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Lundbeck is entering a new era

The “New” Lundbeck
– the building blocks for growth
★ Global growth platform
★ Multiple product company
★ Executing on new product launches
★ Drive growth of diversified portfolio
★ Deliver on late stage pipeline

The “Old” Lundbeck
★ “European” company
★ “One product” company

CNS FOCUS
Submissions and expected approvals

- **2012**
  - **Submissions**
  - Brintellix
  - Abilify Maintena (EU)

- **2013**
  - **Approvals**
  - Selincro
  - CHMP recommendation
  - Abilify Maintena
  - Selincro (EU)
  - Brintellix
  - IV carb. (US)

- **2014**
  - **Submissions**
  - Brexpiprazole (US)
  - Desmoteplase
  - Brintellix
  - Selincro (EU)
  - IV carb. (US)

- **2015**
  - **Approvals**
  - Desmoteplase
  - Brexpiprazole (EU)
  - Brexpiprazole (US)
Abilify Maintena launched in the US

- leverages on the extensive clinical experience with oral Abilify

- is set to expand the long-acting market in schizophrenia

- is expected to reach peak sales of DKK 2-2.5 billion (in total for Lundbeck)

- The global depot market amounts to USD 2.4 billion
  - CAGR of 21% from 2007-2011

Relapse has a significant negative impact on the patients with schizophrenia

Relapse is substantially driven by poor adherence

Adherence is primarily influenced by the patients’ poor insight and acceptance of the efficacy / side effect balance

Abilify Maintena can help physicians address those challenges and protect their patients from the natural course of the disease
Selincro launched in selected European markets

- Selincro is the first and only product targeting alcohol reduction
- Strong interest in the concept from many stakeholders
- Selincro launched in UK, Finland, Norway, Poland and Baltic countries
- Selincro is expected to significantly increase the treatment ratio from currently ~4%
- Peak sales DKK 2-2.5 billion

The Selincro Patient
- Alcohol dependent
- High risk drinking level
- No physical withdrawal symptoms/ no need for immediate detoxification
Brintellix: unique multimodal MoA profile that combines receptor activity and uptake inhibition

Potential clinical effects:
- ↑ mood
- ↓ sexual dysfunction
- ↑ cognition
- ↓ anxiety
- ↓ insomnia

4. Garnock-Jones KP, McCormack PL. CNS Drugs 2010;24:769-796
Brintellix is a new multimodal antidepressant with robust and broad efficacy

- Efficacious in the treatment of depression in adults, elderly and when used as maintenance treatment to prevent relapse
- Is efficacious in the treatment of depressive symptoms in patients with an inadequate response to SSRI/SNRI
- It leads to improvement in the overall depressive syndrome, including the items of the MADRS, response and remission rates and global clinical impression as measured by the CGI-I
- Improves cognitive function in depressed patients, assessed as performance on the neuropsychological tests DSST and RAVLT.
- Improves health-related quality-of-life outcomes (SF-36 MCS), overall health rating (EQ-5D) and overall functioning (SDS)
Brintellix – what do we have?

A solid efficacy profile

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Safety/tolerability: Tolerability better or equal to SSRIs and SNRIs

- Nausea: lower or similar level as SNRI active reference
- Withdrawal rate slightly above placebo level
- At placebo level/neutral effect
- Insomnia, Body weight, Heart rate and blood pressure, ECG, QTc, Hepatic and renal assessments, Sexual side effects are similar to placebo
- Discontinuation symptoms are at or slightly above placebo

Data not yet challenged and final label not yet discussed
Brintellix - cognition data in elderly patients with MDD

- Significant improvement in cognitive functioning vs. placebo on DSST scale
- Significant improvement in cognitive functioning vs. placebo on RAVLT scale
- Path analysis: 83% of effect on cognitive dysfunction was direct
- Only 17% indirect effect as result of improvement in depressive symptoms
- Two ongoing clinical trials in adult MDD patients with cognition tests as primary endpoints

DSST= Digital Symbol Substitution Test, RAVLT = Rey Auditory Verbal Learning Test

1) Efficacy and Safety of Lu AA21004 in a Randomised, Double-Blind, Placebo-controlled, Active-referenced, Fixed-dose Study in Elderly Depressed Patients, Christina K Olsen, PhD et al., APA 2012, poster 8-42

NOT FOR PROMOTIONAL USE
Getting to know Brintellix: A new multimodal antidepressant

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**Efficacy in MDD**

- Comparable to SNRIs (MADRS, HAM-D, CGI; change from baseline, response, remission, relapse prevention)
- In adults, elderly and relapse prevention
- Efficacious in patients who have inadequate effect from SNRI/SSRIs
- To-date, ~70% positive clinical trials

**Exploratory endpoints demonstrate that Brintellix has positive effects on cognitive symptoms of depression**

- These effects are mostly independent of overall improvement in depressive symptoms

**Favourable tolerability profile (>3,000 MDD patients exposed)**

- Placebo levels of sleep disturbance, weight gain, and low treatment emergent sexual dysfunction (TESD)
Lundbeck has significant presence in psychiatric disorders in years to come

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*No active clinical programme ongoing
Why could Lu AE58054 be a new valuable AD treatment?

- Lu AE58054 has a different mode of action compared to existing symptomatic treatments (blockade of 5-HT$_6$ receptors)

- Blocking this particular kind of serotonin receptors (5-HT$_6$ receptors) has beneficial effects on several neurotransmitter systems in the brain

- Lu AE58054 has been shown to have beneficial effects on cognition in animal models

- Lu AE58054 has been shown to have beneficial effects on cognition in AD patients on stable donepezil treatment
Lu AE58054 - Effective in AD patients

24 weeks study of Lu AE58054 in combination therapy with donepezil in Alzheimer’s disease

Clinical phase II

- The primary objective is to explore the effect on cognitive performance after 24 weeks of treatment
  - 278 patients with moderate Alzheimer’s
  - Add-on to donepezil
  - Treatment period of 24 weeks

Lu AE58054 – phase II outcome

- Lu AE58054 (+donepezil) demonstrated significant improvements in cognitive function compared to placebo (+donepezil), as assessed by ADAS-cog
- Secondary endpoints were supportive
- Lu AE58054 was considered overall to be well tolerated
Lundbeck and Otsuka expand alliance to include Lu AE58054

- Co-development and co-commercialization agreement with Otsuka on Lu AE58054
- Lundbeck receives USD 150 million from Otsuka upon signing of agreement
- Clinical phase III program is planned to be initiated in H2 2013
  - 3 trials of more then 2,500 patients
  - Add-on to donepezil
  - Several active dose of Lu-AE58054
- Clinical phase II study results is planned to be presented at AAIC in Boston in July
Expected main events in 2013

**H1 2013**

- Approval of Abilify Maintena the US ✔
- Final approval of Selincro by the EU Commission ✔
- Presentation of Brintellix data at APA 2013 on 18-22 May, San Francisco ✔

**H2 2013**

- Presentation of Lu AE58054 data at AAIC 2013 in July in Boston
- Start of pivotal programme on Lu AE58054 in Alzheimer’s
- Approval of Brintellix in Europe (CHMP recommendation) and North America
- Recommendation of Abilify Maintena from CHMP in Europe
Thank you...