



## PRESS RELEASE

### PAION COMPLETES FIRST PART OF PHASE Ib STUDY OF THE ANESTHETIC/SEDATIVE CNS 7056

- Effect of CNS 7056 can be reversed by antagonist flumazenil
- No re-sedation observed after administration of flumazenil
- Data strengthen safety profile of CNS 7056

Aachen (Germany), 11 May 2009 – The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today announces the positive results of the first part of the Phase Ib study with the new short-acting intravenous anesthetic/sedative CNS 7056, which further strengthens the safety profile of the compound.

Following the successful proof of concept study reported in January 2009, the randomized, open, dose-escalation multiple dose Phase Ib study further evaluates the sedation and recovery profile of CNS 7056. Before commencing the second part of the study in volunteers undergoing a standard colonoscopy procedure, the reversal of sedation induced with CNS 7056 by the benzodiazepine antagonist, flumazenil, has been examined in a double-blind design. In total, six volunteers received a high single dose of CNS 7056 on two consecutive days. After successful sedation the subjects either received flumazenil or matching placebo on Day 1 and the alternate treatment on Day 2 in a randomized manner. The results reveal that a single dose of flumazenil is able to reverse the effects of CNS 7056 within approximately 1.5 minutes in volunteers with deep sedation/loss of consciousness. Subsequent re-sedation after administration of flumazenil was not observed.

These data provide further support for an important safety feature of the compound, i.e. the opportunity to reverse sedation/loss of consciousness when desired (e.g. in case of an inadvertent overdose).

“These data again confirm the high potential of our translational approach which is based on the predictability of the animal data for this compound,” commented Dr. Wolfgang Söhngen, PAION’s CEO. “The fact that the volunteers do not encounter a re-sedation after administration of flumazenil adds to the USP of this compound and represents an important advantage over current treatment options.”

In the subsequent open part of the trial which is currently ongoing, volunteers undergoing a colonoscopy will receive different dosages of CNS 7056 followed by “top ups” (i.e. multiple dose) as required to maintain an adequate sedation level for 30 minutes. The study is being performed in the US and is expected to complete before the end of 2009.

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#### **About CNS 7056**

CNS 7056 is a new short-acting sedative and general anesthetic 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. The clinical proof of concept study, reported in January 2009, showed that, after intravenous administration, CNS 7056 rapidly induces sedation. 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 anesthesia and ICU sedation. PAION initiated partnering discussions in parallel to the ongoing Phase II in order to accelerate the further development of CNS 7056 for territories outside Japan, where the compound is partnered to Ono Pharmaceuticals.

### **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 specialized 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 has a "Search & Develop" business model, which is based on its core expertise in drug development. Where appropriate, particularly during the late stages of the clinical development, PAION seeks to collaborate with experienced partners.

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