EXPERT OPINION



# Long-term survival of high-risk melanoma patients immunized with a Hyper-IL-6-modified allogeneic whole-cell vaccine after complete resection

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***Objective:*** Two single arm, Phase II trials (3 and 5) were undertaken to determine the efficacy and toxicity of an adjuvant treatment using Hyper-IL-6 gene-modified whole-cell allogeneic melanoma vaccine in patients with stage IIIB–IV resected disease.

***Research design and methods:*** Ninety-seven and 99 patients were enrolled into Trials 3 and 5, respectively. The primary endpoint was disease-free survival (DFS), and the secondary was overall survival (OS). Vaccine was administered eight times every 2 weeks (induction), every month (maintenance) until patient's death. At progression, maintenance was continued or induction was repeated followed by maintenance.

***Results:*** Median follow-up was 10.5 and 6.2 years for Trials 3 and 5, respectively. No grade 3 or 4 toxicities were observed. An extension of DFS and OS was observed, when compared with historical non-treated controls. DFS probability at 5 years for Trials 3 and 5 was, respectively, 54.8% and 40.6% for stage IIIB, 25.0% and 24.0% for IIIC, and 8.5% and 17.7% for IV. OS probability at 5 years was, respectively, 66.7% and 56.3% for IIIB, 43.8% and 39.8% for IIIC, and 26.1% and 41.2% for IV.

***Conclusions:*** Continuous vaccination, regardless of the disease progression, re-induction, and immunization of patients until death resulted in patients a long-term survival.

**Keywords:** advanced melanoma, genetic melanoma vaccine, long-term survivals, Phase II clinical trials, re-induction

*Expert Opin. Investig. Drugs (2012)* ***21****(6):773-783*

## 1. Introduction

Melanoma is still a deadly disease and its incidence is steadily increasing. Until now, there is no therapy to successfully cure high-risk melanoma patients. Various systemic treatment approaches, including chemotherapy, biochemotherapy, or radiotherapy, have not resulted in the significant extension of patients' overall survival (OS) and were tested in clinical trials with a limited therapeutic success [1]. However, some therapies such as treatment with interleukin (IL)-2 have induced durable clinical remissions in a fraction of patients [2]. Recently, B-RAF inhibitors demonstrated significant tumor clinical responses and extension of OS in advanced melanoma patients with measurable disease who had mutated B-RAF gene [3]. However, the tumor responses were transient and recurrence of the disease was observed.

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