

IMPROVED METHODS FOR THE CLINICAL MANUFACTURE OF PROTEINS USED IN CANCER IMMUNOTHERAPY

SUMMARY

Interleukin-15 (IL-15) is an immune system modulating protein (cytokine) that stimulates the proliferation and differentiation of T- lymphocytes. In the clinical context, IL-15 is being investigated for use in the treatment of diseases such as cancer. Manufacture of IL-15 for clinical use can be problematic. The National Cancer Institute seeks partners to co-develop or license methods that facilitate pharmaceutical purification and processing of Interleukin-15 (IL-15).

REFERENCE NUMBER

E-123-2008

PRODUCT TYPE

- Therapeutics

KEYWORDS

- immunotherapy, immunotherap, immunotherapeutic, immunomodulation, immunoregulatory, immune system, modulating protein, cytokine, IL-15, T- lymphocytes, interleukin

COLLABORATION OPPORTUNITY

This invention is available for licensing and co-development.

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DESCRIPTION OF TECHNOLOGY

The National Cancer Institute's Biological Research Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods to facilitate pharmaceutical purification and processing of Interleukin-15 (IL-15).

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Deamidation of IL-15 can lead to protein degradation that interferes with its pharmaceutical purification and processing. This invention describes substitutions of IL-15 amino acid sequences that are predicted

to reduce deamidation of a specific amino acid residue found within the IL-15 protein. The substituted IL-15 amino acid sequences may advantageously facilitate the refolding, purification, storage, characterization, and clinical testing of IL-15.

Further R&D Needed:

- Pre-clinical validation
- Perform genetic modifications to the IL-15 expression plasmid
- Transfer the plasmids into host cells suitable for expression
- Select clones expressing the modifications and establish seed banks
- Culture modified host cells at bench scale and induce IL-15 expression

POTENTIAL COMMERCIAL APPLICATIONS

Facilitates manufacture of biological cancer therapeutics

COMPETITIVE ADVANTAGES

- Could facilitate development of cancer immunotherapies by improving clinical manufacture of IL-15
- Potential to decrease the immunogenicity of pharmacologically active IL-15 in comparison to existing methods of manufacture.

DEVELOPMENT STAGE

- Prototype

PATENT STATUS

- **U.S. Issued:** US 8,415,456 Issued 4 April 2013

THERAPEUTIC AREA

- Cancer/Neoplasm