KAIROS: A non-interventional study of ofatumumab in patients with relapsing remitting multiple sclerosis who previously received another disease-modifying therapy

Felix Bischof[1], Marie Groth[2] und Josef Redolfi[2]

[1]Medicum Gesundheitszentrum - Praxis für Neurologie und Psychiatrie, Konrad-Zuse-Straße 14, 71034 Böblingen

[2]Novartis Pharma Vertriebs GmbH, Roonstr. 25, 90429 Nürnberg

Background: Ofatumumab is a fully humanized anti-CD20 monoclonal antibody that selectively depletes $CD20^+$ B and T cells. In the pivotal studies ASCLEPIOS I and II (COMB157G2301 and -2), ofatumumab demonstrated a significant reduction in inflammatory activity as well as a reduction in disability progression in patients with relapsing multiple sclerosis (RMS) compared to teriflunomide (Hauser et al., NEJM, 2020). However, there are no clinical routine data of patients switching from other therapies to ofatumumab.

Aim: The aim of the KAIROS study is to close this data gap and to describe the patient populations switching to ofatumumab depending on the reason for therapy switch. In addition, important clinical parameters for effectiveness, safety and tolerability as well as effects on quality of life, therapy satisfaction, adherence and socio-economic parameters are examined in clinical practice.

Methods: KAIROS is a prospective, multicenter, non-interventional study (NIS) in Germany. Around 300 patients at 40 study centers will be included. Patients who previously received a disease-modifying therapy (DMT) approved for RMS in Germany and switched to ofatumumab for safety, tolerability, efficacy, or other reasons are eligible. Prospective primary data are collected via questionnaires and an electronic case report form (eCRF) over a treatment period of one year (max. 1.5 years). In addition, the medical history of the participants including disease duration, EDSS, MRI parameters and relapses is documented.

Results: Here, we present the data of the first interim analysis, which includes the basic characteristics of patients enrolled to date. In addition, relevant clinical information including the medical history of approximately 150 RMS patients (~50% of the study participants) will be shown.

Conclusions: The data collection provides important insights about the use of ofatumumab in everyday medical practice. In addition to real world clinical data, patient questionnaires enable an assessment of the therapy satisfaction and quality of life of RMS patients who switch from another disease-modifying therapy to ofatumumab. The collected data expand the findings from interventional clinical trials and thus enable better RMS management in medical practice.

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