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BRAIN ATROPHY AND DISEASE-FREE STATUS OVER 4 YEARS OF FREEDOMS STUDY

Eli Silber,¹ Ernst-Willhelm Radue,² Nicola De Stefano,³ Paul O'Connor,⁴ Daniela Piani-Meier,⁵ Gordon Francis,⁶ Davorka Tomic,⁵ Ludwicz Kappos⁷. ¹King's College Hospital, London; ²Medical Image Analysis Center, University Hospital Basel, Basel, Switzerland; ³University of Siena, Siena, Italy; ⁴St. Michael's Hospital, Toronto, ON, Canada; ⁵Novartis Pharma AG, Basel, Switzerland; ⁶Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; ⁷University of Basel, Basel, Switzerland

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Objective Evaluate the relationship between Disease-Free (DF) status and brain atrophy over 4 years from the fingolimod phase III FREEDOMS study and extension.

Method DF-status was defined as the maintained absence over 0–48 months of all the following: confirmed disability progression, confirmed relapses, new Gd-enhancing T1-lesions and new/enlarged T2-lesions; patients having any one or more of these measures were defined as not DF (nDF). In these posthoc-analyses, Percentage Brain Volume Change (PBVC) during months 0–12, 0–24, 0–36 and 0–48 was dichotomized by DF-status at month-48 (DF or nDF) in the overall study population (OSP) and by treatment-group (fingolimod 0.5 mg; combined fingolimod 0.5 and 1.25 mg; and placebo-fingolimod patients [Plc-fingolimod]).

Results In the OSP, DF-patients had lower PBVC during the core-study and extension, versus nDF patients (DF/nDF): month 0–12, $-0.17\%/-0.60\%$; month 0–24, $-0.53\%/-1.14\%$; month 0–36, $-0.94\%/-1.52\%$; month 0–48 $-1.36\%/-2.08\%$. Continuously-treated fingolimod 0.5mg patients had lower PBVC over month 0–48 versus switch patients: DF (fingolimod/Plc-fingolimod; % difference): $-1.12\%/-1.66\%$; 38.8%; nDF: $-1.77\%/-2.54\%$; 35.7%.

Conclusions Patients DF over 48-months experienced less brain volume loss (BVL) than nDF patients over 4-years. A treatment delay of 2 years with fingolimod was associated with more BVL.