



## PRESS RELEASE

### PAION AND ERGOMED COMPLETE ENROLMENT OF PHASE IIa STUDY WITH CNS 5161 IN OPIOID-REFRACTORY CANCER PAIN

- Open label study completed
- Analgesic effects observed at all doses
- Full data package available end Q1 2009

Aachen (Germany) and Frankfurt (Germany) 22 December 2008 - The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8; London AIM: PAI) and ERGOMED Clinical Research Limited today announce the completion of an open-label, single-centre Phase IIa study with PAION's intravenous NMDA receptor antagonist CNS 5161. The study has been completed by PAION and ERGOMED under a Revenue Sharing and Co-Development Agreement signed in July 2006.

In the study, a total of 24 patients with opioid-refractory cancer pain were recruited into six ascending dose groups. Patients received six doses of the compound over a 24 hour period. The goals of the study were to determine the maximum tolerated dose and to assess efficacy and pharmacokinetic parameters of CNS 5161. Increasing analgesic effects were detected with increasing doses. Significant side-effects or psychomimetic effects, often associated to the NMDA receptor antagonist compound class, have not been observed. The company expects full results of the study at the end of the first quarter 2009.

CNS 5161 is an NMDA receptor antagonist for the treatment of neuropathic pain and late-stage cancer pain. Prior to the now completed Phase IIa study, which was the first multiple administration study of CNS 5161, proof of concept clinical trials have been conducted to profile the compound as a novel therapy to treat neuropathic pain. Two Phase I studies have demonstrated the safety and tolerability of CNS 5161 as well as showing evidence of analgesia in a pain model. In addition, two small Phase II studies have been completed giving single intravenous infusions of CNS 5161 to patients with long standing intractable neuropathic pain. Both studies reported analgesic effects of CNS 5161 without psychomimetic effects.

Dr Wolfgang Söhngen, CEO of PAION commented: *"It is very encouraging that despite the small study size, analgesic effects were observed throughout all patient groups without significant side-effects. Together with ERGOMED, we are going to decide on the next steps once the full results become available. Larger studies are required to fully prove the promising profile demonstrated by this study and it is likely that partners will be sought to undertake these studies."*

Dr Miroslav Reljanovic, CEO of ERGOMED added: *"We are very pleased with the results from this study with CNS 5161 and we look forward to working with PAION to realise its full value."*

Pain is an inevitable consequence of most solid cancers. It has been estimated that nearly three million patients in the seven major markets will require treatment for cancer pain annually and that more than 70 % of late stage cancer patients suffer from moderate to severe pain (Source Apex Healthcare). Opioids are commonly used for managing moderate to severe cancer pain, but it has been estimated that around 20 % of patients will experience opioid-refractory pain that has to be treated using alternative therapies.

###

**Contacts**

Dr Peer Nils Schröder  
Director Corporate Communications & Investor Relations  
PAION AG  
Martinstrasse 10-12  
52062 Aachen - Germany  
Phone +49 241 4453-152  
E-mail [pn.schroeder@paion.com](mailto:pn.schroeder@paion.com)  
[www.paion.com](http://www.paion.com)

Teathers  
Nomad and broker (AIM)  
Shaun Dobson/Claes Spång  
Phone +44 20 7131 3000

ERGOMED Group  
Dr Miroslav Reljanovic  
CEO  
Phone +385 1 4628-503  
E-mail [info@ergomed-cro.com](mailto:info@ergomed-cro.com)

**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.

**About ERGOMED Group**

ERGOMED is a specialized international clinical development company offering contract clinical research and co-development partnerships to biotechnology and pharmaceutical companies worldwide in the fields of neurology, oncology and immunology. ERGOMED's approach to clinical research ensures effective patient recruitment, reducing the time and costs of clinical trials and complementing the drug discovery capabilities of its customers and partners. The Company has a dual business model offering standard clinical trial management contracts and also co-development partnerships to share the risks and rewards of clinical development. For further information visit [www.ergomed-cro.com](http://www.ergomed-cro.com)