

## **PAION: Desmoteplase study in stroke completed Hope for future of stroke treatment?**

**Aachen (Germany), 16 October 2003** – PAION GmbH completes successfully its Phase II study in acute stroke. The analysis of the second part of the DIAS study has met the high expectations for this substance, which is already known as the “vampire thrombolytic”:

- **Efficacy:** Desmoteplase showed a clear dose response curve and led to improved blood circulation in the damaged brain area. By administering Desmoteplase the blood flow was re-established and expansion of the damaged brain area was prevented. PAION’s independent advisory board of stroke experts now recommends to continue with the investigations in a Phase III study.
- **Safety:** A known side effect of thrombolysis is intracranial bleeding. Based on earlier results, new dosages were established showing a safety profile which clearly exceeds the expectations of the drug when administering the optimal dose.
- **Time Window:** The outcome of the study gives reason to believe that in future the treatment of stroke may be possible up to nine hours after onset of symptoms. Today treatment is limited to three hours after stroke.

Prof. Dr. med. Werner Hacke, director of the neurological university clinic of Heidelberg and principal investigator of the DIAS study, is pleased with the results: *“The study emphasises that by using new diagnostic techniques, an effective and safe thrombolysis could also be possible in a longer time window. I hope that in future more centres will use this technique and I appreciate that PAION was able to attain acceptance of the demanding study design. An effective thrombolytic treatment in an extended time window could mean for more patients less occurrences of paralysis, less speech disorders, less suffering”.*

Dr. med. Wolfgang Soehngen, Managing Director and CEO of PAION sees in the results high motivation for his team and potential investors: *“Now we are looking for financial sources for the rapid development of the product. Pharmaceutical companies and financial investors show high interest since PAION has the chance to considerably bring forward stroke treatment with Desmoteplase.”*

## **Study Design**

The DIAS study (“Desmoteplase In Acute ischemic Stroke”) was a multicentre, placebo controlled, randomised phase II study, in which in the second half three doses were tested against placebo. 25 hospitals from Europe, Australia and Asia participated in DIAS. In total 102 patients (55 thereof in the second half of the study) were treated in the time window between 3 and 9 hours after the onset of first stroke symptoms. MRI (Magnetic Resonance Imaging) was used in the study in order to identify patients who could profit most from a lysis therapy. Parallel to this study a US study with the same design is presently carried out.

## **Desmoteplase and Stroke**

Desmoteplase is a genetically engineered version of a blood clot-dissolving protein from the saliva of the vampire bat *Desmodus rotundus*. Desmoteplase acts in a similar way as rt-PA, but is almost exclusively activated through fibrin. As a result of this “selective lyse” Desmoteplase is able to dissolve the blood clot without affecting the clotting system and without increasing the risk of intracranial bleeding.

Stroke ist the third leading cause of death in Europe and the USA – behind heart disease and cancer. At the same time the treatment of acute stroke and its serious long-term disabilities is up to now only possible in a dissatisfying manner. The only approved thrombolytic rt-PA must be administered within three hours after the onset of stroke symptoms. Therefore only a fraction of all stroke patients can profit from such therapy.

## **PAION GmbH**

PAION GmbH, a biopharmaceutical company with its head office in Aachen is specialised in the development of innovative therapeutic products for the treatment of stroke. With core competencies in clinical development and international drug registration, PAION is ideally equipped to successfully launch

and develop a promising portfolio of stroke products. An experienced international management team and the support of leading investors are the basis for rapid global growth and the fulfilment of PAION's vision to become the "PAIONeer in Stroke".

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