News Release

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Evotec Announces Positive Phase I/II Clinical Trial Results with Insomnia Treatment EVT 201

For further information please contact:

Joern Aldag
President &
Chief Executive Officer

+49.(0)40.560 81-242
+49.(0)40.560 81-333 Fax
joern.aldag@evotec.com

Anne Hennecke
Director,
Investor Relations &
Corporate Communications

+49.(0)40.560 81-286
+49.(0)40.560 81-333 Fax
anne.hennecke@evotec.com

Evotec AG
Schnackenburgallee 114
22525 Hamburg
Germany
www.evotec.com

Hamburg, Germany | Oxford, UK – Evotec AG (Frankfurt Stock Exchange: EVT, TecDAX 30) announced today top-line results of the proof-of-principle study for its $GABA_A$ modulator EVT 201, for the treatment of insomnia. The Phase I/II study, which was conducted in an established clinical model of insomnia in healthy adults, has been completed with positive results. EVT 201 significantly reduced wake after sleep onset (WASO) while significantly increasing the total sleep time and quality of sleep with no subjective residual effects. As with previous clinical studies, the compound was well tolerated without significant adverse events.
The drug was tested at four doses and placebo, a dose-response relationship was established with significant efficacy at the top three doses.

Prof Anthony Nicholson, Principal Investigator, commented: "This is a second dose ranging trial carried out here at the Human Psychopharmacology Research Unit of the University of Surrey. In both studies the 2.5 mg dose improved sleep quality and sleep maintenance through the night. Of particular interest was that improved sleep continuity was accompanied by a marked increase in deep (slow wave) sleep. There were no subjective reports of residual effects and no cognitive and psychomotor effects were observed 10 hours after dosing. This profile of efficacy together with freedom from significant adverse effects suggests that EVT 201 holds much promise in the management of insomnia."

Dr John Kemp, Executive Vice President Research & Development at Evotec, added: "Approximately 50% of the adult population experience symptoms of insomnia on a regular basis. Only a fraction, however, are using a sleep aid. The results indicate that EVT 201 is a substance that could help people fall asleep quickly, stay asleep throughout the night and allow them to awake without feeling residual effects. If this profile is confirmed in phase II patient trials, it could represent a significant step forward in the treatment of this significant and underserved medical condition. Importantly, we now understand the dose-response relationship of EVT 201 allowing us to select the optimal doses for the upcoming Phase II clinical trials."

Study design

The phase I/II clinical trial was a double-blind, placebo controlled, cross-over trial designed to determine the efficacy and side effects of 4 doses (1.0, 1.5, 2.0 and 2.5 mg) of EVT 201 compared to placebo in 12 volunteers. Each subject received in a randomised fashion all treatments once with at least a week between treatments.
The study was conducted in a sleep laboratory setting using the traffic

noise model of insomnia in healthy male volunteers. In this setting recorded traffic noise is played throughout the night thereby provoking insomnia. Sleep was measured using the measurement techniques of polysomnography and a battery of psychometric tests, as well as subjective assessments. This is a well accepted model for investigating compounds for this indication and has been used with several compounds currently in development.

Notes to the editor

About EVT 201
EVT 201 is a partial positive modulator of the $GABA_A$ receptor complex. Compared to many currently marketed sleep drugs it appears to have a differentiated preclinical profile and mechanism of action. In 2005, a first Phase I/II proof-of-principle study in subjects with induced insomnia was completed with encouraging results. A second Phase I/II study was conducted to determine the optimum dose for a Phase II study in patients which is expected to start in Q3 2006.

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) 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. Approximately 50% of the adult population experience symptoms of insomnia on a regular basis. However, only a fraction of patients are diagnosed, with even fewer using a sleep aid. However, the US market for prescription insomnia treatments is expected to grow from US$ 2.1 billion in 2004 to more than US$ 3.5 billion in 2009 (Nature Review Drug Discovery, Jan 2006). Physicians highlight that the most critical clinical drivers for an insomnia treatment are lack of next day hang-over potential, lack of potential addiction issues and the agents' ability to induce, maintain and improve the quality of sleep. They indicate that the entry of novel treatments with differentiated profiles in terms of dosage, mode of action and clinical profile is 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 contract research partnerships, the Company is providing 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 (CNS). Evotec has three clinical programmes: EVT 201, a GABAA modulator for the treatment of insomnia, EVT 101, a subtype selective NMDA receptor antagonist for the treatment of Alzheimer's disease and EVT 301, a selective and reversible inhibitor of MAO-B for the treatment of Alzheimer's disease.
In contract research, Evotec has established itself as the partner of choice for pharmaceutical and biotechnology companies worldwide. The Company provides innovative and often integrated solutions from drug target to clinic through an unmatched range of capabilities, including early stage assay development and screening through to medicinal chemistry and drug manufacturing.
In 2005, Evotec has generated sales of EUR 80 million with 604 people located in Hamburg, Germany and near Oxford and in Glasgow, UK.
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