



## PRESS RELEASE

### PAION INITIATES PHASE Ib STUDY OF THE ANESTHETIC/SEDATIVE CNS 7056 IN VOLUNTEERS UNDERGOING COLONOSCOPY

- Aim of trial is to study a variety of (repeat-) doses to achieve an overall 30 min sedation time
- Study also evaluates reversal of sedation with an established antagonist

Aachen (Germany), 20 April 2009 – The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today announces the start of a Phase Ib multiple dose study with the new short-acting intravenous anesthetic/sedative CNS 7056 in volunteers undergoing colonoscopy.

The randomized, open, dose-escalation multiple dose Phase Ib study will evaluate the sedation and recovery profile of CNS 7056 in volunteers undergoing colonoscopy. In the first part of the study the reversal of sedation induced with CNS 7056 by the benzodiazepine antagonist, flumazenil, will be examined in a double-blind design. This approach is intended to provide further support for an important safety feature for the compound, i.e. the opportunity to reverse sedation when desired (e.g. in case of an inadvertent overdose). The first volunteers have been included in this part of the study.

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

PAION last week also had started a single-dose Phase II study examining sedation of patients undergoing endoscopy of the upper gastrointestinal tract. The necessity of performing these two studies is based on the differing length of gastroscopy and colonoscopy interventions. The Phase Ib study with CNS 7056 will allow PAION to generate additional data on pharmacodynamics and pharmacokinetics.

“The results of these two studies will be the basis for the further development in procedural sedation. Performing a colonoscopy in a Phase I setting allows mimicking the clinical routine setting. Thus this study will deliver information usually generated in a Phase II study,” commented Dr. Wolfgang Söhnngen, PAION’s CEO. “Our team has again demonstrated its strength in being able to achieve significant steps in the clinical development in a very focused and efficient way.”

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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 as a sedative for mechanical ventilation in the Intensive Care Unit (ICU). PAION plans to initiate partnering discussions in parallel to the ongoing Phase II in order to initiate 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 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 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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