

Failed pain trial hurts drugmaker

Placebo Effect Bugs Cannabis Drug

While misused for centuries as a narcotic drug, *Cannabis* ingredients are latterly favoured as therapeutic agents. Recent results indicate that the effects were possibly overvalued.

In certain cases, performing strongly counts for nothing. Take GW Pharmaceuticals' humiliation over its lead therapy, Sativex (a potential multiple sclerosis drug). In April this year, the substance failed a European phase III trial (to achieve a statistically significant reduction in the pain of patients with multiple sclerosis). At first sight, the trial was a complete success: Half of the patients in the trial reported a 30 percent reduction in pain.

Unfortunately, so did about 45 percent of the placebo group, meaning that the results have no statistical significance. So it doesn't sound very logical when Justin Gover, managing director of GW Pharmaceuticals, says: "[Our] clinical trials [...] have shown tremendous benefits for patients."

Anyway, GW Pharma now has to consider running a new trial in central neuropathic pain indication, meaning additional costs of several million euros. The British company, that – still? – has approximately 120 employees based at offices in Wiltshire, Cambridgeshire and London, specialises in

cannabis-based medicine and carries out research with special permission from the UK government.



Do the components of *Cannabis sativa* act only as a placebo? Experienced drug users may object to this conclusion.

In addition to the failed MS pain trial, Sativex has been analysed in two further phase III studies for MS spasticity and cancer pain. The cannabinoid drug is administered

as an oral spray and has been approved only in Canada for symptomatic relief of neuropathic pain in MS (in 2005) and as an analgesic treatment for patients with advanced cancer (2007).

Marginal effects?

After GW Pharma's trial disaster, some experts have seemingly abandoned their hopes for Sativex. Paul Cuddon, a British analyst, highlighted in an interview with financial information provider Hemscott: "[These results] indicate that the effect of Sativex is marginal, and we retain our doubts as to whether the product will ever prove a commercial success in any of the indications." Moreover, Cuddon predicted the emergence of a menacing financing gap by the end of 2009. GW Pharma reported a loss of €13.1 million for 2007 and is expected to lose an additional €22 million by 2009.

In the face of GW's lean cash resources of just €23 million, the future is beginning to look uncertain at Porton Down Science Park in Salisbury, Wiltshire, UK. W. KOEPELLE

Venture capital

Seeding Biotech no more

Early stage venture capital company causes concerns by performing a U-turn.

Merlin Biosciences, a popular British early-stage venture capital firm, is carrying out a radical revision of its business. Merlin's founder, Christopher Evans, will shift the focus of his entrepreneurship to late-stage therapies. The three Merlin funds worth more than €550 million will be transferred to a new company called Excalibur, which will provide venture capital services to corpo-

rate finance and private equity. Evans, who will own 75 percent of Excalibur, said that he has an "interest in the later stages of research". The Welsh entrepreneur hopes soon to raise two new funds, both of about €125 million, with a focus on speciality pharmaceuticals, diagnostics, healthcare services and surgical equipment. Biotech start-ups in the UK are likely to struggle to exist for the foreseeable future. -WK-



Will his own cord blood cure him someday? Unlikely – Mum and Dad preferred to invest their money wisely!

Europe

Profitable Stem Cells

Private companies have devised a lucrative business while most experts are apprehensive.



Foto: wk

Nobody knows whether it will work one day. Nobody knows whether it will one day provide a cure. While there is general backing from medical scientists and politicians for the public banking of cord blood, private stem cell banking has raised many concerns. In 2004, the European Union group on Ethics concluded that *“the services proposed by these banks and for which parents pay do not have any realistic use in the foreseeable future. [...] They sell a service, which has presently, no real use regarding therapeutic options. Thus they promise more than they can deliver.”*

Needless to say, such criticism doesn't prevent companies like Cryo-Save, Cells4Life or Cryo-Cell International (to mention a few) from storing samples of children's cells for possible future treatments, or increasing numbers of parents from becoming clients. According to a Cryo-Save spokesperson, nearly 21,000 parents sent the umbilical cords of their newly born babies to the Dutch group in 2007. The company reports especially strong demand in countries like Spain, Italy and Hungary. In addition, Cryo-Save's Chief Executive, Rob Koremans, also favours regions such as the Balkans and India, which seem to be extraordinarily interested in getting stem cells frozen at minus 196°C in the vapour phase of liquid nitrogen.

Lucrative business without expenditures

One can take for granted the fact that stem cell storage is a lucrative business. There isn't much more required than a store room in the basement, a deep freezer, and a person that pays rent and electricity bills on time. While public umbilical cord blood banks

operate free of charge and for the benefit of the general public, commercial companies bill about €1,800 per cryopreservation.

Cryo-Save, for example, offers its service in 36 countries, promoting itself as “Europe's leading adult stem cell storage bank”. The group disclosed skyrocketing profits (up 45% to €5.6 million) and increased revenues (up 51% to €20.5 million) for the fiscal year 2007. To date, more than 70,000 parents have stored the umbilical cords of their children at Cryo-Save's labs, according to the company.

Statements such as the one above should, however, make potential customers sceptical about the reliability of private stem cell banking services (remember the old saying, “a leopard never changes its spots?”). How is it possible that Cryo-Save, “Europe's leading adult stem cell storage bank”, has, by its own account, 70,000 customers, when a British competitor, Cells Limited, alleges that it has “more than 130,000 samples stored in [its] laboratories”?

WINFRIED KOEPELLE

The Netherlands

Ray of Hope against TB

Tuberculosis (TB) kills 1.6 million each year, but apart from an obsolete and barely effective vaccine (the BCG, developed at the Pasteur Institute in France between 1905 and 1921), to date there



TB aerosol from sneeze.

exists no preventive drug against the deadly mycobacterial disease. Recently hopes were raised when the Dutch vaccine maker Crucell reported promising early-stage results with its experimental TB vaccine. Crucell's scientists, who collaborate with the Aeras

Global TB Vaccine Foundation and the South African Tuberculosis Vaccine Initiative (SATVI), demonstrated an immune response in volunteers. That is no more than a flicker of hope, but better late than never!

-WK-