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MEETING ABSTRACT

A1.9

Oncolytic cancer virotherapy with Rigvir®

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An oncolytic, non-pathogenic ECHO-7 virus, adapted and selected for melanoma that has not been genetically modified (Rigvir®) was registered in 2004 in Latvia for melanoma therapy. Here, we describe two retrospective post-marketing studies. In the first study, Caucasian patients (n = 79) who had surgical excision of the primary melanoma tumour and diagnosis verified histologically were included; all were free of disease after surgery [1]. Survival was analysed by multivariate Cox regression. Current international guidelines advise no strict treatment for stage I–II melanoma patients; thus, treatment with Rigvir® was offered. 52 patients received Rigvir® and 27 were observed. The study was approved by the respective ethics committee. Rigvir® significantly prolongs survival in sub-stage IB–IIC melanoma patients following surgery compared to patients who are under observation. The hazard ratio for patients under observation *vs.* treated with Rigvir® is statistically significantly different: 6.27 for all, 4.39 for sub-stage IIA–IIB–IIC, and 6.57 for sub-stage IIB–IIC patients. Safety assessment of adverse events graded per NCI CTCAE did not show any value above grade 2 in Rigvir®-treated patients. These findings are supported and extended by the following 3 case reports: a patient diagnosed with melanoma stage IV M1c, a small cell lung cancer stage IIIA, and a histiocytic sarcoma stage IV [2]. All patients started Rigvir® treatment within a few months after diagnosis. The degree of regression of the disease was determined by CT. Safety assessment of adverse events graded per NCI CTCAE showed no value above grade 1 during Rigvir® treatment. Using current standard treatments, the survival of the 3 patients described is low. In contrast, the patients described here were diagnosed 4.5, 8.0 and 7.6 years ago, and their condition has improved and been stabile for over 2.5, 7.5, and 5 years, respectively. Taken together these results suggest that the mortality of sub-stage IB, IIA, IIB, and IIC melanoma patients treated with Rigvir® was 4.39–6.57 times less than for those under observation, and that Rigvir® can successfully be used in long-term treatment of patients with melanoma stage IV M1c, small cell lung cancer stage IIIA, and histiocytic sarcoma stage IV.

Keywords: Echovirus 7 – immunotherapy – melanoma – oncolytic virotherapy – Rigvir®

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