Press Release

vasopharm Reports Endorsement of Phase III Trial Design in Traumatic Brain Injury by European Medicines Agency

- Company receives protocol assistance from the EMA
- Agreement on endpoint, dosing scheme, trial size and use of Phase II dataset

Wuerzburg, Germany; October 22, 2013 – vasopharm GmbH, a privately held biopharmaceutical company focusing on novel therapeutics for the treatment of cerebro- and cardiovascular diseases, today announced the positive outcome of a scientific advice meeting with the European Medicines Agency (EMA). The EMA's Committee for Medicinal Products for Human Use (CHMP) has agreed to all major items of vasopharm's proposed protocol for the realisation of a European Phase III study of VAS203 in patients suffering from traumatic brain injury (TBI).

In essence, the CHMP agreed on the primary endpoint, the proposed dosing scheme and the trial size. For the final evaluation, the CHMP further agreed to include the available Phase II dataset as supportive information for a potential approval of VA203 in the treatment of TBI patients. VAS203, the company's lead compound, is an allosteric nitric oxide synthase inhibitor and in development for the treatment of TBI patients. The compound met all clinical endpoints for safety and demonstrated strong evidence of clinical benefit in the explorative Phase IIa NOSTRA trial in TBI patients. The trial was completed in 2012.

"It is very encouraging that CHMP experts endorsed our trial design in this important indication," said Dr. Frank Tegtmeier, CSO of vasopharm. "Although the CHMP agreement is not binding, it greatly increases the chances of approval if the trial outcome is positive." He added that details of the trial design, which was established under close consultation with all NOSTRA trial investigators, would be disclosed at a later time point. He also stated that the Phase III trial design will fundamentally reflect the Phase IIa protocol.

The company is also seeking advice from the U.S. Food and Drug Administration (FDA) in order to include U.S.-based clinic trial centres in a single Phase III trial in patients with TBI.

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About vasopharm:

vasopharm is a pharmaceutical company dedicated to the discovery and development of novel therapeutics for the treatment of cerebro- and cardiovascular diseases and their consequences. In this area, the company is focused on the development of therapeutics influencing the bioavailability of nitric oxide (NO), a cellular signalling molecule involved in many physiological and pathological processes. vasopharm's drug candidate VAS203 is an allosteric NO synthase inhibitor and represents a completely new class of modulators of nitric oxide synthase (NOS) enzymes. It antagonises excessive NO production in the cerebral tissue, thereby attenuating secondary damage to the brain and improving the outcome of TBI patients significantly.
For further information, please visit www.vasopharm.com

About traumatic brain injury:

Despite all research activities TBI remains a clinical condition with substantially unmet medical needs. It is the leading cause of death and disability among young adults in the world. TBI accounts for more potential years of life lost than cancer and cardiovascular disease combined. Approximately 1.7 million Americans suffer some degree of traumatic brain injury per year, resulting in 52,000 deaths, 275,000 hospitalizations, and 80,000 cases of long-term disability. Consequences of TBI lead to great personal suffering and family disruption, but also pose a significant financial burden on society. The direct and indirect costs of TBI total an estimated US$ 76.5 billion per year in the United States alone.

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