

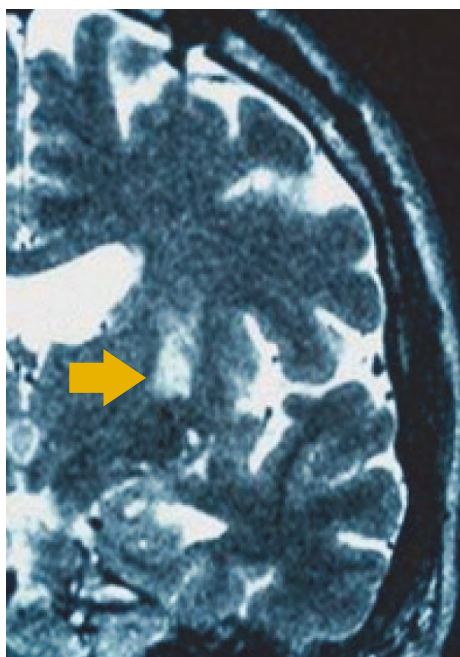
PharmaVentures Client MedGenesis Seals Deal for Parkinson's Treatment

In September MedGenesis announced the signing of an exclusive option and worldwide license agreement for its glial cell line-derived neurotrophic factor (GDNF) protein and convection enhanced delivery (CED) technology as a potential treatment for Parkinson's disease (PD). See Press Release '[MedGenesis Enters Into Agreement with Pfizer Inc. for Potential Treatments for Parkinson's Disease](#)'

On the surface, this is another step forwards in the fight against this cruel and debilitating condition and a significant one at that as this could be the first disease modifying treatment available for Parkinson's sufferers. However those who have been in this field for a few years will be aware that this therapeutic approach has had a colourful past, characterized by a journey over very bumpy roads. It is now hoped to have a much more straightforward yet exciting future path!

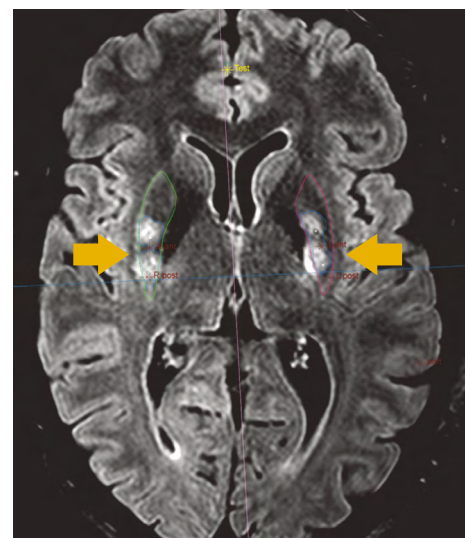
Back in 2004 Amgen was progressing the clinical development of a technology originally developed by Professor Steven Gill, a Neurosurgeon at Frenchay Hospital, Bristol, UK to deliver GDNF directly to the putamen of Parkinson's patients. However a Phase II clinical trial had to be halted, despite promising earlier Phase I results, because of lack of efficacy and some emerging safety concerns. Several of the PD patients participating in the Phase II trial were distraught by these events and a variety of avenues were followed to try and continue treatment of those patients who were receiving the drug during the trial. Whilst unfortunate for the patients involved, the overall risk-benefit ratio was questionable and development of the treatment was stopped. Much of this is summarised in a book written at the time (*Monkeys in the Middle* by Nick Nelson).

Additional studies in non-human primates showed promising results that a potential key to success of this treatment approach lay in the precise delivery of GDNF to the areas of the brain where it was needed. At the time Amgen embarked on their Phase II trial, imaging capabilities and available surgical technologies made this task extremely challenging and it is remarkable that the Amgen team was able to achieve the levels of success they



Gill et al. (2012)

did with the technology available then. Following cessation of the Phase II trial a number of companies, including MedGenesis approached Amgen with a view to licensing GDNF. MedGenesis, despite its small size relative to other potential licensees, was able to convince Amgen that the best chance of successfully developing this treatment for Parkinson's patients lay with them and secured the license to the protein. Critically, what Erich Mohr, Chairman and CEO, and his team at MedGenesis were able to bring to the table was a robust delivery platform which leads to greatly enhanced accuracy and coverage of the treatment in the affected areas of the brain. The platform includes a patented intermittent CED approach, coupled with the use of a robust delivery platform consisting of sophisticated robot assisted surgery, neuro-navigational software, and GDNF drug delivery devices developed



Unpublished data, S Gill

Unprecedented Positioning Accuracy with Verified Superior Coverage of Putamenal Target

by Professor Gill and the UK based Engineering company Renishaw.

Following comprehensive preclinical validation an investigator lead Phase II study was initiated at The Frenchay Hospital (North Bristol NHS Trust) again utilising the expertise of Neurosurgeon Professor Steven Gill, Neurologist, Dr. Alan Whone, and other members of the Bristol team. A pilot study of 6 patients (4 on drug and 2 on placebo) was conducted to assure safety and a further 36 patient cohort is now underway for the main Phase II study with a 9 month double blind placebo controlled phase followed by a 9 month open label phase. Results from the full trial are anticipated in 2016.

Importantly, several key patient associations became directly involved in the development process and contributed both financially and conceptually to these new studies with GDNF in PD. Parkinson's UK and Cure Parkinson's Trust provided

a major grant directly to the Bristol site supporting the current Phase II study, while The Michael J Fox Foundation and Deutsche Parkinson Vereinigung both contributed through direct grants to MedGenesis for the development.

MedGenesis' strategic goal was to secure a commercialisation partner whilst the Phase II study was ongoing to ensure that Phase III planning could be done in parallel with the ongoing trial execution and facilitate a seamless transition between MedGenesis and the commercialising company and also between clinical phases. MedGenesis knew it was important to expose the opportunity to a wide group of big pharma companies who were both active in CNS and had the commercial muscle to potentially bring this successfully to market. As a lean organisation MedGenesis utilises "best

in class" external expertise wherever appropriate to complement their own internal capabilities. PharmaVentures was appointed to assist in securing a partner and executing the deal.

At PharmaVentures we employed our proven processes to engage with all relevant potential partners.

Negotiation of the deal terms was extremely thorough and required meticulous attention to detail on all sides. The negotiations benefited from highly motivated and knowledgeable participants on all sides coupled with the direct involvement of key individuals with decision making power. Conducting many of the discussions face to face also ensured progress at the appropriate rate. In PharmaVentures' experience the combination of shared objectives, highly informed executives and a willingness

to find ways to work through issues to mutually acceptable resolution ensured the deal was closed in a timely manner to all parties' satisfaction.

As with most transactions of this nature, doing the deal is just the beginning and the hard yards of working together to potentially bring this technology to the market is now underway. Ultimately everyone wants to a treatment for Parkinson's patients that can potentially modify the course of the disease and improve their lives. At PharmaVentures we are proud to have played a part in improving healthcare for this debilitating disease.

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