H. LUNDBECK A/S

15 May 2012 – 9AM CET

# Teleconference
# Lu AA21004 on its way to submission

# Company disclaimer

This presentation contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

# Statistically significant clinical phase III results of Lu AA21004

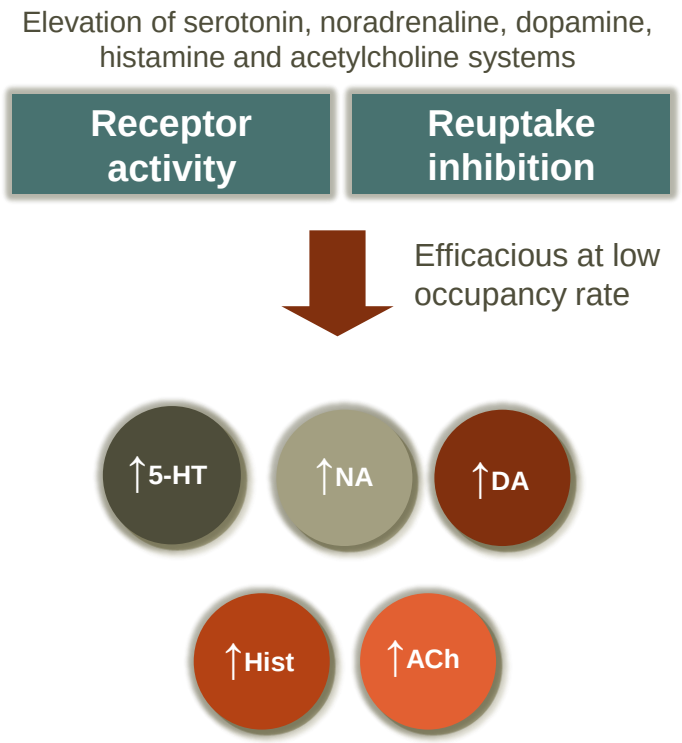
- New clinical phase III data demonstrate the efficacy of Lu AA21004 compared to placebo in the treatment of MDD seen in several previous studies
- Data from six out of eight short-term placebo controlled studies so far have established and repeated statistically significant efficacy of Lu AA21004 in a dose range from 5 to 20mg
- Efficacy of Lu AA21004 is further confirmed in a positive trial in an elderly population, and in a long-term relapse-prevention study in MDD
- Based on the current data package Lundbeck and its partner Takeda intend to submit Lu AA21004 for US registration during the second half of 2012
- Lundbeck plans to submit for the European and Canadian registration during the second half of 2012

# What do we have so far?

- Novel and unique mechanism of action
- Strong efficacy at normal dose
- Potential dose range in label 5-20mg

- Positive relapse prevention study (5 and 10mg)
- Positive study in elderly patients with MDD (5mg)
- Efficacy established at dosages from 5 to 20mg

- Withdrawal rate overall at placebo level
- Safe and well tolerated in short- and long-term studies
  - Sexual side effects at placebo level
  - Attractive side effect profile on several gastrointestinal parameters
  - Weight neutral
  - No safety issues - incl. thorough QT-studies



# The next step

**Timeline for Lu AA21004**

# Clinical programme using Lu AA21004 in MDD

| Clinicaltrials.gov identifier | Estimated enrolment | Study start | Intervention |
|---|---|---|---|
| NCT01140906 | 600 (non-US) | May 2010 | 8 wks. Lu AA21004 (15+20mg); duloxetine (60mg); Placebo |
| NCT01255787 | 615 (non-US) | November 2010 | 8 wks. Lu AA21004 (5+10+20mg); placebo |
| NCT01323478 | 300 (non-US) | April 2011 | 52 wks extension. Lu AA21004 (15+20mg) |
| NCT01163266 | 450 (US) | July 2010 | 8 wks. Lu AA21004 (10+20mg); placebo |
| NCT01153009 | 600 (US) | June 2010 | 8 wks. Lu AA21004 (15+20mg); duloxetine (60mg); placebo |
| NCT01179516 | 450 (US) | August 2010 | 8 wks. Lu AA21004 (10+15mg); placebo |
| NCT01152996 | 1,000 (US) | September 2010 | 52 wks extension. Lu AA21004 (15+20mg) –by invitation only |
| NCT01355081 | 360 (Japan) | May 2011 | 8 wks. Lu AA21004 (5+10mg); placebo |
| NCT01364649 (sexual dysfunct.) | 440 (US+Canada) | May 2011 | Lu AA21004 (10-20mg); escitalopram (10-20mg) |
| NCT01422213 (cognition) | 600 (US) | December 2011 | 8 wks. Lu AA21004 (10+20mg); placebo |
| NCT00635219 | 766 (non-US) | April 2009 | 8 wks. Lu AA21004 (2.5+5+10mg); duloxetine (60mg); placebo |
| NCT00735709 | 560 (non-US) | August 2008 | 8 wks. Lu AA21004 (1+5+10mg); placebo |
| NCT00672620 | 611 (US) | April 2008 | 8 wks. Lu AA21004 (2.5+5 mg), duloxetine (60mg); placebo |
| NCT00672958 | 600 (US) | April 2008 | 6 wks. Lu AA21004 (5mg); placebo |
| NCT00694304 (safety) | 536 (non-US) | May 2008 | 52 wks. Lu AA21004 (2.5-10mg flexible dose) |
| NCT00596817 (relapse) | 400 (non-US) | December 2007 | <76 wks. Lu AA21004 (5+10mg); placebo |
| NCT00707980 | 836 (non-US) | June 2008 | <52 wks. Lu AA21004 (2.5+5+10mg) |
| NCT00811252 (elderly) | 453 (US) | January 2009 | 8 wks. Lu AA21004 (5mg); duloxetine (60mg); placebo |
| NCT00761306 (safety) | 74 (non-US) | June 2007 | 52 wks. Lu AA21004 (5+10mg) |
| NCT00839423 (phase II) | 429 (non-US) | August 2006 | 8wks. Lu AA21004 (5+10mg); venlafaxine XL (225mg); placebo |

# Why does society need a new antidepressant?

**The need for new anti-depressants is there:**

- Prevalent as ever
- High level of non- and insufficient response to first-line treatments
- Disorder driving suffering and social issues both for individuals and relatives
- High mortality
- Long-term outcomes still not satisfactory

**Willingness to prescribe/pay:**

- New MoA gives promise
- Important to provide clear benefits compared to standard care
- Clinical benefits that translate into e.g.:
  - Reduced relapses
  - Decreased sick-leaves
  - Decreased hospitalisations
  - Increased cognitive functioning

**Lu AA21004 - a solution?**

- Unique pharmacological profile
- Effects on multiple neurotransmitter systems
- Potential therapeutic dose range of 5-20 mg (QID)
- Positive safety and tolerability profile

Strong partnership with Takeda

# Thank you…