Medigene halts phase I study

Case of Death

Forensic doctors remove immense burden from German biotech company.

The somewhat mysterious death of a paid volunteer that forced Medigene (Martinsried) to interrupt a clinical phase I trial in Scotland reminded some of a similar incident in London, just two years ago. A 48-year-old man from Edinburgh died of a heart attack, eleven days after taking Medigene's Rhudex (a disease-modifying anti-rheumatic drug candidate).

No comparable events and no signs of cardiac effects due to Rhudex have ever occurred in previous clinical studies, according to company officials. About 80 individuals have been treated with this drug candidate so far, Georg Doenges, a Medigene spokesperson, told *Lab Times*.

An autopsy, conducted at the University of Edinburgh's forensic institute, cleared Medigene of any fault. The coroners didn't find any correlation between the volunteer's death and the drug's administration, revealing that the patient must have been in bad health for years. He had suffered from coronary arteriosclerosis and myocardial hypertrophy, as well as several small infarctions in the past. Indeed it's a little mystery how he passed subsequent clinical examination carried out by Medigene's trial organiser, the clinical research organisation Charles River Labs.

In 2006, six participants in an early-stage UK trial were nearly killed by the administration of another drug, also for rheumatoid arthritis (the "TGN1412 incident"). In that case, the experimental drug was the cause. Tegenero, the company responsible for the study, went bankrupt shortly afterwards.

Given this background, the "not guilty" verdict takes an immense burden off Medigene's mind. The company is heavily dependent on Rhudex, expecting potential sales of more than €1 billion after successful approval. -WK-

Windfall in European countries

Fat Funding

Some of Europe's new biotech blood have had successful funding rounds. Take Denmark's Fluxome Sciences as an example. They received a respectable €13 million from a French venture capital firm as well as cash from additional investors. Fluxome is a 2002 spin-off from Professor Jens Nielsen's research group at the Technical University of Copenhagen and develops nutraceutical ingredients, using engineered yeasts. The company's first product is resveratrol, a polyphenol antioxidant with supposed anticancer and cardioprotective properties.

Grapes contain lots of resveratrol

Germany's Suppremol (Martinsried) closed a whopping €15.7 million financing round in July. The company has, with 1988 Nobel chemistry laureate Robert Huber, a prominent founder. Suppremol is engaged in developing Fc-receptor proteins for the treatment of autoimmune diseases. Esbatech from Zuerich (€14 million) and Serentis from Cambridge, UK (€12.5 million), pulled off big funding rounds as well. -WK-

Belgian Ablynx's prominent partner

Big Deal

Antibody-derived therapeutic proteins to medicate Alzheimer's disease appear to be a big hit. After establishing a €180 million research and licensing collaboration with Boehringer Ing. in 2007, Belgium's Ablynx recently succeeded in extending the deal.

Ablynx was established in 2001 as a spin-off from the University of Brussels. The company has 180 employees and has been led since 2004 by Edwin Moses, a former manager at Oxford Asymmetry (UK) and Evotec (Germany). The firm uses home-grown "nanobodies", a novel class of therapeutic antibodies that lack light chains and therefore resemble the antibodies of camels and llamas. Nanobodies are extremely stable and have the potential to be administered by means other than injection (according to Ablynx's own propaganda). -WK-

UK: Proximagen's Parkinson's pact

Thrilling Tremor

Two years ago, *Lab Times* covered a young London-based neuroresearch spin-off from King's College (see issue 2-2006). Evidently, our report did them no harm. Recently the company, Proximagen Neuroscience, closed a €158 million worldwide licensing contract with Upsher-Smith Laboratories (Minneapolis, USA) for the development and commercialisation of a preclinical stage product for the treatment of Parkinson's disease. In addition, Upsher-Smith will make a €4 million investment in Proximagen (equivalent to 7% ownership). -WK-

Speedel and Cytos much sought-after

Hot Chocolate

Swiss biotech is lusted after. Recently the ETH Zuerich spin-off Cytos signed a research and licence agreement for human vaccines with Pfizer that could bring in €93 million in payments. The US giant has acquired the worldwide exclusive rights to commercialise certain vaccines, which are based on Cytos's "immunodrug" technology.

Another Swiss firm, Speedel, has been snapped up by former owner Novartis for €562 million. Speedel has developed antihypertensive drugs, with a focus on renin inhibition, since 1998, when Novartis got rid of its own renin inhibition section and sold it to its former executive Alice Huxley. After ten years, Novartis has rediscovered renin inhibition and is incorporating its prodigal son back into its own labs. With respect, that doesn't look like an elaborate strategy. -WK-