Theratope(R)
Alberta Heritage Foundation for Medical Research

Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
This report aims to summarise the available evidence on the use of Theratope(R) in the treatment of metastatic breast cancer.

Authors' conclusions
Theratope(R) is a synthetic cancer vaccine under development by Biomira Inc. and Chiron Corp. for treatment of metastatic breast cancer. The vaccine is administered in an out-patient setting. It is designed to stimulate the patient's immune system to control disease with minimal side effects. Active specific immunotherapy is the name given to the process designed to stimulate the body's immune response to cancer antigens. Theratope(R) vaccine incorporates synthetic STn. STn is a carbohydrate epitope on the MUC-1 mucin, expressed by cancers such as cancer of the breast, ovary or colon. The US FDA has designated the investigation of Theratope(R) vaccine for metastatic breast cancer as a Fast Track Drug development program. Biomira is currently evaluating Theratope(R) in a Phase III trial with 900 patients. Approximately 115 sites in North America, Europe, Australia and New Zealand are participating in the study. To be eligible a patient must be either receiving any first-line chemotherapy program for metastatic disease or have recently completed a first-line chemotherapy program. The trial is focusing on two endpoints: extending time to disease progression; and survival in this patient population. Theratope(R) vaccine has been tested on approximately 400 patients, and has been found to have minimal systemic toxicity. Referred to as Delayed Type Hypersensitivity reaction, the reaction is in the form of a local injection site reaction that is usually transient. This reaction is part of the immune response to the vaccine. Results from earlier studies suggest that Theratope(R) vaccine may improve the median survival time for women with metastatic breast cancer over standard treatment alone.

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