

## RESPONSE OF THE MAX PLANCK INSTITUTE OF EXPERIMENTAL MEDICINE TO THIRD PARTY PRESS RELEASES ON THE GERMAN MULTICENTER EPO STROKE TRIAL

In 2003, an investigator-driven clinical multicenter trial (phase II/III) using erythropoietin (EPO) as neuroprotective therapy for patients with acute ischemic stroke was initiated by the Division of Clinical Neuroscience at the Max Planck Institute of Experimental Medicine in Göttingen under the leadership of Professor Hannelore Ehrenreich (ClinicalTrials.gov Identifier: NCT00604630).

This study was built on extensive preclinical work and, importantly, on positive results of a first monocentric proof-of-concept (phase IIb) study with high-dose EPO, published in 2002 (*Ehrenreich et al, Mol Med 2002*).

The second EPO stroke trial, concluded in summer 2008, essentially reproduced the results of the proof-of-concept study and will be published in a peer-reviewed scientific journal. The publication process precludes provision of detailed information at this stage. The positive outcome of two independent trials is likely to put political pressure to further develop EPO for treatment of ischemic stroke on the producer of EPO, Johnson & Johnson (J&J), who had temporarily supported the trial.

On September 17, 2008, a press release was launched by J&J's Ortho Biotech, Raritan, NJ, announcing a higher death rate in EPO versus placebo treated patients in our study. This release was reportedly due to safety concerns, but was not based on solid data analysis. We cannot comment on the true motivation for this press release. Without giving publication details, the MPI of Experimental Medicine declares that the imbalance in deaths in EPO versus placebo groups corresponds to a higher number of patients in the EPO arm treated with thrombolysis despite contraindications. The details will be published soon and correct any misleading impressions caused by the premature press release. Respective regulatory agencies (FDA, BfArM) have already been informed.