Control/Tracking Number: 2024-A-351-ACTRIMS
Activity: Abstract
Current Date/Time: 11/7/2023 3:06:00 AM

NeofiLos Rationale, Design, Patient Characteristics: First Interim Data

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Abstract:
Background: Neuroaxonal damage results in release of neurofilaments such as neurofilament light chain (NfL) into CSF and blood, with elevated NfL potentially indicating RMS disease activity[1][2][3]. Elevated NfL levels may reveal "subclinical" disease before lesions appear on MRI or clinical symptoms appear[4]. Measuring sNfL may help elucidate subclinical disease activity with prognostic value for future disease activity and potentially contribute to optimized decision making.
[1] Thebault S et al. *Mult Scler.* 2022;28(10):1491-1497. [2] Dietmann AS et al. *J Neurol.* 2023;270(3):1416-1429. [3] Kuhle J et al. *Mult Scler.* 2020;26(13):1691-1699. [4] Akgün K et al. *Neurol Neuroimmunol Neuroinflamm.* 2019;6(3):e555.
Objectives: NeofiLos enables office-based centers to access NfL testing aiming to assess utility of serial sNfL measurements in clinical routine in Germany.
Methods: NeofiLos is an ongoing program with utility data collection at ~80 office-based neurologists assessing the utility of sNfL implementation from physician's perspective in 500 RMS patients treated with ofatumumab or other approved first-line disease modifying therapies. sNfL will be measured at baseline followed by quarterly intervals up to 5x per patient. Values embedded into scientific context using patient demographics are reported to treating neurologists.
Results: First interim results will descriptively depict patient demographics including median age, gender and body-mass-index of the patient collective, as well as diagnosis and therapy decisions made by treating neurologists of those patients at baseline. These characteristic data will be set in context with sNfL values and demonstrate the opportunities and challenges of sNfL anticipated to be the first blood-based biomarker available for clinical use in MS. Data are in line with abstract #350.
Conclusions: This is the first clinical practice project making sNfL available for office-based physicians and showing patient characteristics which will allow insights generation into clinical value in clinical routine setting. Thus, this project is a highly valuable source for defining actual gaps and optimizing future MS patient care.

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