P R E S S R E L E A S E

vasopharm's Traumatic Brain Injury Drug Exceeds Expectations in Phase IIa Exploratory Clinical Trial

VAS203 demonstrates potential as safe and effective treatment

Wuerzburg, Germany, September 17, 2012 – vasopharm GmbH, a pharmaceutical company dedicated to the discovery and development of novel therapeutics for the treatment of cerebro- and cardiovascular diseases, today announces that the explorative phase IIa **NOSTRA** trial in Traumatic Brain Injury Patients met all clinical endpoints *for safety* and in addition demonstrated strong evidence of clinical benefit in patients.

Traumatic Brain Injury is caused when an external force impacts the head. It is a condition with high unmet medical need and is the leading cause of death and disability among young adults in the developed world. TBI accounts for more potential years of life lost than cancer and cardiovascular disease combined and there are currently no drugs available to treat this condition.

The NOSTRA (**NO-S**ynthase inhibition in **TRA**umatic brain injury) trial was a European, multicentre, placebo-controlled, double blind study with safety and tolerability as primary endpoints. The study employed 'in vivo' microdialysis to monitor pharmacodynamic and pharmacokinetic properties of the compound VAS203. VAS203 is a novel allosteric NO-synthase antagonist which interrupts the inducible nitric oxide process involved in brain swelling.

In total, 32 patients with moderate to severe traumatic brain injury were enrolled in three cohorts in six study centres in Spain, England, Austria, France and Switzerland. All study centres used continuous microdialysis to monitor cerebral energy household, NO metabolism and concentration of the drug in the brain tissue. VAS203 was administered in addition to standard of care treatment.

Highlights of the Phase IIa trial

Final analysis of the data showed that all clinical endpoints were achieved: the drug demonstrated good safety and tolerability and reached the brain tissues in pharmacologically relevant amounts. Furthermore, mortality was 12.5% in the placebo group versus no deaths in the drug group.

VAS203 did not have any negative effect on the cerebral perfusion pressure. The Therapy Intensity Level (TIL) – a marker evaluating concomitant therapy and intervention by the physicians as a measure for control of intracranial pressure (ICP) – demonstrated a substantial reduction in VAS203 treated patients compared to placebo. Interpretation of data on ICP – often used as a surrogate endpoint in TBI clinical trials – is impractical without reference to the intensity of therapy directed at controlling ICP.

In addition the extended Glasgow Outcome Scale (eGOS) was used off protocol to assess the level of achieved neurological recovery six months post-injury. In comparison to the placebo group, the eGOS determined at six months post-injury, was significantly increased demonstrating a substantially improved recovery in patients receiving VAS203 ($p = 0.006$).

Professor Dr. John Stover, Zuerich, Switzerland, Lead Investigator of the NOSTRA trial, commented:

"These remarkable results represent a major breakthrough in the treatment of traumatic brain injury. There is currently no effective treatment available for patients suffering from this horrendous condition. Using microdialysis, we were able to assess the cerebral safety profile of the drug and to monitor in real time what was going on in the brain. These data not only demonstrated the safety of VAS203 but also its potential benefit in treating patients. This drug definitely warrants further investigation."

Christian Wandersee, Chief Executive Officer of vasopharm, commented:

"We are very pleased and surprised by these results. Working closely with world experts in TBI, the clinical trial was designed to answer crucial questions about VAS203 and its potential to treat patients with traumatic brain injury: we wanted to know whether the drug was safe; if it reached the site of injury in a dose dependent way; and whether it stayed there for any length of time.

Given these results have exceeded expectations, we are now seeking a strategic partner to accelerate the further development of VAS203."

About TBI:

Traumatic brain injury is a condition with high unmet medical need, and is the leading cause of death and disability among young adults in the developed 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. Not only does TBI lead to great personal suffering and family disruption, but poses a significant burden to society with direct and indirect costs in the United States alone being estimated to exceed $ 6 billion per year.

About vasopharm GmbH:

vasopharm is focused on the development of small molecule therapeutics which modulate the bioavailability of biological NO, by addressing the entire NO/cGMP signal cascade and its functional counterpart NOX. vasopharm's drug candidate VAS203 represents a completely new class of NOS modulators targeting cerebral vessels and cerebral tissue. For VAS203, vasopharm received orphan drug designation for the treatment of moderate and severe TBI in Europe. With the aid of data from the NOSTRA trial, the company is currently designing a registration study.

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