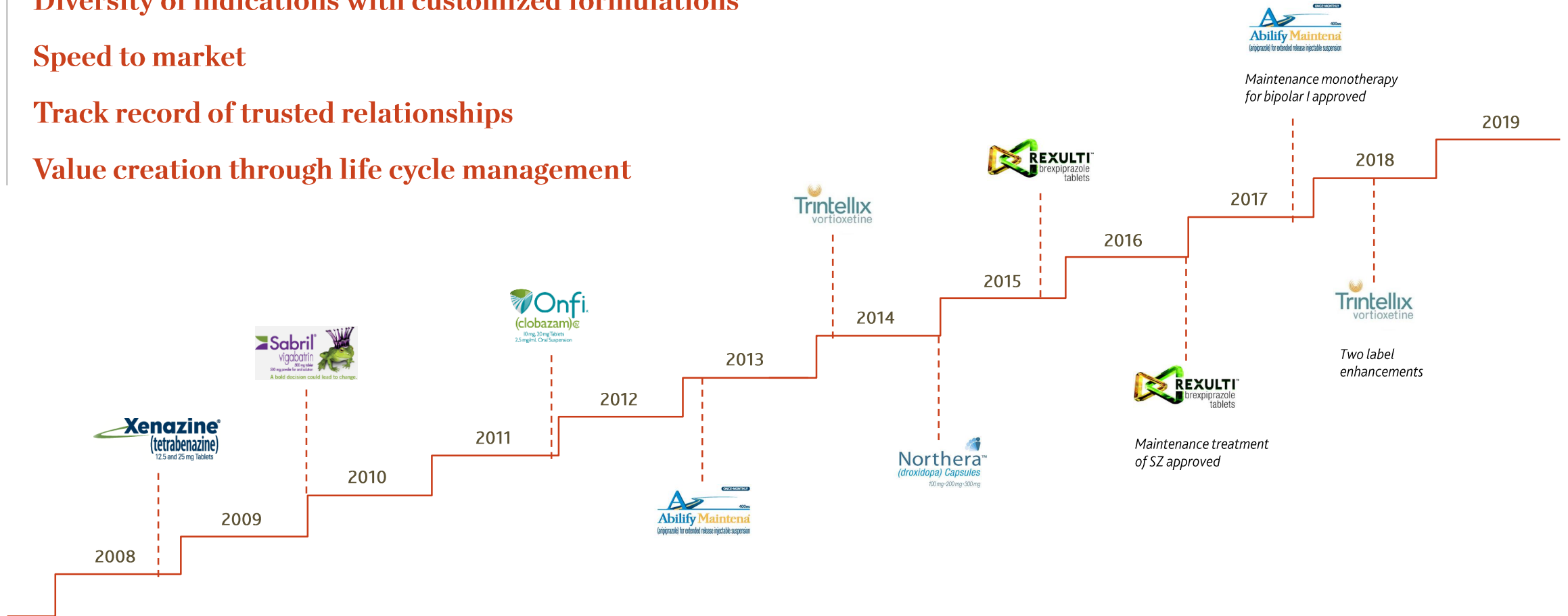
Lundbeck U.S. launch success with 7 products in 10 years

Diversity of indications with customized formulations

Speed to market

Track record of trusted relationships

Value creation through life cycle management



Eptinezumab will benefit from Lundbeck's capabilities

Orphan/Specialty Distribution

Xenazine, Sabril, Northera, Onfi, Abilify Maintena

- Limited patient population
- Limited number of physicians
- Fewer competitors
- Low SG&A requirements
- Specialty pharmacy distribution
- Hub model

Large Specialist-driven/Retail

Trintellix, Rexulti

- Huge markets
- Large number of physicians
- High pricing/payer pressure
- Substantial competition
- High SG&A requirements / DTC
- Longer IP = LCM

Focused launch

Concentrated number of specialists driving majority of the market
Existing IV capabilities
Experienced with medical benefit products
Support services aligned to patient needs

Lundbeck ranked #1

by patient groups four years in a row

PatientView Corporate
Reputation of Pharma,
U.S. Edition

Patient-centricity

Patient information

Patient safety

High-quality products

Transparency in
pricing

Transparency in
clinical data

Transparency in
funding

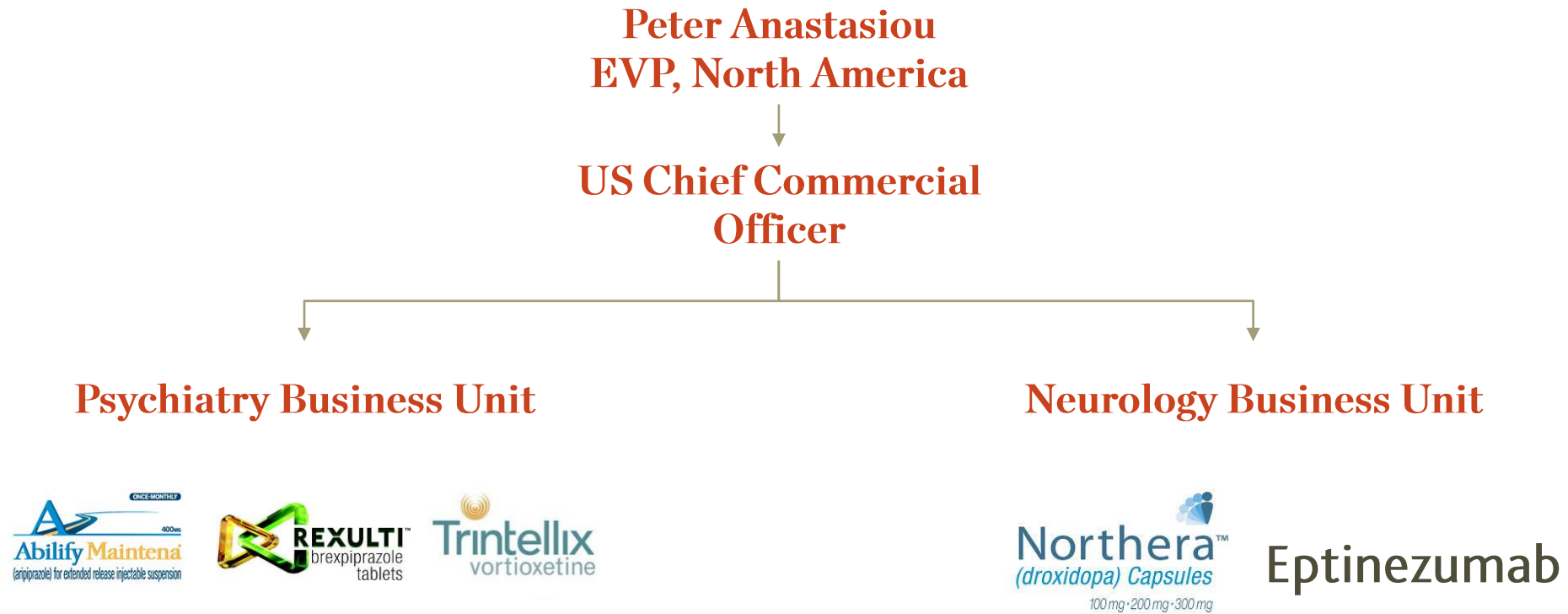
Corporate integrity

Quality of patient-
group relationships

“beyond the pill”
services

...& overall

The U.S. organization has been redesigned to maximize strategic brands while leveraging synergies and reputation in neurology



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Patients are dissatisfied with previous treatments based on tolerability and lack of sustained efficacy

Oral preventives fail

to meet needs of many patients: adherence, safety, tolerability issues¹

Up to 80% discontinue

use of oral preventives within 6-12 months due to lack of efficacy and/or tolerability^{2,3}

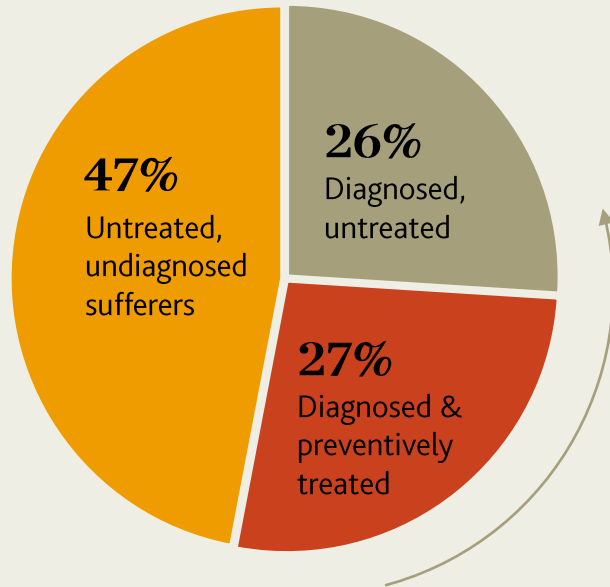
¹Parsekyan D. Migraine prophylaxis in adult patients. *West J Med.* 2000;173(5):341-345.

²Lipton RB, Bigal ME, Diamond M, et al. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology.* 2007;68(5):343-349.

³Hepp Z, Dodick DW, Varon SF, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. *Cephalgia.* 2015;35(6):477-488.

Patients dissatisfied with first generation prevention options will expand the market potential

Migraine prevention market: 13.9m^{1, 2}



Breakout of 27% treated group

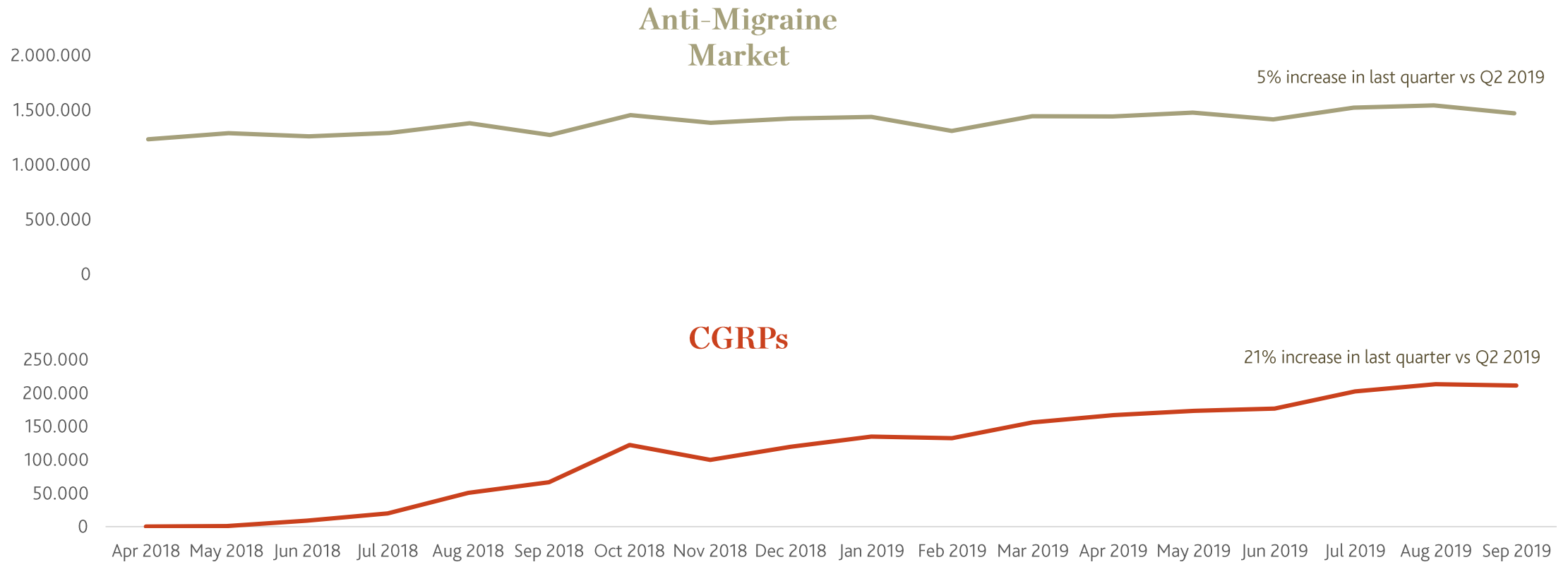
Preventive Treatments	% of Use ³
Botox	10%
CGRP	5%
Other Preventive Treatments (Topiramates, beta-blockers, other anti-seizures, amitryptaline)	85%*

¹2018 DRG Migraine Market Landscape & Forecast, ²Lipton 2007; 13.9M= 62% 4+ Migraines, 38% 15+

³2019 Truven Health Analytics

* Some patients are on combo therapy such as CGRP + Topiramates. For purpose of this analysis, patients on multiple therapies are deduped.

The overall prevention market is growing primarily driven by CGRP class



The commoditization of the S.C. CGRPs provides room for differentiation with eptinezumab

Similar launch timing and product attributes

Products with same indications launched within ~6 months of each other

Similar efficacy results

Differences are limited to side effects and device

Minimally differentiated launch execution

15-20% of TRxs¹ driven by free product voucher

Similar patient targets

Similar patient support programs – Aimovig had a “learning curve”

A commoditized marketplace

82% of HCPs² view current CGRPs as interchangeable

BOTOX has been largely unaffected by the sub-cutaneous (S.C.) CGRP launches as the product has a well entrenched prescriber base

¹Source: IQVIA June 2019 Xponent PlanTrakdata

²Source Q119 RealTimeDynamix: SpherixGlobal Insights (40-Minute Quantitative Online Survey n=99 Neurologists and Headache Specialists, Pediatric Specialists Screened Out)

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Eptinezumab: A specifically designed antibody targeting the CGRP ligand

Selective binding

High **specificity** for CGRP ligand¹

Strong binding

High **affinity** for CGRP ligand¹

Immediate availability

100% bioavailability for **rapid** exposure¹

Eptinezumab design features that appear to allow for rapid response and efficacy that is powerful and sustained^{2,3}

Eptinezumab: fast, effective and sustained elimination of CGRP¹ that delivers meaningful patient outcomes



Fast

Onset of prevention
Day One post-infusion

Onset of prevention starting from Day 1 post- 30 min IV administration; >50% of patients have no migraine 1 day post infusion



Powerful

≥50%, ≥75% and
100% reductions in
migraine days

54.5% and 30.9% of patients achieved the ≥50% and ≥75% responder rates by month 1 and sustained or further increased efficacy with subsequent infusions

Meaningful Monthly 100% responder rate (averaged over Months 1, 2 and 3)



Sustained

for 3 months following
a single administration
and sustained or further
increased with
subsequent infusions

Response rates either sustained or further increased with repeat quarterly IV treatments



Meaningful

Patient improvements

Clinically meaningful improvements in patient-reported Health-Related Quality of Life (HRQoL)

30 min IV treatment translates to only 2 hours per year of patient's time

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Many additional factors allow for eptinezumab to differentiate in the market



Physicians

Epti product profile show great acceptance and willingness to prescribe

Physicians see IV as a path to having **greater control of care and ensure proper compliance**. Physicians are also used to quarterly dosing patterns as they currently follow this for Botox



Patients

Patients are suffering and need preventive medications that work, and work faster

Nearly half of patients on epti felt that their migraine status was much or very much improved as early as Month **1 while 60% of patients** felt their migraine status was much or very much improved by month 6¹



Specialists

Customer base is highly specialized with neurologists and headache centers

Customer base is highly concentrated with 650 accounts writing **~50% of prescriptions** and 2,000 accounts writing **~80% of prescriptions**. 95% have access to IV capacity and >70% have IV capacity in-house²



Market Access

Broad access is expected given the product covered Medical Benefit

The reimbursement process for Medical Benefit products differs from S.C. CGRPs Pharmacy Benefit products

1) Patient Global Impression of Change for patients with more than 15 migraine headache days. 2) Account mapping and market research conducted by Argon

Physicians prefer to have greater control over the total patient care and create an emotional connection

With IV infusions, MDs KNOW their patients are compliant

Increases their confidence when making subsequent treatment decisions

Eases uncertainty about therapeutic responses and eliminates doubt about compliance

- Is the patient not responding to medication?
- Was it not taken as prescribed?
- Was the drug not approved by insurance?

“IV infusions give you the comfort the patient is compliant, and compliance leads to more effective medications and better results.”

Neurologist

“If they only did what I told them to do it wouldn’t be so challenging to care for them.”

Headache Specialist

“Knowledge is power- We can help patients more when we know if they are compliant.”

Primary Care

“Being sure of compliance means you know the drug was approved and patient took it. It leads to a more productive and therapeutic relationship. They trust me, I trust them.”

PA

Empower the right patients to ask for eptinezumab's fast and sustained powerful prevention

87%

Patients who rate efficacy as top reason for accepting prevention Rx

43%

Patients who are afraid of doing something wrong with self-injection

26%

Patients who prefer HCP administered treatment

Priority patient targets

Speed of treatment and efficacy

To be taken care of

To have the assurance of correctly administering

To be free of thinking of medicine daily, monthly

She wants more than freedom from pain.

“I wish I could worry less and live more”

~650 accounts are driving 50% of the migraine prevention volume with almost all having IV access

~ 650

Headache/ Pain Centers,
Neurology Practices, and
Hospitals

See an average of 200-300
migraine patients per month
Often see patients at a quarterly
cadence

95%

Have IV access¹

80%

Have in-office access¹

80%

Have
prescribed
an IV to their
patients for
migraine¹

83%

Have
prescribed
Botox to
their
patients for
migraine¹

Medical vs. pharmacy benefit dynamic

Retail S.C. Drugs: Pharmacy Benefit

CGRP retail products managed under a pharmacy benefit

Tight monitoring limits physician choice in prescribing through more utilization mgmt.

Rebating is more common with pharmacy benefit products due in part to electronic capture of utilization

Significant patient cost sharing

Office Infusion Drugs: Medical Benefit

Eptinezumab will be managed mainly under a medical benefit

Less utilization management

Payer rebating is less common

Fewer plans require patient cost sharing

Eptinezumab access process will resemble Botox more than CGRPs

Botox is also administered by a healthcare professional and managed via medical benefit

Setting expectations: while there are many advantages with medical benefit products, a short-term challenge exists

As with all physician administered drugs, eptinezumab will have a Not Otherwise Classified (NOC) code or miscellaneous J code for up to a year*

All medical providers use standardized coding systems when submitting claims for reimbursement of services and supplies

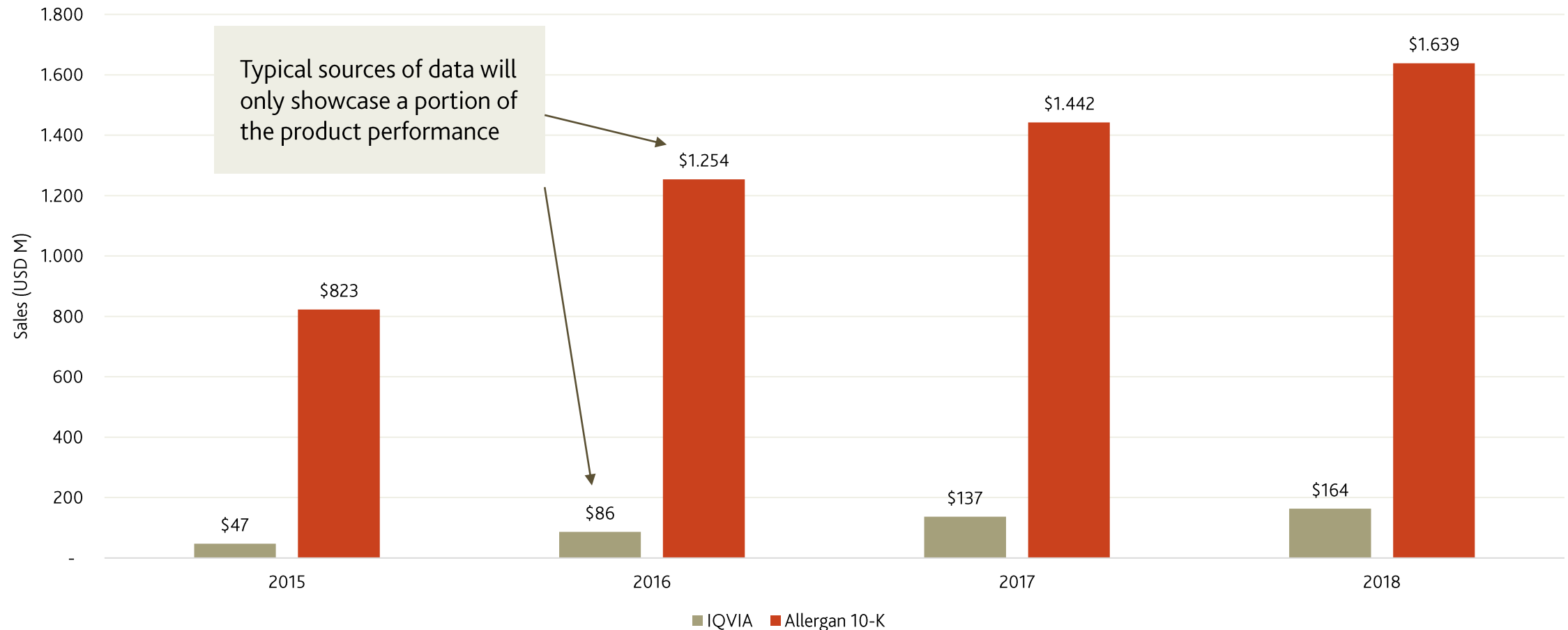
J codes are used for drugs for physician administered products

NOC codes can create provider administration burden and perception of payment uncertainty and delays, but most are accustomed to this with new products

Payer coverage criteria also takes time to be established, which may cause some HCPs to be more conservative in their uptake at launch

*CMS has announced quarterly opportunities to apply and receive codes for drugs. Eptinezumab could receive a permanent J code earlier than Q1 2021

Setting expectations: data for physician administered products are less transparent than retail (e.g. Botox)



Global reach

Global reach

Already planning Canada/EU filings
Preparing the path for China, Japan and emerging markets

Market Access

Initiate study to facilitate EU market access
Building insights and relationships to prepare global markets

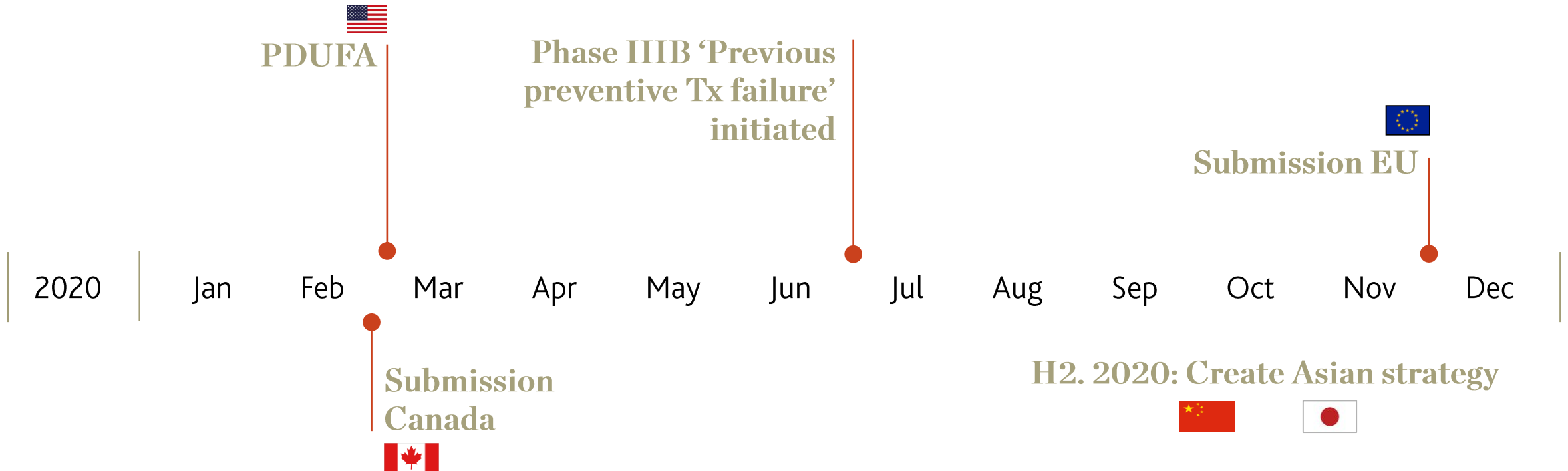
Expanding eptinezumab

Drive 'Treat & Prevent' study
Define and pursue future indications



**Global path
forward for
eptinezumab**

Wheels are in motion for global roll-out



Eptinezumab: Poised for success

- In summary

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Lundbeck is well positioned to successfully launch eptinezumab

2

The migraine market still has substantial unmet need

3

Eptinezumab has fast, powerful and sustained control in prevention of migraine

4

Eptinezumab's profile as an infused product further differentiates it

Dr. Messoud Ashina, MD, PhD, DMSc - Professor of Neurology; Faculty of Health and Medical Sciences; Rigshospitalet Glostrup

What makes migraine unique?

Migraine

Presenter

Dr. Messoud Ashina

1. Health impact/burden
2. Migraine symptoms
3. Migraine subtypes: episodic and chronic
4. Management: acute and preventive treatment
5. Patients eligible for preventive treatment
6. Unspecific migraine preventatives
7. Rationale behind CGRP
8. Discovery and human experiments
9. First proof of concept small molecules CGRP receptor antagonists
10. Monoclonal antibodies
11. Summary of phase 2 studies
12. Summary of phase 3 studies
13. Summary on safety & tolerability
14. Onset of effect

Executing on *Expand and Invest to Grow* - In summary

Strategic brands up 29%

**New studies with
brexpiprazole**

**Acquisitions of Abide and
Alder ▶ moving into
migraine, Tourette
syndrome and pain**

**Trintellix approved in
Japan, Rxulti launch in
Europe**

**Portfolio Management
Board and closer
collaboration between
Commercial and R&D**

**Three FiH-studies and one
PoC-study with internal
projects; clinical pipeline
now containing 11
compounds**

Thank
you!