

:: Facts Sheet VAS203

Overview

Traumatic Brain Injury (TBI) is a major cause of death and disability among a predominantly young male population, mostly victims of automobile accidents. Annually, within the U.S. alone, head trauma is the cause of about two million emergency room visits, roughly 475,000 hospital admissions, nearly 52,000 deaths and approximately 80,000 cases of severe long-term disability (e.g. functional and cognitive disorders, learning disabilities). The estimated annual TBI market is over \$ 500 million each in the U.S. and Europe. Currently, there is no effective therapy available to treat this condition.

In the majority of patients suffering from TBI, the skull remains intact and the trauma is classified as closed head injury (CHI). These patients are at high risk of developing life threatening increase in intracranial pressure (ICP) for up to five days after the insult. Currently no pharmacological treatment with proven benefit is available to overcome and prevent this critical increase of ICP, which is recognized as an indicator of poor prognosis regarding degree of disability and death.

Development Status of VAS203

vasopharm has developed VAS203, an allosteric NO synthase inhibitor. VAS203 rapidly lowers excessive NO production and controls the deleterious consequences of CHI in a region-specific manner. In pre-clinical, proof-of-principle studies, application of VAS203 had a positive and significant effect on reduction of ICP increase as well as on neurological outcome, measured in behavioural tests. VAS203 is the first drug which targets both blood vessels and tissue of the brain and represents a completely novel pharmacological approach.

VAS203 is covered by a number of US and international patents owned by **vasopharm**. These patents provide exclusivity at least until 2022. Patents cover both the target and composition of matter.

vasopharm completed a first-in-man study in July 2007. In June 2008 a clinical trial phase Ib (repetitive dosing) was successfully completed. The primary objective of an explorative European phase IIa multicenter study is to investigate safety and tolerability as well as pharmacodynamic effects of VAS203 in patients with CHI, in comparison to placebo.