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Evotec Reports Details of the Positive Proof-of-Concept Phase II Study in Insomnia with EVT 201

- **Very robust findings on the key problems faced by insomniacs, i.e. sleep onset and sleep maintenance**
- **Evotec to host a conference call today at 11:00 am CET (10:00 am UK time, 5:00 am EST, 7:00 pm AEST) directly from the worldsleep07 congress in Australia**

Hamburg, Germany | Oxford, UK – Evotec AG (Frankfurt Stock Exchange: EVT) presented today at the worldsleep07 congress in Cairns, Australia the details of the results from its first Phase II clinical trial of EVT 201 in patients with primary insomnia. EVT 201 is a partial positive allosteric modulator (pPAM) of the GABA_A receptor complex. The double-blind, placebo controlled cross-over study of two doses of EVT 201 (1.5mg and 2.5mg) in 67 completed patients was conducted in sleep labs in the US using objective polysomnography (PSG). After having published top-line results in a press release on 4 June 2007, the results of the detailed analysis are herewith reported.

The detailed analysis showed that all endpoints achieved an even higher level of statistical significance than first indicated. The pre-specified intention-to-treat analysis of the study showed that on both of the co-primary endpoints of Total Sleep Time (TST) and Wake After Sleep Onset (WASO) the statistical significance of both doses against placebo was $p < 0.0001$.

Highly statistically and clinically meaningful effects were also found on both the Latency to Persistent Sleep (LPS) and TST in the second half of the night, indicating strong effects on both sleep onset and sleep maintenance. In addition to these objective PSG results, there were highly significant improvements, at both dose levels, on the subjective perception of sleep quality.

The following morning there was no subjective perception of any residual sedation. The Digit Symbol Substitution Test (DSST) showed a small but clinically insignificant change tested the next day 9 h after dosing.

The PSG analysis also showed that EVT 201 did not have a negative impact on sleep architecture unlike many benzodiazepine full agonists.

As in all previous clinical studies, EVT 201 was demonstrated to be safe and well-tolerated at both doses. No serious or unexpected adverse events were reported.

The table below shows the actual results for each of the primary and selected secondary endpoints:

Parameter N=67	Placebo	EVT 201 1.5 mg	EVT 201 2.5 mg
Adjusted mean WASO (mins)	63.9	47.2 (26%) p<0.0001	38.2 (40%) p<0.0001
Adjusted mean TST (mins)	379	412 (9%) p<0.0001	424 (12%) p<0.0001
Adjusted mean LPS (mins)	42.3	25.2 (40%) p<0.0001	21.6 (49%) p<0.0001
Adjusted mean Total Wake Time 2 nd half (mins)	42.9	32.1 (25%) p=0.0008	26.7 (38%) p<0.0001
Adjusted mean Slow Wave Sleep (mins)	29.7	30.4 (2.4%) NS	29.9 (0.7%) NS
Subjective sleep quality (very good/good)	41.2 %	75.2% p<0.0001	78.7% p<0.0001
Adjusted mean DSST (number correct)	58.5	56.2 p= 0.0028	54.3 p<0.0001
Subjective residual sedation (very alert/somewhat alert in %)	52.6 %	57.6% NS	48.0% NS

The large effect size on Total Wake Time (TWT) for the second half of the night indicates that EVT 201 is highly effective in maintaining sleep throughout the night. This was further confirmed by the hour-by-hour analysis of TWT. Although the study was not powered for such an analysis, the reduction in TWT produced by EVT 201 was statistically significant for all hours of the night apart from hour 7 which came very close to reaching statistical significance (p= 0.058).

Commenting on the results, Dr John Kemp, Chief Research & Development Officer, Evotec AG, said: “I’m absolutely delighted with the results of this proof-of-concept Phase II study. The magnitude of effect on sleep maintenance appears more robust than those seen with other agents in similar cross-over design studies. In particular, we are not aware of similar studies that have demonstrated such statistically significant effects on Total Wake Time in the second half of the night and Total Wake Time each hour.”

Jörn Aldag, President and Chief Executive Officer, Evotec AG, said: “Although certain aspects of insomnia are addressed by current treatments, there is no drug yet available which meets all the needs of insomnia patients. In our study EVT 201 demonstrated extremely robust findings on all key aspects of the problems faced by insomniacs, i.e. sleep onset and sleep maintenance and yet was without the patients feeling any drug hang-over effects after waking in the morning. We believe this gives EVT 201 a very competitive profile compared to the currently available insomnia treatments and to those in late stage clinical development.”

Principal Investigator Dr James Walsh, Executive Director of the Sleep Medicine and Research Center, St John's Mercy Medical Center, Chesterfield, Missouri, US, said: "Due to its partial positive allosteric modulation of GABA_A receptors, EVT 201 provides a novel approach to the treatment of insomnia, yet since the GABA_A system is a well understood pathway, the risk of unexpected side effect findings are low compared to completely novel mechanisms. This together with robust effect sizes seen in this study, particularly with regard to sleep maintenance, offers considerable promise for the drug as a treatment for insomnia patients."

A second Phase II clinical trial of EVT 201 in elderly patients with primary insomnia for further differentiation is ongoing. Top-line results from this trial are expected to be announced in October 2007.

Webcast Presentation and Conference Call

Evotec will hold a conference call today at 11.00 am CET (10.00 am UK time/05.00 am EST, 07.00 pm AEST) to present details on positive Phase II study in insomnia with EVT 201. Dr John Kemp, Chief Research & Development Officer, and Dr Tim Tasker, Executive Vice President, Clinical Development will lead the call.

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Webcast	www.evotec.com

The on-demand version of the webcast will be available on our website: www.evotec.com - Investors – Webcasts.

Notes to the editor

Study design

This US, multi-centre, double-blind trial was designed to evaluate the efficacy of EVT 201 in a three way cross-over design in 67 patients with primary insomnia. Patients were screened for entry into the study and the eligibility criteria included: a diagnosis of primary insomnia according to DSM (Diagnostic and Statistical Manual of Mental Disorders) IV; mean LPS > 20 minutes, mean WASO ≥ 40 minutes, mean TST 240-420 minutes inclusive, all determined during two consecutive nights PSG evaluation. Patients received two dose levels of EVT 201 and placebo, in a random order, for two nights with a 5-12 day washout between each period.

The primary endpoints of this trial were to assess Wake After Sleep Onset (WASO) as well as Total Sleep Time (TST) determined by polysomnography (PSG). The secondary endpoints included additional PSG-based measures such as Latency to Persistent Sleep, number of awakenings and effects on sleep architecture. In addition, patients evaluated sleep quality and quantity. Residual sedation was assessed by the Digit Symbol Substitution Test (DSST) and a categorical patient rating. Safety measures included adverse events and laboratory data.

About EVT 201

EVT 201 is a partial positive allosteric modulator (pPAM) of the GABA_A receptor complex. Acting on GABA_A receptors it addresses the gold standard mechanism for insomnia with more than 90% of current insomnia drugs using this mechanism. Importantly, however, its close to ideal half life of 3 to 4 hours and its partial agonist activity gives EVT 201 a differentiated preclinical profile and mechanism of action.

The headline results of the first Phase II study with EVT 201 were very positive in terms of all key aspects of the problems faced by insomniacs, i.e. sleep onset and sleep maintenance and yet the patients didn't feel any drug hang-over effects after waking in the morning.

Furthermore, in two previous Phase I/II proof-of-principle studies in subjects with induced insomnia, EVT 201 significantly reduced Wake After Sleep Onset (WASO) while significantly increasing the Total Sleep Time (TST) and quality of sleep with no subjective residual effects. The studies were conducted in a sleep laboratory setting using the traffic noise model of insomnia in healthy male volunteers. In this setting an average of 52 decibels of recorded traffic noise is played throughout the night thereby provoking insomnia. This model has been used to evaluate several insomnia treatments currently in development and on the market. EVT 201 showed no tolerance/dependence liabilities in pre-clinical studies and no interaction with alcohol.

About Insomnia

Good quality and refreshing sleep is a prerequisite for continued good health and daily functioning. Insomnia patients suffer from a) difficulty falling asleep; b) difficulty maintaining sleep due to waking up frequently during the night with difficulty returning to sleep or due to waking up at early hours and c) unrefreshing sleep. In 2005, the Sleep in America poll found that 54% of the adult population reported symptoms of insomnia at least a few nights a week. However, only a fraction of patients are diagnosed, with even fewer using a sleep aid. The insomnia market is estimated to be worth US\$ 6.1 billion across the major markets in 2007, and is set to be impacted by the launch of new drug classes (Datamonitor, Pipeline Insight: Insomnia, April 2007). Physicians highlight that the ideal insomnia drug has the ability to induce, maintain **and** improve the quality of sleep without causing next day hang-over and the absence of addiction liabilities. Key unmet needs include improvements in sleep maintenance and more effective treatments in the elderly population. The entry of novel treatments with differentiated profiles in terms of dosage, mode of action and clinical profile are expected to accelerate growth within the market.

About Evotec AG

Evotec is a leader in the discovery and development of novel small molecule drugs. Both through its own discovery programmes and through research collaborations, the Company is generating the highest quality research results to its partners in the pharmaceutical and biotechnology industries.

In proprietary projects, Evotec specialises in finding new treatments for diseases of the Central Nervous System. Evotec has three programmes in clinical development: EVT 201, a partial positive allosteric modulator (pPAM) of the GABA_A receptor complex for the treatment of insomnia, EVT 101, a subtype selective NMDA receptor antagonist for the treatment of Alzheimer's disease and/or pain, and EVT 302, a MAO-B inhibitor in development for smoking cessation.

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