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Plant-based production and preclinical analysis of biosimilar Trastuzumab

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Production of therapeutic proteins by plant bioreactors offers a valuable alternative to the pharmaceutical industry for manufacture of valuable biologic drugs with tremendous potential for improved production capacity, cost-savings and safety over classical animal cell-based production systems. PlantForm Corp. has been working on a biosimilar version of trastuzumab, a therapeutic antibody that is used for treatment of breast cancers that specifically over-express human epidermal growth factor receptor 2 (HER2). A scalable production system for trastuzumab has been developed that involves transient infection of Nicotiana benthamiana plants. Plant-produced trastuzumab is >99% pure and has been shown to entirely lack plant-specific 1,3-fucose and 1,2-xylose post-translational glycomodifications. Plant-produced trastuzumab has identical HER2-binding kinetics with Herceptin®, its commercial counterpart produced by Chinese hamster ovary (CHO) cells. Also, plant-produced trastuzumab has similar potency to Herceptin® in an *in vitro* antibody-dependent cell-mediated cytotoxicity (ADCC) assay targeting specific human cancer cells that over-express HER2. We are currently developing an animal model of breast cancer by transplanting human cells that over-express HER2 into immunodeficient mice. This model will be used to test whether plant-produced trastuzumab and commercial Herceptin® have equivalent efficacies for arresting the growth of HER2-specific cancer.

Biography

Michael D. McLean has worked with Dr. J. Christopher Hall for more than 10 years at the University of Guelph and has played a major role in the development of a system for the production of therapeutic antibodies and proteins in plants. This system has been adapted as a platform technology for antibody production by PlantForm Corporation. McLean has also worked on research topics such as antibody selection and development, antibody purification, antibody function and therapeutics, and bioremediation of environmental contaminants using plants engineered to express antibodies. Together, Hall and McLean have published over 20 papers, 3 patents, and raised over $5M for their academic research programs. Before working with Hall, McLean taught genetic engineering in the Molecular Biology department at Guelph and performed research on crop protection. Prior to that, he was a research fellow at the Children's Hospital of Eastern Ontario in Ottawa on a team that identified a gene associated with human spinal muscular atrophy (SMA). McLean earned his Ph.D. at the University of Georgia in the area of plant genomics and has worked in biotechnology for more than 20 years.

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