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## **gMS<sup>®</sup> Pro Expanded Disability Status Scale Blood Test Based on Anti-GAGA IgM Antibodies Detects Rapid Multiple Sclerosis Disability Progression**

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**Background:** Findings from the Betaferon<sup>®</sup>/Betaseron<sup>®</sup> in newly emerging MS for initial treatment (BENEFIT) study demonstrated that clinically isolated syndrome patients positive for gMS-Classifier1 had higher risk for faster progression in one confirmed Expanded Disability Status Scale (EDSS) point, despite Interferon beta-1b treatment, than patients negative for gMS-Classifier1.

**Objectives:** Confirm that gMS-Classifier1, analyzed in the BENEFIT study, detects relapsing remitting MS (RRMS) patients at risk for faster progression in one confirmed EDSS point.

**Methods:** Sera of RRMS patients with masked identity and retrospective clinical data from ACP, USA were screened by the gMS<sup>®</sup>Pro EDSS test (Glycominds, Israel). For 76 (53F, 39.8±7.4 years) of the 432 analyzed patients (18-50 years) there were two EDSS scores separated by at least six months interval, earliest available EDSS and most recent EDSS. Forty-seven patients had received Disease Modifying Therapy (DMT). We tested whether the gMS-Classifier1 can identify patients that had confirmed EDSS progression of one point and patients that did not progress using Cox proportional-hazards regression model. The classification rule for a positive gMS<sup>®</sup>Pro EDSS test was having at least one of Anti-Glc(G1) (2,3,4,or 6)Glc(G) (Anti-GAGA2,3,4,or 6) IgM values greater than pre-defined thresholds.

**Results:** Survival analysis demonstrated that patients positive for the blood test (n=7, median survival 1157 days) progressed faster in at least one EDSS point than patients negative (n=69, median survival 2705 days) (Hazards ratio 6.9 (95%CI 2.0-23.4), p=0.002). Analyzed confounding factors that did not remain in the model were age, sex, MS DMT and time from blood withdrawal to most recent EDSS assessment.

**Conclusions:** The present analysis supports the BENEFIT study results indicating that the gMS<sup>®</sup>Pro EDSS blood test may be a useful tool to detect breakthrough RRMS patients at risk for faster disability progression despite DMT treatment.