the patient population in helping to identify responders versus non-responders to determining the efficacy of the therapeutic. Biomarkers can be a valuable tool in making better decisions that will reduce the cost for drug development and enable therapies to reach the most appropriate patient population faster.

Summary of Invention

In one aspect, there is provided an ex-vivo method for testing whether a patient will respond therapeutically to a method of treatment comprising administration of an immunogenic composition, wherein the testing method comprises the steps of:

- obtaining a biological sample from the patient;
- measuring levels of IL10 and IFNγ in said biological sample;
- calculating IL10/ IFNγ ratio; and
- comparing said IL10/ IFNγ ratio with a threshold level, wherein low IL10/ IFNγ ratio indicates that the patient will develop a prophylactic or therapeutic response towards the immunogenic composition with low IL10/ IFNγ ratio being below 5.

In another aspect, there is provided the use of IL10/ IFNγ ratio as a biomarker for predicting whether a patient is or is not susceptible to developing prophylactic or therapeutic response by administration of an immunogenic composition.

Description of the Invention

The invention provides materials and methods for predicting the efficacy of a treatment involving the administration of an immunogenic composition to a patient (i.e. immunotherapy treatment) using biological markers (biomarkers) that have been determined to be substantially reliable signature which correlates with the desired clinical

outcome. The biomarkers are present in biological samples obtained from the patient, prior to the treatment with the said immunogenic composition. The ability to predict the clinical outcome of a treatment, before its initiation, will enable clinicians and patients to identify ineffective therapy, make informed decisions regarding the course of treatment, including whether to abandon or to allow alternate therapy implementation.

The Applicant has now identified new tool and vaccination strategy. More specifically, the present Invention relates to the use of the interleukin-10 /interferon-gamma (IL10/IFNγ) ratio as a biomarker for predicting whether a patient is or is not susceptible to developing prophylactic or therapeutic response, preferably immune response, by administration of an immunogenic composition. Alternatively, the interferon-gamma/ interleukin-10 (IFNγ/ IL10) ratio can be used as a biomarker according to the present invention, but in that case conclusions should be adapted.

Van den Boogaardt et al, 2006 (Transplantation, 82, 844-848) have shown that the interferon-gamma/interleukin-10