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UIC Experience: Human islet transplantation for treatment of type 1 Diabetes and biological license application

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Management of type 1 diabetes is burdensome both to the individual and to society as a whole, costing over 100 billion dollars annually. Near perfect control of blood glucose levels can be restored by islet transplantation, without the risk of serious hypoglycemic episodes that are associated with intensive insulin therapy. Islet cell transplantation offers immense promise as a cell-based, functional cure for diabetes. The UIC islet transplant research team successfully completed a Phase 1/2 clinical trial and currently undertaking two phase 3 clinical trials. A total of 29 participants have been successfully transplanted and have achieved insulin independence after 1-3 islet transplants. Although the duration of islet graft survival cannot be predicted, participants report freedom from glycemic labiality and life-threatening hypoglycemic episodes. The required sample size for a single arm Phase 3 trial is in the range of 20-30 patients. According to this, UIC has approached the end of the trial and is in the process of filing a licensure that will make this treatment a standard care for type 1 diabetes. In the US, in order to introduce a biological product into interstate commerce, a Biologics license is required. Granting of the license certifies that the biological product is safe, pure, and potent; and the facility in which it is manufactured meets all standards designed to ensure that it continues to be safe, pure, and potent.This is a remarkable achievement considering that few academic institutions hold a licensure for biological product in the USA.

Biography

Barbara Barbaro has completed her MS and Ph.D at the University of Messina, Italy. For the past 10 years she has worked on Human Islet isolation moving from the preclinical phase to phase I/II clinical trial and now concluding phase III. She played a key role in the developmental phase of the preclinical and clinical study of an innovative methodology used to evaluate and assess the potency of human islets. This methodology is predictive of clinical outcome and was requested from FDA.Currently working with FDA to apply for licensure of the biological product of human islet isolation.

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