Teleconference
Lu AA21004 on its way to submission
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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

Elevation of serotonin, noradrenaline, dopamine, histamine and acetylcholine systems

Reuptake inhibition

Efficacious at low occupancy rate
The next step

**Timeline for Lu AA21004**

- 9 posters at APA 2012, incl. MDD in elderly patients
- Headline conclusions high dose phase III studies
- Submission of MAA in EU
- Submission of NDA in the US

Q2 2012 | Q3 2012 | Q4 2012
Clinical programme using Lu AA21004 in MDD

<table>
<thead>
<tr>
<th>Clinicaltrials.gov identifier</th>
<th>Estimated enrolment</th>
<th>Study start</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>NCT01140906</td>
<td>600 (non-US)</td>
<td>May 2010</td>
<td>8 wks. Lu AA21004 (15+20mg); duloxetine (60mg); Placebo</td>
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<tr>
<td>NCT01255787</td>
<td>615 (non-US)</td>
<td>November 2010</td>
<td>8 wks. Lu AA21004 (5+10+20mg); placebo</td>
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<tr>
<td>NCT01323478</td>
<td>300 (non-US)</td>
<td>April 2011</td>
<td>52 wks extension. Lu AA21004 (15+20mg)</td>
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<tr>
<td>NCT01163266</td>
<td>450 (US)</td>
<td>July 2010</td>
<td>8 wks. Lu AA21004 (10+20mg); placebo</td>
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<tr>
<td>NCT01153009</td>
<td>600 (US)</td>
<td>June 2010</td>
<td>8 wks. Lu AA21004 (15+20mg); duloxetine (60mg); placebo</td>
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<td>NCT01179516</td>
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<td>NCT01152996</td>
<td>1,000 (US)</td>
<td>September 2010</td>
<td>52 wks extension. Lu AA21004 (15+20mg) –by invitation only</td>
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<td>NCT01355081</td>
<td>360 (Japan)</td>
<td>May 2011</td>
<td>8 wks. Lu AA21004 (5+10mg); placebo</td>
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<td>NCT01364649 (sexual dysfunct.)</td>
<td>440 (US+Canada)</td>
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<td>Lu AA21004 (10-20mg); escitalopram (10-20mg)</td>
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<tr>
<td>NCT01422213 (cognition)</td>
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<td>8 wks. Lu AA21004 (10+20mg); placebo</td>
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<td>NCT00635219</td>
<td>766 (non-US)</td>
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<td>NCT00735709</td>
<td>560 (non-US)</td>
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<td>NCT00672620</td>
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<td>NCT00672958</td>
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<td>NCT00694304 (safety)</td>
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<td>52 wks. Lu AA21004 (2.5-10mg flexible dose)</td>
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<td>NCT00596817 (relapse)</td>
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<td>December 2007</td>
<td>&lt;76 wks. Lu AA21004 (5+10mg); placebo</td>
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<td>NCT00707980</td>
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<td>NCT00811252 (elderly)</td>
<td>453 (US)</td>
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<td>NCT00761306 (safety)</td>
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<td>NCT00839423 (phase II)</td>
<td>429 (non-US)</td>
<td>August 2006</td>
<td>8wks. Lu AA21004 (5+10mg); venlafaxine XL (225mg); placebo</td>
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Why does society need a new antidepressant?

The need for new antidepressants 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...