Sector: Pharmaceuticals
Sub-sector: Immunosuppressant

GIFT15, a biological immunosuppressant for systemic administration or *ex-vivo* use

Information Summary

Reference code:	ROI 06087
Technology overview:	Novel *ex-vivo* administered or injectable immunosuppressant inhibiting IL15 regulated immune responses
Application:	solid organ transplantation, graft versus host disease, autoimmune diseases, and the prevention of neutralizing antibodies against recombinant therapeutic proteins
Validation:	in animal models and *in vitro* mechanistic studies
Inventors:	Galipeau, Jacques; Rafei Moutih
Opportunity :	Research partnership; license
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Technology Description

The new immunosuppressant, GIFT15, is a biological product consisting of granulocyte macrophage colony stimulating factor (**G**MCSF) and interleukin (**I**L)15 linked in a **F**usion **T**ransgene.

The patent application covers the fusion protein under various forms and its use in appropriate therapeutic areas. Existing prior art related to GMCSF and IL15 are considered in commercialization and patent strategies.

The fusion protein has been successfully isolated on a laboratory scale.

Performance

GIFT15, has been shown to 1) suppress natural killer (NK) cells and NK T recruitment in vivo, 2) block the IL15 dependent IFN-gamma response in mouse splenocytes, and 3) sustain the engraftment of allogeneic and xenogenic cells which were rejected otherwise in immunocompetent mice.

Advantages

GIFT15 induces an immunosuppressive effect delivered systemically and ex-vivo.

- **No neo-antigen**. Ex vivo administration to peripheral blood lymphocytes achieves immuno-suppression similar to its systemic delivery, and avoids the generation of neutralizing antibodies.
- **No toxicity**. As the product is not introduced into patients, metabolism, excretion, pharmacokinetics and dynamics are not applicable. Only administration and dosing have to be optimized.
- **A product vs a method**. GIFT15 may be made available as a biological product to blood collection agencies or hospital blood banks handling autologous blood donations.

Market Need and Opportunity

The US organ and tissue transplantation market is estimated to rise from $11.7 billion in 2005 to $15.1 billion in 2010. Drugs for only 1 of the 70 autoimmune diseases, multiple sclerosis, sold for $2.4 billion in Europe in 2006 alone. Transplantation medicine and autoimmune disorders represent high economic burden and unmet medical needs.

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Dr. Jacques Galipeau

MD, University of Montreal, 1988
Specialty (internal medicine) McGill-affiliated Jewish General Hospital
Subspecialty (hematology, oncology) Tufts-affiliated New England Medical Center, Boston
Scientific fellowship (gene therapy) St-Jude Children's Research Hospital, Memphis, Tennessee
Clinician/Scientist, Lady Davis Institute for Medical Research
Associate Professor of Medicine and Oncology, McGill University, 1997

In 1997 Dr Galipeau initiated a research program in cell and gene therapy of severe illnesses such as cancer, anemia, heart disease and hemophilia. His research is funded by multiple peer-reviewed public and philanthropic societies. Dr. Galipeau plays a major leadership role in the Canadian Stem Cell Network as therapeutics theme leader and is an active member of the Montreal Center for Therapeutics in Cancer and the Jewish General Hospital Cancer research program. He has also been on staff as a clinical hematologist at the Jewish General Hospital since 1997. He is a tenured Associate Professor Medicine and Oncology at McGill University. Since 2001 he is Medical Director of the Cell and Gene Therapy Program at the Montreal Center for Experimental Therapeutics in Cancer.