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Clinical effectiveness of an inteferon beta 1a biosimilar: Results from an open-label, multicenter, observational study

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Background: Blastoferon® is a pharmaceutical product of interferon beta 1a currently marketed in Argentina and Latin America as a biosimilar to the innovator interferon beta 1a for the treatment of MS. Although regulatory requirements for biosimilars are on debate, there is consensus about the necessity to obtain evidence of the effectiveness of these drugs on clinical grounds. The aim of this study was to assess the clinical effectiveness of Blastoferon® from an open-label, multicentre, retrospective, observational, post-marketing study.

Methods: We evaluated a cohort of all adult relapsing-remitting MS patients from 4 Latin-American centers that were treated with Blastoferon® for a minimum of 12 months. Baseline clinical and demographic data, relapses and EDSS scores during treatment were collected for analysis. Clinical outcome measures of effectiveness were the proportion of relapse-free patients, the progression of disability as assessed by EDSS score and the annualized relapse rate. Wilcoxon signed-rank test was used to compare relapse rate and EDSS score before and after interferon treatment.

Results: Our cohort included data from 78 MS patients treated for a median of 25 months (range: 12-57). The median time of disease was 6 years (range: 1-33). Fifty-eight (74.3%) patients remained relapse-free during the period of treatment with Blastoferon®. The mean annualized relapse rate in the 2 years before treatment was 0.59 (95%CI: 0.49-0.68). After 25 months of treatment, these figures drop to 0.15 (95%CI: 0.08-0.21). The drop in relapse rate was highly significant (Wilcoxon signed-rank test: $z=6.43$, $p<0.00001$). The median EDSS score at treatment onset was 2 (range: 0-7.5), whereas the median of this score after treatment was 3 (range: 0-8.5). However, this difference was not significant (Wilcoxon signed-rank test: $z=0.95$, $p=0.34$).

Conclusion: Treatment of relapsing-remitting MS with Blastoferon® reduced the relapse-rate of the disease.

Biography

Dr. Marcelo Kauffman is a neurologist with MSc and PhD degrees in Molecular Biology. He has been the person in charge of the pre-clinical and clinical development of Blastoferon as an advisor of Bio Sidus S.A. Clinical Research Department. He has been the author of 5 papers presenting the results of the different pre-clinical and clinical Blastoferon studies. Currently, he holds the position of Chief of the Neurogenetic Clinic of Hospital JM Ramos Mejia in Buenos Aires, Argentina and is a lecturer in the School of Medicine of the University of Buenos Aires.