

**FOR CONSUMER MEDIA****New treatment for patients with bipolar I disorder**

***First sublingual treatment for moderate to severe manic episodes associated with bipolar I disorder, one of the leading causes of disability<sup>1</sup> affecting an estimated 623,000 patients in the UK,<sup>2,3</sup> becomes available today<sup>4</sup>***

**Monday 16th January 2011, H. Lundbeck A/S, UK:** Lundbeck Ltd today announced that Sycrest<sup>®</sup> (asenapine) is being launched in the UK for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults.<sup>4</sup> This offers a new treatment choice for people with this serious and disabling disorder.<sup>1</sup>

Bipolar I disorder (also known as manic depressive disorder) is a long-term condition, characterised by alternations between two poles of extreme moods - mania (including symptoms such as episodes of elevated moods, extreme irritability, decreased sleep and increased energy) and depression (which may include overwhelming feelings of sadness and suicidal thoughts), or a combination of both.<sup>2</sup>

“Coping with bipolar I disorder presents a very different challenge for each individual,” said Alison Cairns from Bipolar Scotland, Suzanne Hudson from Bipolar UK and Margaret Edwards from SANE. “an increased number of treatment options give patients and their health professionals the best chance of finding the right treatment for them, and Bipolar Scotland, Bipolar UK and SANE today welcome the addition of another treatment for bipolar I patients in UK.”

Bipolar disorder affects close to 30 million people worldwide,<sup>5</sup> and an estimated 623,000 people in the UK.<sup>2,3</sup> The launch comes as a new piece of patient insight research, including 988 respondents from UK, has shown that many bipolar patients have concerns about their current treatment, with 44% of patients not satisfied with its efficacy.<sup>6</sup> Over a third (40%) of patients stated that they were prompted to switch medication as a result of side effects associated with existing antipsychotics.<sup>6</sup> Unwanted weight gain, a well-established side-effect of antipsychotic treatments,<sup>1</sup> was the most experienced side-effect, reported by 79% of the respondents.<sup>6</sup>

“Recovering from Bipolar Disorder is extremely challenging “said Nicola Oliver, a UK patient with Bipolar I Disorder. “Not only do you have to overcome your symptoms, but you have to contend with the side effects of treatment. On my current medication I have put on over 2 stones! It is thoroughly demoralising and I often reconsider the benefits of taking it.”

## P r e s s   R e l e a s e

“We are pleased that people with bipolar disorder experiencing manic episodes will have the option of this new treatment, which offers hope for effective management of distressing symptoms.” said Marjorie Wallace, Chief Executive of SANE.

“Many bipolar patients are concerned about the side effects of taking antipsychotics,” adds Professor Allan Young of Imperial College and West London Mental Health Trust. “The availability of a new treatment option is likely to be valuable in my daily practice.”

-ENDS-

### **About Sycrest**

Sycrest is marketed as Sycrest in Europe, and as Saphris® in other markets worldwide. Sycrest is marketed in Europe by Lundbeck.

Sycrest is a sublingual tablet indicated for the treatment of moderate to severe manic episodes of bipolar I disorder in adults. It is an antipsychotic that differs structurally from currently available medications to treat bipolar disorder and has a functional activity profile that is different.<sup>7</sup> The clinical significance of this is unknown.

Sycrest has been granted Marketing Authorisation in Europe for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults.<sup>8</sup>

### **A Summary of Sycrest Clinical Trials**

The efficacy of Sycrest was demonstrated in two similarly-designed, three-week, double-blind, randomised, placebo- and active-controlled (olanzapine) monotherapy trials (n= 488 and n=489). In these trials, Sycrest demonstrated efficacy as early as day two and a reduction of manic symptoms associated with bipolar I disorder in adults over three weeks compared with placebo (-11.5 vs -7.8, p<0.007 and -10.8 vs -5.5, p<0.0001, respectively).<sup>9,10</sup> This efficacy was sustained over 12 weeks in a subsequent double blind extension study.<sup>11</sup> Post hoc analyses of the 3-week trials showed that Sycrest, but not olanzapine, improved depressive symptoms compared with placebo at day 7.<sup>12</sup>

The efficacy of Sycrest as adjunctive therapy to the mood stabilisers lithium or valproate was also demonstrated in a 12-week, placebo-controlled trial involving 326 patients who were partially non-responsive to lithium or valproate monotherapy for two weeks at therapeutic serum levels.<sup>13</sup> The use of this treatment as an adjunct resulted in improved reduction of manic symptoms compared to lithium at week 3, and at week 12.<sup>13</sup>

In clinical trials, fewer patients experienced clinically significant weight gain (≥7% increase in weight) with Sycrest compared with olanzapine.<sup>11,14</sup> Combined short and long term studies have shown that the mean weight gain with Sycrest was 0.8 kg,<sup>4</sup> and observations from a 12-week study showed the mean weight change to be 1.9 kg vs. 4.1 kg seen in olanzapine patients.<sup>11</sup>

### **About bipolar I disorder**

Bipolar disorder (also known as manic-depressive disorder) is a chronic, episodic illness so named because sufferers alternate between two poles of extreme moods - mania (which may include symptoms such as episodes of elevated moods, extreme irritability, decreased sleep and increased energy) and depression (which may include overwhelming feelings of sadness and suicidal thoughts), or a combination of both.<sup>2</sup> The spectrum of bipolar disorders includes bipolar I disorder and bipolar II disorder.<sup>1,2</sup>

## P r e s s   R e l e a s e

Bipolar disorder affects close to 30 million worldwide,<sup>5</sup> including an estimated 623,000 people in the UK<sup>2,3</sup> and it affects 1% of the UK population with men and women affected equally.<sup>2</sup> The societal cost of bipolar disorder in UK has been estimated at £2 billion per year.<sup>1</sup>

### **About the UK patient insight research<sup>6</sup>**

The Patient Insight Research was conducted by Lundbeck in partnership with four charities, including Bipolar Scotland, Bipolar UK, Equilibrium and SANE. The research involved 988 patients, of whom 27.5% were diagnosed with bipolar I disorder, and took place during November and December 2011. Of those respondents who specified their gender, 67.3% were female and 32.7% male, and 56.4% of the patients were aged between 40 and 59. The largest proportions of patients involved in the survey were from Scotland (16.1%), Greater London (14.0%), and Northern Ireland (1.6%).

### **Key findings include:<sup>6</sup>**

- Nearly half of the respondents (43.8%) indicated that they were not satisfied with the effectiveness of their current medication in managing their condition
- The most common side-effect reported by three quarters of the respondents (78.5%) was unwanted weight gain
- High cholesterol similarly was stated as one of the top three non-psychiatric co-morbidities by 181 respondents (18.3%)
- Over a third of respondents (35.8%) said it took more than 10 years for their symptoms to be properly recognised and for them to be diagnosed with bipolar disorder
- Nearly half of respondents (47.1%) considered they had been misdiagnosed in the past
- Nearly half of the respondents (42.8%) stated they do not always remember to take their medication
- Over a third of respondents (34.1%) stated that since their diagnosis they relied on bipolar charities as a source of information (including a charity website or helpline)

### **About Lundbeck**

H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from central nervous system (CNS) disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, schizophrenia, insomnia, epilepsy and Huntington's, Alzheimer's and Parkinson's diseases.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark. Today Lundbeck employs approximately 5,900 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with CNS disorders. In 2010, the company's revenue was DKK 14.8 billion (approximately EUR 2.0 billion or USD 2.6 billion). For more information, please visit [www.lundbeck.com](http://www.lundbeck.com).

### **About SANE**

SANE, a UK-wide charity set up to improve the quality of life for people affected by mental illness, has three objectives:

1. to raise awareness and combat stigma about mental illness, educating and campaigning to improve mental health services
2. to provide care and emotional support for people with mental health problems, their families and carers as well as information for other organisations and the public
3. to initiate research into the causes and treatments of serious mental illness such as schizophrenia and depression and the psychological and social impact of mental illness

SANE Services offer emotional support and information:

SANEline– 0845 767 8000 6pm – 11pm



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SANE mail - [http://www.sane.org.uk/what\\_we\\_do/support/email/](http://www.sane.org.uk/what_we_do/support/email/)  
SANE Support Forum (peer support) - [http://www.sane.org.uk/what\\_we\\_do/support/supportforum/](http://www.sane.org.uk/what_we_do/support/supportforum/)  
For more information, visit the SANE website at [www.sane.org.uk](http://www.sane.org.uk)

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