Ofatumumab in different RMS patient populations in everyday clinical practice in Germany

Background:
While safety and efficacy of ofatumumab versus teriflunomide were shown in a representative RMS population as part of the approval studies ASCLEPIOS I and II (COMB157G2301 and -2), data from clinical routine are still missing.
The AIOLOS study ("A NIS evaluating injectable treatments [ofatumumab, glatiramer acetate and interferon β1] in patients with relapsing MS"), is a prospective NIS expected to enroll 800 treatment-naïve RMS patients into one of two treatment arms: ofatumumab or other injectable therapies (interferon beta-1a or -1b or glatiramer acetate). Patients with mild/moderate disease are observed in this study.
The KAIROS study ("A NIS of ofatumumab in patients with relapsing remitting MS who previously received another DMT") is a prospective NIS expected to enroll 300 relapsing remitting MS patients. Patients who previously received a DMT approved for RMS and switched to ofatumumab for safety, tolerability, efficacy, or other reasons are eligible for study enrollment.

Objective:
Two ongoing German non-interventional studies (NIS) evaluate ofatumumab in relapsing multiple sclerosis (RMS) patients in routine clinical practice. RMS patients either receive ofatumumab as first-line therapy or after switching from any disease-modifying therapy (DMT).

Methods:
In both trials prospective primary data is collected via questionnaires and an electronic case report form (eCRF) and includes clinical parameters for effectiveness, safety, and tolerability as well as effects on quality of life, therapy satisfaction, adherence, and socio-economic parameters.

Results:
Interim analyses will show differences between patients receiving ofatumumab as first-line treatment (approx. 240 patients) and patients having switched to ofatumumab (approx. 300 patients) with regards to baseline criteria, effectiveness, safety, and tolerability. In addition, the data from everyday clinical practice are comparable to that from the pivotal trials of ofatumumab.

Conclusions:
The combined interim analyses of the two NIS provide detailed insights on effectiveness, safety, and tolerability of ofatumumab in both treatment-naïve patients and after switching to ofatumumab in everyday clinical care in Germany. The comparison with data from ofatumumab clinical trials confirms the favorable safety and efficacy profile of ofatumumab in the treatment of RMS.

Gereon Nelles[1], Felix Bischof[2], Josef Redolfi[3] and Carola Wagner[3]

[1]Neuromed-Campus, Werthmannstr. 1c, 50935 Cologne, Germany
[2]Studienzentrum Dr. Bischof GmbH, Konrad-Zuse-Straße 14, 71034 Böblingen, Germany
[3]Novartis Pharma Vertriebs GmbH, Roonstr. 25, 90429 Nuremberg, Germany