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Evotec Reports Phase I Safety Data from Tyramine Interaction Study with EVT 302

Hamburg, Germany — Evotec AG (Frankfurt Stock Exchange: EVT; NASDAQ: EVTC) announced today encouraging results of a Phase I safety study investigating the potential interaction of EVT 302, a reversible and highly selective inhibitor of monoamine oxidase B (MAO-B) in development for smoking cessation, with tyramine. The study was undertaken to determine potential safety advantages of EVT 302 versus non-selective MAO inhibitors and less selective MAO-B inhibitors already on the market. These MAO inhibitors are known to interact with tyramine, a natural constituent of some drinks or food such as red wine, cheese or chocolate. In extreme cases, the interaction can dangerously elevate blood pressure. As a result, some agents require patients to adhere to strict dietary restrictions to prevent the intake of food containing high levels of tyramine.

The study results showed that at the lowest dose tested, predicted to be at least twice the therapeutic dose, EVT 302, like placebo, did not increase the sensitivity to tyramine. Doses of EVT 302 for the current study were chosen based on the previously performed human PET imaging studies which showed that the lowest dose chosen for this study was already supramaximal for full inhibition of brain MAO-B. Selegiline was included as a control as it is a marketed MAO-B inhibitor with less subtype selectivity than EVT 302. At its recommended therapeutic dose selegiline does not require dietary restrictions, although it increases tyramine sensitivity slightly. Higher doses produce more dramatic increases in tyramine sensitivity. In this study, the therapeutic dose of selegiline did increase the sensitivity to tyramine compared to placebo. At the highest EVT 302 dose tested (>5 fold the expected therapeutic dose), a small increase in tyramine sensitivity was produced, which was within the range of that produced by the therapeutic dose of selegiline.

Dr Tim Tasker, Executive Vice President Clinical Development at Evotec commented: "We are pleased that the results of this tyramine interaction study support a favorable profile for EVT 302. At a dose that we expect to be higher than the therapeutic dose, EVT 302 produced no increase in tyramine sensitivity and only showed changes at doses much greater than its expected therapeutic dose. Based on these results, the ongoing EVT 302 Phase II smoking cessation quit rate proof-of-concept study is being conducted without tyramine restriction. Overall, it is encouraging that supratherapeutic doses of EVT 302 show comparable results to selegiline at therapeutic doses and that at the lowest – supratherapeutic dose, EVT 302 was not shown to be different from placebo."



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Tyramine when ingested with food is normally metabolized by MAO-A, and it is inhibition of this form of MAO by older generation MAO inhibitors which results in the potential for tyramine interaction. Such interaction with tyramine was not expected with EVT 302 since it is highly selective for MAO-B. Preclinical and clinical studies have demonstrated EVT 302 can achieve complete blockade of MAO-B without inhibition of MAO-A.

The study reported today was performed double blind in 59 healthy young male subjects. The study assessed whether EVT 302 (administered at 3 different doses up to steady state) resulted in an increase in the sensitivity to tyramine in enhancing blood pressure. The study included selegiline, a marketed MAO-B inhibitor with less selectivity than EVT 302 over MAO-A, and as an active comparator.

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 of the Central Nervous System. Evotec has four programs in clinical development: EVT 201, a partial positive allosteric modulator (pPAM) of the GABA_A receptor complex for the treatment of insomnia, EVT 302, a MAO-B inhibitor in development for smoking cessation, EVT 101, a subtype selective NMDA receptor antagonist for the treatment of Alzheimer's disease and/or pain, and a P2X₇ antagonist for the treatment of inflammatory diseases. In addition, Evotec has a number of proprietary projects in preclinical development as well as a worldwide license agreement with Pfizer to research, develop and commercialize small molecule vanilloid receptor (VR1) antagonists for the treatment of pain. For additional information please go to www.evotec.com

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 forwardlooking 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



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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.