



## PRESS RELEASE

### PAION ANNOUNCES SUCCESSFUL COMPLETION OF PHASE I STUDY WITH THE SEDATIVE/ANAESTHETIC CNS 7056

- Study completed ahead of schedule
- No safety issues
- Target profile expected to be met

Aachen (Germany), Cambridge (United Kingdom), 19 November 2008 - The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8; London AIM: PAI) today announces that it has successfully completed a Phase I study with its intravenous sedative/anaesthetic CNS 7056. The study was completed ahead of schedule because the target criterion, more than 50% of the volunteers reaching loss of consciousness for more than 5 minutes, was reached in the 9th of the 10 planned cohorts. No serious adverse events have been reported to PAION. The company expects to report headline data of the study early in 2009, and will progress to the next stage of development rapidly thereafter.

Wolfgang Söhnngen, CEO of PAION commented: *"Within less than six months of the acquisition, we are now getting first proof for the great potential of the CeNeS products. We now look forward to seeing the unblinded data in the near future. As we have not received any negative reports during the study, we are confident that the profile of CNS 7056 will meet our expectations. With its expected quick on/off sedative profile and thus anticipated faster recovery, CNS 7056 could mark an important progress for a variety of indications. For the time being, we will focus on the use in colonoscopy and upper gastrointestinal endoscopy through our own development efforts. With a partner on board, we may also investigate additional indications to rapidly exploit the broad potential of this exciting project."*

CNS 7056 is a new short-acting sedative/anaesthetic that acts on GABA<sub>A</sub> receptors in the brain. Pre-clinical studies demonstrated that, after intravenous administration, the compound quickly induces sedation. Importantly, the sedative effects disappear extremely rapidly after cessation of administration.

A total of 81 subjects were enrolled in the double-blind placebo-controlled Phase I study which was designed to explore safety, tolerability and pharmacokinetics of single ascending doses of CNS 7056 in healthy volunteers. Furthermore, the efficacy of the substance was ascertained by assessing the sedation of the volunteers. At the end of each dosing cohort, the Data Monitoring Committee met to evaluate the study data prior to allowing escalation to the next highest dose cohort, as appropriate. In addition, the study included a direct comparison with midazolam, the standard drug used for procedural sedation. The inclusion of midazolam-treated volunteers permits the effective evaluation of the competitive efficacy and safety profile of CNS 7056.

CNS 7056 is initially being developed as a sedative agent for hospital and outpatient procedures, such as endoscopies. It has further potential for the

induction and maintenance of anaesthesia, for long term sedation in the intensive care unit and other situations where the short half-life would present an advantage over existing alternatives.

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#### **About CNS 7056**

CNS 7056 is a new short-acting sedative and general anaesthetic that acts on GABA<sub>A</sub> receptors. The substance was added to PAION's portfolio by acquiring CeNeS who in turn had acquired the substance from GlaxoSmithKline. CNS 7056 is a water-soluble, rapid and short-acting GABA<sub>A</sub> receptor modulator interacting with the benzodiazepine site. Preclinical data show that, after intravenous administration, CNS 7056 rapidly induces sedation which is maintained during continuous administration. Importantly the sedative effects rapidly disappear after cessation of administration. The rapid offset of effect of the compound is due to its metabolism by esterase enzymes that are widely distributed throughout the body. Therefore it is anticipated that CNS 7056 can be clinically developed as a sedative agent for day case procedures, the induction and maintenance of anaesthesia and as a sedative for mechanical ventilation in the Intensive Care Unit (ICU). In 2007, CeNeS completed a license agreement for CNS 7056 with Ono Pharmaceuticals. Under this agreement, Ono will develop and commercialize CNS 7056 for the Japanese territory.

#### **About PAION**

PAION is a biopharmaceutical company headquartered in Aachen, Germany. Since the acquisition of CeNeS Pharmaceuticals, which was completed in June 2008, the company has a second site in Cambridge, UK. The company is specializing in developing and commercializing innovative drugs for the hospital-based treatment of central nervous system (CNS) disorders and thrombotic/cardiovascular diseases, indications for which there is a substantial unmet medical need. PAION intends to further expand its portfolio of drugs by exploiting its core expertise in identifying high-potential compounds, licensing or otherwise acquiring them and advancing them through the clinical development and regulatory approval process. Where appropriate, particularly during the late stages of the clinical development and approval process and the commercialization phase, PAION seeks to collaborate with experienced partners.

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