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First-hand experience with ofatumumab at ASCLEPIOS study sites in Europe

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Introduction

- Ofatumumab (Kesimpta®), a fully human anti-CD20 monoclonal antibody, is approved by the European Commission for the treatment of relapsing forms of multiple sclerosis (RMS) in adults with active disease defined by clinical or imaging features.
- Ofatumumab can be self-administered at home by a once-monthly subcutaneous injection via prefilled syringe or the Sensoready® autoinjector pen[1,2]
- The phase III ASCLEPIOS I and II trials demonstrated superior efficacy and a similar safety profile of ofatumumab versus teriflunomide[1].

Objective

- As ofatumumab has been recently approved, treating physician's first-hand experience on ofatumumab therapy from the pivotal ASCLEPIOS I and II trials is helpful for treating RMS patients with ofatumumab in clinical practice.

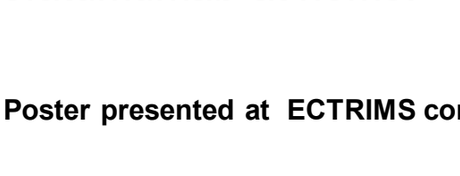
Methods

- As part of this survey, data was collected via an online questionnaire from ASCLEPIOS phase III study investigators. 46 investigators completed the survey (Germany, n=14; Italy, n=10; Portugal, n=10; Spain, n =12).

Results

- The benefit-risk ratio of ofatumumab was assessed as either very good (43%) or good (57%) by the investigators, none of whom gave neutral, poor, or very poor as an answer (Figure 1).

Figure 1 Benefit-risk-ratio of ofatumumab

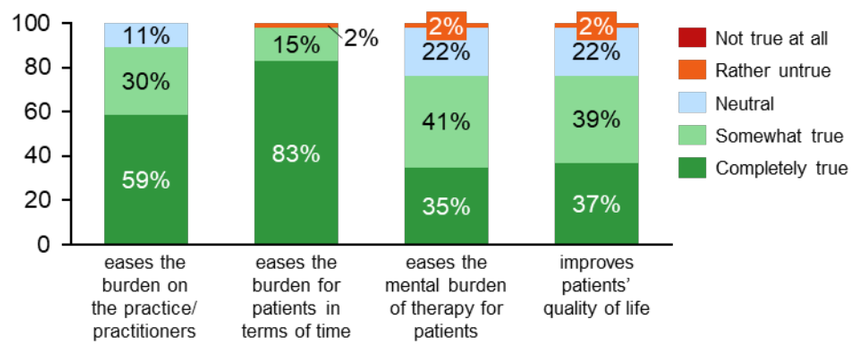


- The shorter B-cell repletion time after discontinuing ofatumumab compared to other anti-CD20 therapies[3], and the consequently higher flexibility in treatment, is seen as an advantage over other anti-CD20 therapies by 91% of the investigators.
- All investigators acknowledged that treatment with the highly effective therapy ofatumumab makes sense in patients who have just experienced the onset of MS (for all patients: 28%; for highly active patients: 72%). Most investigators (93%) were in favor of self-injection of ofatumumab at home.

Poster presented at ECTRIMS congress, Vienna, 2021.

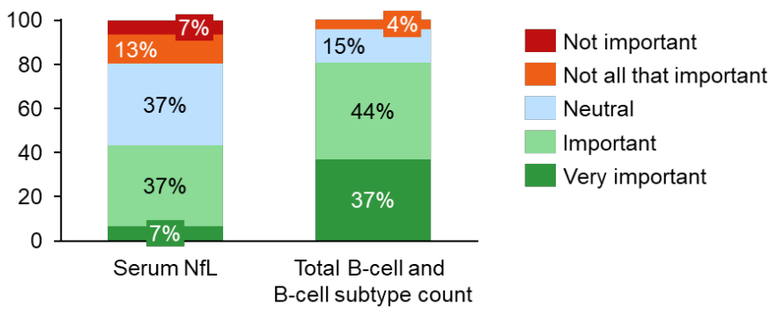
- Despite having only experience in the ASCLEPIOS trials with the pre-filled syringe and not the Sensoready® autoinjector pen, the results regarding improvement of patients' quality of life, using the subcutaneous self-injection, were very positive (Figure 2).

Figure 2 Subcutaneous self-injection of ofatumumab once monthly...



- Investigators rate the following points, associated with the route of administration, as major to be considered when determining the treatment for patients: respecting patient's relevant wishes (83%), the expected compliance of the patient (83%), possible side effects associated with the route of administration (63%) and the practice's/hospital`s capacities (54%).
- 44% of the investigators considered Serum Neurofilament light chain (NfL) and 81% total B-cell and B-cell subtype counts as (very) important to be monitored in clinical practice (Figure 3).

Figure 3 Important parameters for routine clinical monitoring



Conclusions:

- After gaining experience with ofatumumab within clinical trials, European neurologists consider ofatumumab a very efficient and safe treatment option.
- They rate the self-administered subcutaneous injection once a month as offering high convenience for patients and as facilitating processes at high-occupancy clinics and office-based practices.
- All investigators consider ofatumumab as a therapy option for newly diagnosed patients.
- Limitation: A detailed inquiry of the risk and safety assessment for ofatumumab was not part of this survey

References

1. Hauser SL et al., N EnglJ Med 2020;383:546-57
2. Bar-Or A et al. Poster presentation at ACTRIMS 2020; West Palm Beach, Florida, USA
3. Savelieva M et al. Poster presentaion at ECTRIMS 2017; Paris, France

This study was sponsored by Novartis Pharma GmbH, Nuremberg, Germany.