



PRESS RELEASE

PAION'S NOVEL SEDATIVE/ANAESTHETIC CNS 7056 MEETS TARGET PROFILE IN HUMAN PROOF OF CONCEPT STUDY

- Sedation with fast and predictable on- as well as offset
- Favourable safety profile
- New Phase I/II studies in preparation

Aachen (Germany), Cambridge (United Kingdom), 9 January 2009 - The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8; London AIM: PAI) today reports the first human data of its intravenous sedative/anaesthetic CNS 7056. The Phase I proof of concept study compared intravenous CNS 7056 to placebo and a standard dose of midazolam, the current gold standard for procedural sedation. The anticipated favourable profile was observed and no safety issues were raised. Volunteers treated with increasing doses of CNS 7056 were successfully sedated at the higher dose cohorts as expected and recovered to full consciousness rapidly.

A total of 81 subjects were enrolled in the double-blind placebo- and midazolam- controlled Phase I study. The study was designed to explore the safety, tolerability and pharmacokinetics of single ascending doses of CNS 7056 in healthy volunteers. Efficacy was ascertained by assessing the sedation of the volunteers by standardized methods. Midazolam-treated volunteers were included to allow an initial assessment of the comparative efficacy and safety profile of CNS 7056. The stopping criterion for the study was pre-determined as more than 50% of the volunteers reaching loss of consciousness for more than 5 minutes. In the 9th out of 10 planned doses this criterion was met. No serious adverse events occurred, even at doses that induced unconsciousness.

Dose dependent sedation, with a rapid onset of effect, was observed after administration of CNS 7056 at doses of 0.05 mg/kg and higher. Doses of CNS 7056 (0.075 – 0.20 mg/kg) that induced peak sedation levels similar to or greater than those achieved with midazolam (0.075 mg/kg) showed a markedly shorter duration of sedative effect with recovery from sedation within approximately 10 minutes compared to approximately 40 minutes for midazolam. The peak sedative effect of CNS 7056 was reached within four minutes in these dose groups, with initial onset of sedation being observed after approximately one minute. For midazolam, the peak effect was reached after approximately 15 minutes. Duration and depth of sedation increased with higher doses of CNS 7056, while the recovery was still earlier as compared to midazolam.

The company now plans one study with healthy volunteers in colonoscopies and one study with patients undergoing upper gastrointestinal endoscopies. Both studies are expected to start no later than Q3 2009.

CNS 7056 is an ester and pre-clinical studies showed that it is rapidly hydrolysed by tissue esterases to an inactive metabolite. This mechanism of deactivation should result in a more predictable onset and offset profile compared to that seen with drugs that are predominantly metabolized by the liver and, secondly, a lower risk of pharmacokinetic drug interactions. Pharmacokinetic analysis from the current Phase I study confirmed that CNS 7056 was rapidly converted to its inactive metabolite in man. The plasma clearance of CNS 7056 was approximately three times more rapid than the clearance of midazolam. The pharmacokinetic profile of CNS 7056 was linear within the dose range examined.

PAION will now progress to the next stage of development and start seeking a partner for territories outside Japan in parallel to the commencement of Phase II. In Japan, CNS 7056 is partnered with Ono Pharmaceuticals.

Wolfgang Söhngen, CEO of PAION commented: *“The positive data meet our expectations. We are positive that CNS 7056 could be a valuable alternative for procedural sedation by avoiding the potential for prolonged or overly deep sedation thus potentially reducing the intensity of supervision needed. We will seek ways to explore its potential also in other indications. It was especially re-assuring to see that sedation, to the level of unconsciousness, could be achieved without safety concerns. PAION’s management and project team are proud to see that these results confirm our high expectations for the potential of this compound, which was in the pre-clinical development phase when we completed the CeNeS acquisition last summer.”*

Note: An updated company presentation including the new data on CNS 7056 will be available on www.paion.com starting Monday, 12 January 2009.

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About CNS 7056

CNS 7056 is a new short-acting sedative and general anaesthetic that acts on GABA_A 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_A receptor modulator interacting with the benzodiazepine site. After intravenous administration to human volunteers, 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 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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