

Dr Silviu Itescu: Pioneer of adult stem cell therapies

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A Quinquagenarian from Australia, Dr Silviu Itescu, is based out of the US and has been traveling tirelessly between New York and Melbourne with the sole objective of rapid development and commercialization of therapies to treat patients with bone and joint diseases.

Melbourne-based Mesoblast and its subsidiary Angioblast, based in New York, have been working on commercializing adult stem cell-based products for large clinical indications with unmet clinical needs that present long-term sustainable market opportunities. The products manufactured by the company are used for the treatment of cardiovascular and neurological conditions, diabetes, eye diseases, bone marrow regeneration, bone fractures, cartilage degeneration and musculoskeletal conditions.

BioSpectrum recognized his efforts and awarded him with the BioSpectrum Asia Pacific Bioscience Industry Person of the Year Award for 2011.

Dr Itescu, who was born in Romania, studied in Australia from the age of seven until he completed his masters in medicine at the University of Melbourne. Following this, he relocated to the US for nearly 20 years with the desire to broaden his

knowledge base and also to expose himself to different cultures and complementary expertise. Commenting on this, Dr Itescu says, "I was intrigued by biology and I had a strong desire to make a substantial contribution and to help those in need. During the course of my training, I kept asking fundamental questions about science and biology as a tool for developing new therapies."

While working as the head of Transplantation Immunology at Columbia University Medical Center, US, Dr Itescu specialized in the field of immunosuppressant to prevent the rejection of transplanted organs. He was the first person who proved that certain adult stem cells from bone marrow could be used to repair damaged hearts by creating new small capillary vascular networks. "My area of clinical focus was cardiovascular medicine and the major unmet needs in patients with advanced heart failure and the lack of alternatives available to them. My extensive work in cardiac transplantation only served to further underline the lack of sufficient meaningful therapies," says Dr Itescu.

Dr Itescu established Angioblast Systems in 2001 with a focus on development and commercialization of novel therapeutic products for the treatment of cardiovascular diseases and vascular disorders. Driven by the fascination towards stem cell research, Dr Itescu began to look for more effective ways of restoring damaged tissue, particularly the heart. His global search led him to South Australia's Hanson Institute where scientists had identified adult stem cells with the potential to regenerate heart tissue and to form new blood vessels to improve the heart's blood supply. The same cells were also able to replace bone at the site of fractures and form blood vessels to deliver nutrients and oxygen to the new bone.

Dr Itescu acquired worldwide license in 2004 to commercialize orthopedic applications of proprietary adult stem cell technology that was developed by scientists at South Australia's Hanson Institute and Institute of Medical and Veterinary Science and formed a company called Mesoblast by raising funds through IPO at Australian Securities Exchange. Mesoblast has been aiming to generate a series of high margin, off-the-shelf adult stem cell products that are obtained from a single donor, commercially expanded and frozen, and subsequently used in potentially thousands of unrelated or allogeneic recipients at the time and place of need.

During his journey as an entrepreneur, Dr Itescu faced many challenges. He says, "The challenges were the high risk associated with a novel platform technology, the uncertainties associated with early stage companies in a difficult commercial situation and the skepticism by investors that a transition of science and clinical medicine to entrepreneurial leadership could be successfully achieved."

While speaking about the growth of the company and the changing regulatory scenario, Dr Itescu says, "The current challenges for Mesoblast are in executing our late stage clinical programs, to demonstrate that we can use our resources and cash wisely to broaden our product pipeline and to successfully build an international team as part of a global biopharmaceutical company."

With the strong backing from his family, core investors, the medical community and support of a key group of executives, Mesoblast has been able to sail smoothly. Dr Itescu says, "We have also been supported by an experienced and thoughtful Director Leadership group. Obviously persistence, diligence, focus, setting priorities and goals, and retaining an executive group of people; provide the expertise and complementary skills to de-risk outcomes."

Mesoblast has unlocked significant value from its proprietary platform technology and has identified many commercial opportunities and markets. Recently, it announced outstanding clinical trial results of its stem cell product, Revascor, in patients with congestive heart failure, an application with multi-billion dollar revenue potential. The strength of its results underpinned Mesoblast's ability to successfully enter into a major strategic alliance with global biopharmaceutical company, Cephalon, in December 2010.

Dr Itescu, who is a member of the US President's Council on Bioethics and the US Food and Drug Administration's Biological Response Modifiers Advisory Committee on cell therapy, has guided Mesoblast's growth. The company's core strategy is based on three focus areas: products to treat cardiovascular and neurodegenerative diseases; intravenously-delivered products to treat a wide range of inflammatory and immune-based conditions including diabetes, lung diseases, and joint diseases; and the company's suite of orthopedic products for repair of bone and cartilage tissues. Mesoblast's deal with Cephalon is the biggest-ever global stem cell licensing deal valued at \$1.7 billion.

Mesoblast's first-rate clinical results along with its strategic alliance with Cephalon, underscores its position as the world's leading stem cell and regenerative medicine company. Mesoblast now boasts of a market capitalization of approximately \$1.5 billion, and has \$280 million cash on hand. The firm, is increasing the numbers of its new strategic domestic and international institutional investors, and has a growing number of commercial opportunities. "We expect successful launch of our products globally within the next few years," concludes Dr Itescu.