First European cell therapy wins INSEAD award

By Sarah Wachter, Knowledge Contributor

How the first stem cell therapy to win EU approval got to where it is.

Stem cells have long been held up as a real game-changer in development of new drugs. They have been the stuff of Nobel prizes. These cells are used to generate body tissues to replace the tissues and organs that no longer function effectively. That potential was turned into real promise by a co-winner of an INSEAD award at the Fifth Annual Healthcare Alumni Summit held in Zurich in October 2013.

Eduardo Bravo, CEO of European cell therapy company TiGenix, with a distinguished track record behind him in big pharma, walked away with the prize for the development of ChondroCelect, the first cell therapy to get EU approval under new regulations that went into force in 2009. The therapy will be made available to 130,000 patients in Europe and the U.S. to repair torn cartilage of the knee.

Turning basic stem cell research into routine therapies is a complex and risky multi-stage process that also involves meeting strict regulatory guidelines. Speaking to INSEAD Knowledge on the sidelines of the INSEAD Health

Summit, Bravo explained his strategy to get ChondroCelect off the ground: first, he didn’t wait for the i’s to be dotted on the new regulations. Second, TiGenix followed the same rigorous drug testing, from pre-clinical to clinical to randomised trials - the first time any company has done so for a cell therapy product.

Partnerships were key to getting ChondroCelect launched, Bravo explained. The therapy started as a collaboration between a rheumatologist at the University of Leuven in Belgium and a consultant with in-depth knowledge of cartilage growth, which led to a patent and creation of a startup, Cellerix, the precursor to TiGenix.

The product was first manufactured inside this university hospital research group. But today, ChondroCelect is manufactured at a state-of-the-art facility in Sittard-Geleen just outside Rotterdam, thanks in part to a novel financing scheme: the province of Limburg injected 5 million euros into the company. “It’s a very good model on how to use public money – looking for returns, sharing risk, and sharing the upside as well. Typically, governments tend to give grants,” Bravo said.

To reduce costly clinical trials, TiGenix had ChondroCelect classified as an orphan drug, which meant the company could conduct smaller, less expensive tests.

“Being such a small organisation [as TiGenix has been] since its inception, means you not only need the help of the founders, but then the hospitals that participated, and the people that helped us build the manufacturing facility to get that approved,” he said.

Bravo also said a critical element of the success of ChondroCelect, [by way of advice for other SMEs], is to contact regulatory authorities early and often. “We were also partners with [regulatory] agencies, making sure that we went, hand in hand, to ensure they could have the first cell therapy product approved on European standards,” he went on to say.

TiGenix is also taking part in another innovative collaboration, REGENER-AR (the last two letters stand for rheumatoid arthritis). TiGenix coordinates the consortium, which receives 6.5 million euros from the European Commission that was earmarked at trans-national partnerships that spur scientific developments. The REGENER-AR collaborative, made up of ten organisations from five European countries - small biomedical concerns, universities, and research institutes - is aimed at developing a cell therapy for rheumatoid

arthritis.

Find article at

https://knowledge.insead.edu/responsibility/first-european-cell-therapy-wins-insead-award

About the series

Healthcare Management

The **Healthcare Management Initiative** at INSEAD was founded on the belief that many of the systemic challenges of the healthcare industry globally can benefit from the application of principles that stem from rigorous, evidence-based thought leadership.