Dozens of millions for Eyevensys and Gensight (France)

Eyes on Gene Therapy

Painting: A. Dürer

Boehringer Ingelheim's capital investment unit, the Boehringer Ingelheim Venture Fund (BIVF), has put a little money into their big hope gene therapy. The BIVF recently announced an equity investment in French firm Eyevensys, a start-up that was founded in 2009. Eyevensys develops a patented, minimally invasive, non-viral method of gene therapy. Their electrotransfer device allows the injection of plasmids into muscle cells in the eye, "containing the gene encoding for a therapeutic peptide or protein to treat ocular diseases", according to the Eyevensys website. The Paris-based company raised €1.6 million in early 2012, whilst their second stage of fundraising is underway and is expected to reach about €5 million.

Since its conceptualisation in 1972, gene therapy has been the big hope of both sufferers of hereditary diseases and the pharmaceutical industry alike. Given the steady failures since then, there's still a wide gap between lucrative dream and poor reality. But to gain control over the future markets, the industry has to invest. Novartis did just that, earlier this year, when investing €31 million in Paris-based Gensight Biologics, which also plans to treat eye diseases. The first genetic drug, Glybera, was approved in the EU last November. Glybera, developed by the Dutch biotech firm Uniqure, is to treat lipoprotein lipase deficiency (LLD), a rare disease that prevents people from properly metabolising certain fat particles. Being the most expensive drug ever, costing insurance companies €1.2 million per patient, Glybera is scheduled to go on the market by mid-2013 – if anyone is willing to pay for it. -WK-

Data fraud in the pharmaceutical industry: the Steve E. case

Forger Behind Bars

Photo: Public domain/unknown

Fraudulent data manipulation isn't restricted to the academic milieu, as a recent case shows. In Glasgow, a supervisor at contract research organization Aptuit, Steve E., has been convicted of manipulating clinical trials. His results had always suggested that a number of preclinical drugs, tested in animal experiments, were effective. In reality, they weren't, or were far less effective than suggested, because E. had selectively reported analytical data over a number of years, dating back to 2003. Within years, E. manipulated hundreds of studies. After many years and an internal investigation, E.'s superiors got wise to him and informed the British Medicines and Healthcare Products Regulatory Agency (MHRA) about "serious irregularities". The MHRA launched an investigation and found lots of addled eggs, laid by E.

Now all the faked experiments must be analysed again and partly repeated, meaning a huge delay and considerably higher costs for the unhappy pharmaceutical companies including Roche and AstraZeneca that had their drugs tested at Aptuit's facility. Patients will also suffer, since certain drugs must now receive delayed approval. In March 2013, an Edinburgh court found E. guilty, "for altering pre-clinical trial data" by disrespecting good laboratory practice (GLP). In April, the court jailed him for three months. E. is the first person in the UK that has been prosecuted successfully since UK research regulations were tightened in 1999. -WK-