This technology describes biomarkers to predict immunotherapy toxicity.

Immunotherapy is one of the most promising breakthroughs in cancer therapy in the last 30 years. These drugs enhance patient’s immune system recognition and attack on tumors. In contrast to the majority of recent cancer breakthroughs—such as molecularly targeted therapies that may be relevant for only 5% of a particular cancer type—immune checkpoint inhibitors have demonstrated broad efficacy.

Often overlooked in the growing excitement surrounding these drugs is the possibility of immune-mediated toxicities. In some instances, cancer immune therapy stimulates the patient’s immune system to attack normal tissues and organs, resulting in diverse adverse effects that may involve the central nervous system, pituitary gland, thyroid, lungs, liver, colon, skin, kidney, adrenal gland function, and heart.

In contrast to the toxicities of conventional chemotherapy or molecularly targeted therapies, the onset and duration of these events are unpredictable. While rates of these events with single-agent immune therapy remain low, when these drugs are used in combination (as is currently approved for melanoma), rates may exceed 30%.

Immune-related adverse events require cessation of immunotherapy, administration of high-dose corticosteroids and other immune suppressants, and in some cases may be permanent and even life-threatening. Although there has been tremendous effort put forth to develop predictive biomarkers for immunotherapy efficacy, to date there are no clinical or laboratory biomarkers that predict who will develop immune-related toxicity or when it will occur.

The present invention provides a biomarker for predicting immune-related toxicity and immunotherapy efficacy. A pilot comparison of patients before and during treatment suggest that the identified biomarker could serve to identify those patients most likely to develop immune-mediated toxicities, as well as help guide treatment selection, monitoring parameters, and clinical suspicion.

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