

A Personalized Immunotherapeutic Vaccine (Gliovac Or ERC1671) Against Recurrent Glioblastoma Multiforme (GBM)

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Description

Patients suffering from a glioblastoma multiforme (GBM) present a very poor prognostic. GBM is the most malignant glioma with a median overall survival of 14 months from diagnosis when treated with standard radio and chemotherapy in EU [1]. When relapsing, statistics suggest an imminent death around 1 to 4.5 months (95% IC) [1]. To date, patients with glioma are hopeless. In the EU, 13,000 new cases of high grade gliomas are diagnosed each year. In the US there are approximately 18,000 new cases of brain cancer diagnosed each year of which 10,000 are gliomas [2]. Therapeutic immunization against GBM would offer a new treatment modality for patients. This has been accomplished recently by Epitopoietic Research Corporation (ERC), a pharmaceutical company, that has successfully developed a vaccine for the treatment for late stage glioma brain cancer for which no therapy exists currently. Recently Bota et al., and Schijns et al., reported data on first clinical results [2,3].

The vaccine, called ERC1671 (also named GLIOVAC), is an advanced immunotherapy based on a preparation of tumor cells, which stimulates anti-tumor immunity to recognize cancer cells. This novel cancer treatment is composed of a combination of autologous tumor cells, generated from freshly resected glioma tumor tissues, and similarly prepared allogeneic tumor cells, of three different donor cancer patients. In late stage GBM patients it showed promising antineoplastic activity during the first clinical evaluation [3].

The GLIOVAC treatment induces an oligoclonal immune response following a presentation of a large panel of allogeneic and

autologous tumor-associated antigens (TAA) found in cancer cells, which minimizes the chance of immune escape, and has presented impressive results in terms of safety and efficiency. The simultaneous use of tolerance-breaking immunostimulatory allogeneic (from other patients) tissue-derived antigens, in combination with immune response-focusing autologous tumor antigens, prepared from the treated patient's tissue, stimulates immune pathways that are both activated (triggered), and boosted by the allogeneic components, and focused by the autologous tumor antigen components, towards tumor associated antigens of the patient's tumor. As a result, these oligoclonal immune pathways are able recognize and attack the patient's own tumor as shown in histological analysis [2].

To further improve the immune response programming activity of GLIOVAC, Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) is used as immunological adjuvant, which is known to facilitate and increase antigen presentation in different types of cancers [4]. Also a low dose of cyclophosphamide precedes the treatment to deplete immunosuppressive regulatory T-cell. Six-month survival for 9 Gliovac patients was 100% versus 33% in control group. At week 40, the published historic overall survival was about 10% -Data of control patients are from the publication of Barker et al. 1998- as published in detail by Schijns et al. 2015, while in the Gliovac-treated group the survival at 40 weeks was 77%. These results indicate that Gliovac has low toxicity and a significant efficacy [3]. See Table 1 for more detailed patient data. In the USA a phase II trial has recently been initiated in recurrent, bevacizumab naïve GBM patients (trial number NCT01903330).

References

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Patient Number	Follow Up	Efficacy	OS From Relapse
1	5 cycles	Tumor regression Stable 17 wk	>25w
2	4 cycles	Stable 28 wk	>40w
3	4 cycles	Stable 37 wk	>40w
4	5 cycles	Stable for 30 weeks	>45w
5	3 cycles	Stable for 26 weeks	>35w
6	6 cycles	Tumor regression	>65w
7	8 cycles	Stable for 30 weeks	>45w
8	8 cycles	Tumor regression	>60w
9	8 cycles	Tumor regression	>40w

Table 1: Treatment of patients with GLIOVAC.

Treated Patients (average age: 48 year old) with KPS >60 information. For each patient identified by their anonymization code for non clinical analysis, the following data are indicated: date of the surgery of the relapse, date of the first administration of Gliovac treatment, number of cycle initiated, date of treatment arrest, efficacy of the treatment in term of changes in tumor mass, death date, cause of death, overall survival (OS) from the relapse detection. NA: Not Applicable, Un: Unknown.

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