

An immunotherapeutic platform

Located in Strasbourg, France, Transgene SA is a research and development biotech company that focuses on vaccines and immunotherapy for the treatment of cancer and infectious diseases. Philippe Archinard, the company's CEO, claims that Transgene strategically engaged in the research of a narrow range of products in order to have more substantial data for future development. Since 2005, the company has adapted this strategy and although they have not yet brought any of their products to market, Transgene is currently involved in multiple clinical trials for the treatment of a wide range of cancers and infectious diseases.



Philippe Archinard, CEO of Transgene

The company was established in 1979, and in 1992 it began an in-depth examination of gene transfer technology. This technology utilises disabled viruses as vectors to target cancerous or disease-causing cells. Transgene uses two viral vectors in its platform, the adenovirus and the vaccinia virus, both of which have an advanced safety profile in humans. In their immunotherapeutic approach, the company employs vaccination strategies with the use of combination therapies, and aims to overcome the problems of immune tolerance. Additionally, Transgene is

working on the oncolytic properties of virotherapy, as well as a pro-drug gene-directed enzyme for the treatment of fluorouracil (5-FU) sensitive tumours.

With a variety of drugs currently in their pipeline, Archinard claims that Transgene's research and development is not necessarily linked to the field of application. "I would not say that we have more expertise for one or the other field," he says. "But for our internal field of indication we are involved in two main areas, solid tumours and chronic diseases. At this stage we have several products in clinical development, four of which are being actively pursued."

TG 4010, a therapeutic cancer vaccine aimed at stimulating an anti-tumour immune response, is in phase IIB clinical trial. Based on a recombinant vaccinia virus, TG 4010 is being trialled on patients with advanced non small cell lung cancer (NSCLC) and according to Archinard will undergo another clinical trial in 2010. TG 4010 is targeted at Mucin 1 (MUC1) positive tumours, which include lung, prostate and kidney cancers, as well as pancreatic, ovarian, stomach and colorectal cancers, and many others. Another important product in Transgene's pipeline is TG 4040 which is an anti-infectious immunotherapy product for hepatitis C (HCV). "We are actively preparing for the

beginning of a phase II trial for HCV," says Archinard. "We should be in a large international phase II trial early next year." The hepatitis C virus that causes liver inflammation is considered to be a major public health problem, and it can lead to liver cancer. TG 4023 is Transgene's suicide gene therapy. This product is just entering phase I trials in patients with primary and secondary liver cancer. It consists of the Modified Vaccinia Ankara (MVA) which is a strain of the vaccinia virus, combined with FCU1, a highly potent suicide gene. The MVA-FCU1 penetrates tumour cells and induces cell death.

One product, TG 1042 is currently in phase II clinical trials on patients with Cutaneous B-cell lymphoma (CBCL). This is an immune enhancement gene therapy aimed at the treatment of primary and metastatic solid tumours such as bladder cancer and hepatocellular carcinoma, as well as CBCL.

Transgene has a three-fold public relation strategy regarding their research and development. They are focusing on developing their hepatic vaccine profile and examining the technology for new indications. They are also actively working in the field of oncolytic viruses and they have begun the development of some monoclonal antibodies.

Archinard, who joined the company in December 2004, has over twenty years of experience in the biotech industry. He has a PhD in biochemistry from Lyon University and completed the management development programme at Harvard Business School. In his view, Transgene is in good financial shape. "It's true that in the past year we have

Company headquarters in Cedex France



established some good bases to move forward," he says. "We have a cash position of EURO 72.9 million and although we don't have revenue coming in from sales yet, we do have revenue from our partnerships. Other than that we receive state funding from the government."

Transgene has a collaborative agreement with Roche since 2007. Transgene's most recent collaborative event with Roche was announced at the beginning of September 2009. It involves the launch of a phase IIB trial with TG 4001/R3484, an immunotherapeutic product for the treatment of Human Papilloma Virus (HPV) induced diseases, such as pre-cancerous cervical lesions. The trial is being carried out in Europe and the US and involves 200 patients.

It also has entered into licensing agreements with Merck, ICRT, Ajinomoto,

Aventis and Cayla, as well as various manufacturing and sub-contracting agreements with EUROVACC and many others. The company also works closely with academic communities in France and abroad. Transgene aims to jointly develop an immunotherapeutic platform. "Our products target large medical needs," says Archinard. "Only big pharmaceutical companies have the capabilities to complete the development, and market these products world wide. This is why

product partnering is traditional in this industry. Basically the finish line is only reached when your product is on the market. We are not there yet, but we are very optimistic. We feel we have the right shareholder structure and the right capabilities. Indeed, especially at a time when the financial market is having some difficulties, we have nothing to complain about."

The company has a broad patent portfolio. Its headquarters are in Illkirch-Graffenstaden (near Strasbourg), France, and they have a smaller team in Lyon, as well as an office in Maryland in the US. Transgene expects their first product, TG 4010, to reach market five years from now.



Transgene S.A.
Boulevard Gonthier d'Andernach
Parc d'innovation
CS80166
67405 Illkirch-Graffenstaden Cedex
France
Website: www.transgene.fr