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## **Evotec and Roche to Develop EVT 101 for Treatment-Resistant Depression**

**Hamburg, Germany and Basel, Switzerland** – Evotec AG (Frankfurt Stock Exchange: EVT; NASDAQ: EVTC) and Roche (SWX: RO, ROG; OTCQX: RHHBY) announced today that they have entered into an agreement for Phase II clinical development of EVT 101 in patients with treatment-resistant depression. The potential value of this transaction exceeds USD 300 million.

Evotec will be responsible for conducting Phase II studies for EVT 101, a compound originally discovered by Roche and developed from discovery stages through clinical studies by Evotec.

**Eugene Tierney, Head of CNS at Roche, said:** “Our aim is to alleviate the suffering of the many patients with treatment-resistant depression. As many as one in three depressed patients are not adequately treated by currently available medicines. We believe that EVT 101 has the potential to become an effective new therapy for the high unmet need of these patients.”

Evotec will also conduct Phase I safety and tolerability studies for EVT 103, a next generation compound to EVT 101. Roche will fully fund these development programs. In addition, for the option to buy back rights to the entire EVT 100 family of compounds, Roche has agreed to pay Evotec an upfront fee of USD 10 million.

**Dr Klaus Maleck, Chief Financial Officer of Evotec, said:** “This product development agreement with Roche is clear evidence of the value Evotec has created with the EVT 100 compound family over the past few years, benefiting patients and, ultimately, shareholders. We are delighted to enter into this partnership with Roche, providing obvious benefits to both parties.”

### **Terms of the Agreement**

This agreement covers possible development of the entire EVT 100 family of compounds, with a total potential deal value exceeding USD 300 million.

Roche has committed to fund clinical development of EVT 101, as well as EVT 103, the follow-on compound to EVT 101.

If Roche exercises its buy-back option after the completion of the Phase II study, Evotec will receive a USD 65 million lump-sum payment from Roche in exchange for returning the asset, as well as the entire EVT 100 family to Roche. Evotec would be eligible for further development, sales

performance, and scalable double-digit commercial payments.

In the event that Roche decides not to exercise its buy-back option, Evotec will be granted exclusive worldwide rights to the entire EVT 100 family of compounds. Evotec will then get rights to all indications under revised terms from the original contract signed between Evotec and Roche at the end of 2003.

### **Background Information**

#### **About Treatment-Resistant Depression**

More than 120 million people are estimated to suffer from depression globally. According to the National Institute for Mental Health, some of the symptoms include persistent sad, anxious or “empty” mood, feelings of hopelessness or pessimism, feelings of guilt, worthlessness or helplessness, or loss of interest or pleasure in hobbies and activities that were once enjoyed.

According to European Neuropsychopharmacology (D. Souery, 1999) it has been recognized that about one third of patients treated for major depression disorder do not respond satisfactorily to the first antidepressant pharmacotherapy. Treatment-resistant depression is a term used in clinical psychiatry to describe cases of major depressive disorder that do not respond to adequate courses of at least two antidepressants. There is currently no specific therapy approved for treatment-resistant depression, and there are few new mechanisms in clinical development for depression.

#### **About the EVT 100 Compound Family**

At the end of 2003, Evotec Neurosciences GmbH (ENS), a subsidiary of Evotec AG, acquired an exclusive license from Roche to develop and market an extensive patent portfolio covering NMDA receptor NR2B subtype selective antagonists (the EVT 100 family) for the treatment of a variety of CNS disorders such as Alzheimer’s disease, neuropathic pain and Parkinson’s Disease. Roche had retained rights to reacquire the compounds in the future. The compounds were in late pre-clinical development and included structures with good oral availability.

Evotec advanced the development of this compound family. A first Phase I safety and tolerability study with EVT 101, the lead compound, was successfully completed in 2006. In 2008, Evotec conducted two Phase Ib studies. These studies were designed to show safety and tolerability over longer periods at higher doses than the initial Phase I study, as well as provide signs of CNS activity in order to guide potential therapeutic doses. Results from a Phase Ib 4-week repeat dose study in young and elderly healthy subjects showed that the drug was well tolerated up to the highest dose tested. In addition, a sub-study, in which drug cerebral spinal fluid concentration was measured, demonstrating that EVT 101 penetrates the brain and leads to concentrations that should produce a high level of NR2B receptor blockade. In support of this, results from a second, brain imaging Phase Ib study provided the first evidence that the same doses as in the other Phase Ib study have an effect upon brain function in humans, producing specific modulation of neuronal activity in relevant brain areas and, importantly, were also well tolerated. In parallel, Evotec successfully lifted the IND hold by the FDA on this compound with all the studies requested by the FDA having been completed satisfactorily.

Evotec has also completed all the pre-IND enabling studies for EVT 103, the next

generation molecule to EVT 101.

**About Evotec AG**

Evotec is a leader in the discovery and development of novel small molecule drugs. Both through its own discovery programs and through research collaborations, it is generating the highest quality research results to its partners in the pharmaceutical and biotechnology industries. In proprietary projects, Evotec specializes in finding new treatments for diseases related to neuroscience, pain, and inflammation. Evotec's portfolio comprises five clinical compounds: EVT 101, a subtype selective NMDA receptor antagonist for the treatment of depression in partnership with Roche, EVT 201, a partial positive allosteric modulator (pPAM) of the GABA<sub>A</sub> receptor complex for the treatment of insomnia, EVT 302, a MAO-B inhibitor in development for smoking cessation, a P2X<sub>7</sub> antagonist for the treatment of inflammatory diseases and a vanilloid receptor (VR1) antagonist for the treatment of pain in partnership with Pfizer. In addition, Evotec has a number of proprietary projects in preclinical development.

For additional information please go to [www.evotec.com](http://www.evotec.com)

**About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in *in-vitro* diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2008 sales by the Pharmaceuticals Division totalled 36.0 billion Swiss francs, and the Diagnostics Division posted sales of 9.7 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested nearly 9 billion Swiss francs in R&D in 2008. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at [www.roche.com](http://www.roche.com).

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**Forward-Looking Statements**

*Information set forth in this press release contains forward-looking statements, which involve a number of risks and uncertainties. Such forward-looking statements include, but are not limited to, statements about our expectations and assumptions concerning regulatory, clinical and business strategies, the progress of our clinical development programs and timing of the results of our clinical trials, strategic collaborations and management's plans, objectives and strategies. These statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. In particular, the risks and uncertainties include, among other things: risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured; risks relating to our ability to advance the development of product candidates currently in the pipeline or in clinical trials; our inability to further identify, develop and achieve commercial success for new products and technologies; competing products may be more successful; our inability to interest potential partners in our technologies and products; our inability to achieve commercial success for our products and technologies; our inability to protect our intellectual property and the cost of enforcing or defending our intellectual property rights; our failure to comply with regulations relating to our products and product candidates, including FDA requirements; the risk that the FDA may interpret the results of our studies differently than we have; the risk that clinical trials may not result in marketable products; the risk that we may be unable to successfully secure regulatory approval of and market our drug candidates; and risks of new, changing and competitive technologies and regulations in the U.S. and internationally.*

*The list of risks above is not exhaustive. Our Annual Report on Form 20-F, filed with the Securities and Exchange Commission, and other documents filed with, or furnished to the Securities and Exchange Commission, contain additional factors that could impact our businesses and financial performance. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based.*