



PRESS RELEASE

PAION REACHES AGREEMENT WITH FDA ON PHASE IIB STUDY DESIGN FOR ITS SHORT-ACTING ANAESTHETIC/SEDATIVE CNS 7056 IN PATIENTS UNDERGOING COLONOSCOPY

- Regulatory pathway cleared to start Phase IIb study
- Study initiation expected within one month

Aachen (Germany), 27 April 2010 – The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today announces that it has reached an agreement with the FDA on the design of the planned Phase IIb study with its new short-acting intravenous anaesthetic/sedative CNS 7056 in patients undergoing colonoscopy. PAION expects to initiate the study within a month.

The study will be conducted in multiple sites in the US. It is designed to evaluate the safety and pharmacokinetics of CNS 7056 as well as the success of the sedation, the time to peak sedation and the time to full recovery and discharge, in comparison to the gold-standard agent, midazolam.

The Phase IIb trial is a double-blind, randomized, parallel group study examining three doses of CNS 7056 compared with midazolam in 160 patients undergoing a colonoscopy. The patients will receive one of three different doses of CNS 7056 or midazolam followed by “top-ups” as required to maintain an adequate sedation level to undergo a standard colonoscopy procedure.

Approximately nine months are scheduled for the patient recruitment phase. Based on the results of the successfully concluded Phase Ib and IIa studies, this Phase IIb study is aimed to further refine the optimal dose regimen before moving into Phase III.

“Our team has done an excellent job in coming to an agreement with the FDA in such a short period of time,” commented Wolfgang Söhngen, CEO of PAION. *“We are looking forward to achieve the next value inflection point for our key value driver.”*

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About CNS 7056

CNS 7056 is an innovative short-acting general anesthetic/sedative that is initially being developed for use in minor medical interventions (procedural sedation). Sedatives are used, for example, in endoscopic procedures such as colonoscopies. After intravenous administration CNS 7056 rapidly induces the desired sedation. Importantly, this sedative effect quickly disappears. This rapid offset of the effect is due to its metabolism by tissue esterase enzymes that are widely distributed throughout the body. CNS 7056 is being developed as a sedative agent for day case procedures and for the induction and maintenance of anesthesia. It could also be used as a sedative during artificial respiration in the Intensive Care Unit (ICU).

CNS 7056 is licensed to ONO Pharmaceutical for the Japanese market. PAION is exploring partnering opportunities for the territories outside Japan, in order to be able to initiate the development of CNS 7056 in other indications as early as possible.

About PAION

PAION is a biopharmaceutical company headquartered in Aachen, Germany and with a second site in Cambridge, UK.

The company is focusing on the clinical development of drug candidates for diseases or interventions 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.

Contact

Ralf Penner

Director Investor Relations & Public Relations

PAION AG

Martinstrasse 10-12

52062 Aachen – Germany

Phone: +49 241 4453-152

E-mail: r.penner@paion.com

www.paion.com

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