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A randomized phase II/III study of the CSF-470 therapeutic vaccine plus BCG plus rhGM-CSF versus IFN- α 2b in high risk cutaneous melanoma patients in the stages IIB, IIC and III

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Adjuvant treatment of high-risk cutaneous melanoma (CM) patients (pts) is still an unsolved issue, since the cost-benefit ratio of high-dose IFN- α 2b is under discussion. We have developed CSF-470 therapeutic vaccine, consisting in four lethally-irradiated allogeneic CM cell lines + BCG + rhGM-CSF as adjuvants, currently being tested vs. medium-dose IFN- α 2b in post-surgical stage IIB-III CM pts (Phase II/III trial). The phase II part of the study was finished after randomization of 30 pts: 19 pts received CSF-470 and 11 pts IFN- α 2b. During the two-year treatment, pts in the vaccine arm received a total of 13 vaccinations. Our results demonstrate a clear superiority of CSF-470 plus BCG plus GM-CSF vs. IFN- α 2b: a) with a mean follow-up of 43 months a significant benefit in the distant metastasis-free survival (DMFS) for CSF-470 was observed: Vaccine arm 61.5% vs. IFN- α 2b 22.7% ($p=0.025$). Median OS in vaccinated pts is still undefined, b) QOL was significantly superior for CSF-470 vs. IFN- α 2b treatment ($p<0.0002$), c) CSF-470 had less toxicity than IFN- α 2b; CSF-470 main toxicity was grade 2 reaction at the injection site; 3/19 pts presented grade 3 allergic reactions easily handled with anti-histamines and corticosteroids; d) DTH reaction vaccine was higher in DMF pts as compared to progressing pts and e) immune monitoring showed a significant increase in peripheral blood NK cells, a decrease in Tregs and development of anti-CM cells Abs at 6 months after initiation of treatment. The phase III part of the study is currently ongoing to complete 108 pts.

Biography

María Marcela Barrio graduated in 1991 as a Biologist at the University of Buenos Aires and obtained her PhD working on monoclonal antibodies at the Fundación Instituto Leloir. She became a member of The National Scientific and Technical Research Council (CONICET) in 2007. She has been working in cancer immunology as part of Dr. Mordoh's team since 1984. At present, she is Sub-director of the Centro de Investigaciones Oncológicas Fundación Cáncer. She has published more than 40 scientific papers in her specialty. She is working in translational research for the development of therapeutic vaccines for cutaneous melanoma.

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