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

Carola Wagner[1], Nicole Sabouret[1], Benjamin Ettle[1]

Poster #4070

[1] **Novartis Pharma GmbH, Nuremberg, Germany**

Background & Methods

Results & Conclusions

Disclosures

Carola Wagner, Nicole Sabouret and Benjamin Ettle are employees of Novartis Pharma GmbH, Nuremberg, Germany and work on behalf of Novartis Pharma Vertriebs GmbH

This study is financed by Novartis Pharma GmbH, Nuremberg, Germany.

Background & Methods

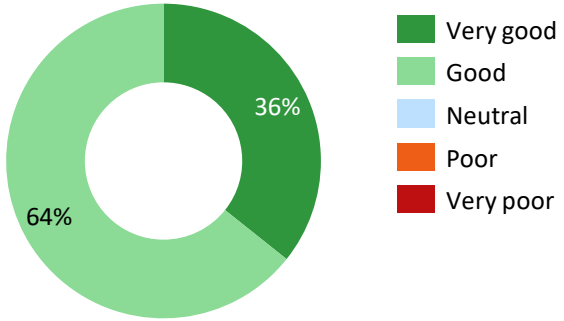
- Ofatumumab (Kesimpta®), a human anti-CD20 monoclonal antibody, was approved by the FDA for the treatment of relapsing forms of multiple sclerosis (RMS) in adults.
- Ofatumumab can be self-administered by a once-monthly injection, delivered subcutaneously[1,2]
- The phase III ASCLEPIOS I and II studies demonstrated superior efficacy of ofatumumab versus teriflunomide[1].
- Data on convenience and satisfaction as well as on implementation of ofatumumab as a therapy for RMS in real life are not part of the pivotal ASCLEPIOS trials.
- As part of this survey, data was collected via an online questionnaire from the German ASCLEPIOS phase III study investigator. 14 investigators of 10 different ASCLEPIOS study sites in Germany participated in the survey.

[1] Hauser SL et al., N Engl J Med 2020;383:546-57. [2] Bar-Or A et al. Poster presentation at the ACTRIMS Forum; February 27-29, 2020; West Palm Beach, FL.

Safety rating

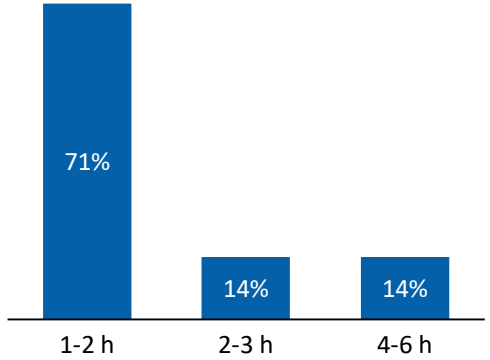
Benefit-risk-ratio

How would you assess the benefit-risk-ratio of ofatumumab?



n=14

First dose administration



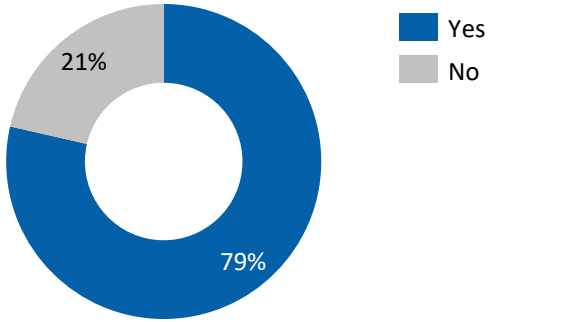
The phase III ASCLEPIOS I and II study protocol stated that patients had to stay in the hospital for approx. 5 hours after their 1st drug administration (Ofatumumab or Teriflunomide).

How long would you in the future monitor patients after their first ofatumumab injection in the practice/hospital?

n=14

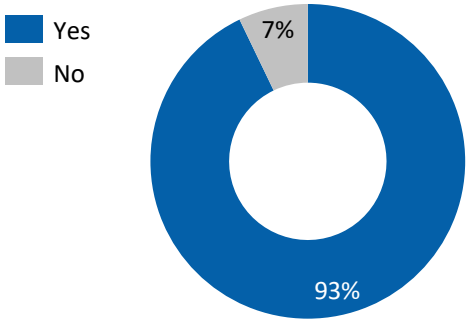
Dosage of ofatumumab

Do you rate the comparatively low dose of ofatumumab (20 mg) as advantageous compared to other anti-CD20 therapies?



n=14

B-cell repletion time



Do you rate the shorter B-cell repletion time after discontinuing ofatumumab therapy[1] and the consequently higher flexibility in treatment as an advantage over other anti-CD20 therapies?

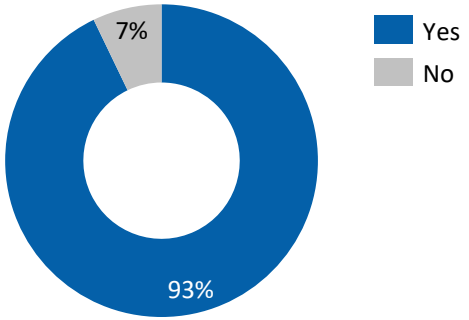
[1] Savelieva M et al.; ECTRIMS congress 2017

n=14

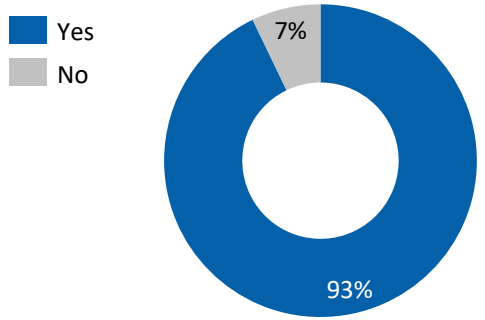
Route of administration

Subcutaneous administration

Ofatumumab is the first monoclonal antibody in MS therapy that does not need to be given as an infusion.
Do you think the subcutaneous route of administration is an advantage?



n=14



Self-injection at home

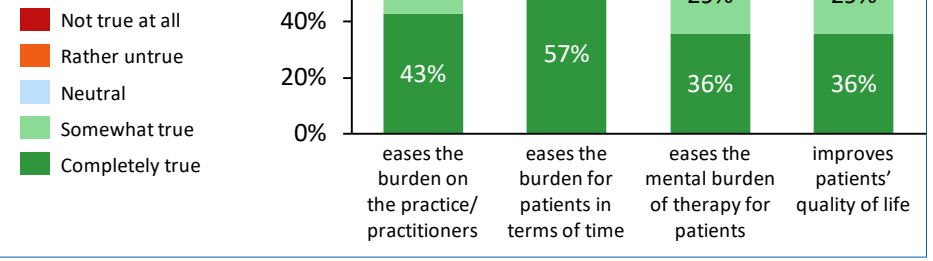
Would you be in favor of self-injections of ofatumumab at home?

n=14

Subcutaneous self-injection

Subcutaneous self-injection of ofatumumab once monthly …

(Ofatumumab pre-filled syringe was used as study treatment in the ASCLEPIOS trials)

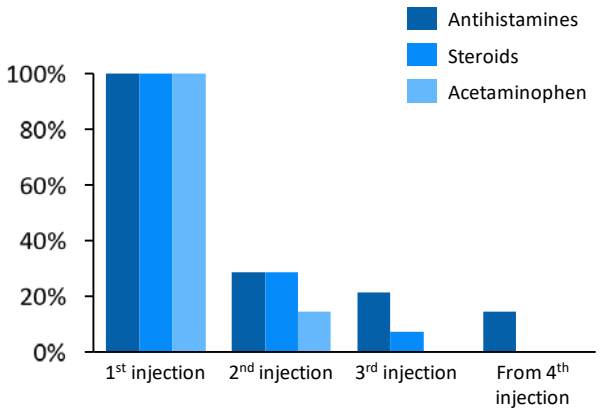


n=14

Premedication

The phase III ASCLEPIOS I and II study protocol recommended a premedication prior to sc injection with steroids (1st injection only), acetaminophen and/or antihistamines upon discretion of the investigator.

Before the injection of ofatumumab in the future, would you use premedication of:



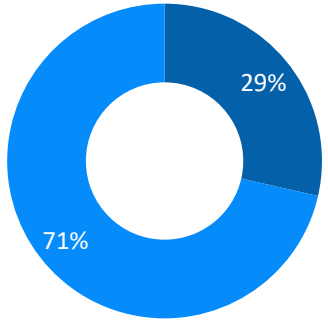
n=14

Results & Conclusions

Therapy

Therapy of newly diagnosed MS patients

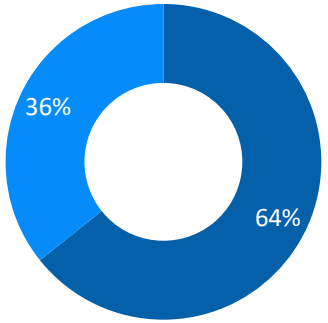
Do you think treatment with the highly effective therapy ofatumumab makes sense in patients having just experienced the onset of their MS ?



n=14

Long-term therapy

Would you potentially use anti-CD20 therapy as a long-term strategy?



n=14

[1]Restrictions mentioned: lack of long-term data, family planning, immunoglobulin levels, safety (incl. unknown adverse events)

Conclusions:

- The majority of German investigators consider ofatumumab's benefit-risk ratio as (very) good and rate the subcutaneous self-injection of ofatumumab as user-friendly, timesaving for patients and as a relief for high-occupancy clinics and office-based practices.
- 71% of the German investigators see no need to apply an extensive follow-up after 1st drug administration as specified in the phase III ASCLEPIOS studies` protocol[2], but plan instead to reduce this time to 1-2 hours. Due to the favorable risk-benefit-ratio seen in the phase III ASCLEPIOS trials[2], there is no formal obligation for a safety follow-up after 1st drug administration given in the US or EU label.
- In the future, most of the German investigators interviewed intent to give steroids, antihistamines and acetaminophen as premedication prior to the first ofatumumab injection only. In the phase III ASCLEPIOS studies, premedication was recommended upon discretion of the investigator. Since there was only limited benefit of premedication detected in the trials[1], no formal obligation for premedication is given in the US or EU label.
- All investigators consider ofatumumab as a therapy option for newly diagnosed patients.
- Limitations: A detailed inquiry of the risk and safety assessment for ofatumumab was not part of this survey.

[2] Hauser SL et al., N Engl J Med 2020;383:546-57