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Development of pluripotent stem cell based therapies for neurologic and oncologic disorders

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Human embryonic stem cells (hESCs) can proliferate indefinitely yet, upon appropriate cues, differentiate into all somatic cell lineages. These two properties of hESCs enable the development of hESC-derived therapeutic cell populations which can be batch manufactured in central manufacturing facilities, cryopreserved, and distributed for "on demand" use at healthcare providers. Protocols have been developed to differentiate hESCs into neural, cardiomyocyte, hepatocyte, islet, osteoblast, chondrocyte, and hematopoietic cell populations which have been shown to be functional in either *in vitro* or *in vivo* animal models of human disease. Our group has established protocols to produce oligodendrocyte progenitors that upon transplantation into animals with spinal cord injuries can remyelinate denuded axons, induce axonal sprouting, and improve locomotor activity. Extensive preclinical studies have been completed to examine the activity, biodistribution, dosing, delivery, and potential toxicity and tumorigenicity of the oligodendrocyte progenitors. The safety of these cells is now being tested in the clinic in subjects with complete spinal cord injuries. In addition, our team has developed methods to produce dendritic cells from hESCs that have the antigen processing and presentation functionality to stimulate immune responses. In collaboration with Cancer Research UK, *Asterias* is preparing for a clinical trial using these hESC derived dendritic cells as a cancer immunotherapy in non-small cell lung carcinoma in the neoadjuvant setting.

Biography

Jane Lebkowski has been actively involved in the development of cell and gene therapies since 1986 and is currently a Chief Scientific Officer and President of R&D at *Asterias* Biotherapeutics Inc, where she is responsible for all preclinical and product development of *Asterias*' products. From 1998 to 2012, she was a Senior Vice President of Regenerative Medicine and Chief Scientific Officer at Geron Corporation. She led Geron's human embryonic stem cell program, being responsible for all research, preclinical development, product development, manufacturing and clinical development activities. She has completed her PhD in Biochemistry from Princeton University in 1982 and completed a Post-doctoral Fellowship at the Department of Genetics, Stanford University in 1986. She has published over 70 peer reviewed papers and has 13 issued U.S. patents. She is on the Board of Directors of the American Society for Gene and Cell Therapy. She has served as an Industry Representative to FDA's Office of Cell, Tissue and Gene Therapy Advisory Board.

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