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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Ofatumumab

Trial Indication(s)

Multiple Sclerosis

Protocol Number

COMB157GUS13

Protocol Title

Real world study to evaluate patient and care partner ratings on early experience of injection and device for KESIMPTA® (ofatumumab) indicated for multiple sclerosis

Clinical Trial Phase

Phase IV

Phase of Drug Development

Phase IV

Study Start/End Dates

Study Start Date: November 24, 2021 (Actual)
Primary Completion Date: February 15, 2023 (Actual)
Study Completion Date: February 15, 2023 (Actual)

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Reason for Termination (If applicable)

NA

Study Design/Methodology

This was a US-based, observational cross-sectional study with primary data collection via questionnaires directly administered to patients with Multiple Sclerosis (MS) receiving KESIMPTA. Study participation did not, in any way, impact upon the standard of care that patients were receiving or any benefits to which patients were otherwise entitled. The treatment decision was required to be determined prior to, and independently of, the study. All aspects of treatment and clinical management of patients were in accordance with local clinical practice and applicable local regulations and at the discretion of the treating prescriber. No alterations to routine clinical practice were mandated or recommended as part of this study.

Neurologists and advanced practice providers specializing in MS treatment, who are likely to prescribe KESIMPTA based on a referral survey response, were targeted for recruitment onto the study's physician panel. These neurologists/providers were contacted via e-mail and phone with the referral opportunity and provided relevant study information.

Recruiting neurologists/advanced practice providers assessed patients for study participation at the time of presentation for a routine clinic visit, according to the defined selection criteria. No clinic visits were required for participation in this study and all eligible patients were consecutively proposed to be enrolled in the study through physician panel referral.

Centers

United States(1)

Objectives:

The study aimed to evaluate ratings on injection experience and device usability in patients self-administering KESIMPTA using the Sensoready® pen.

The primary objective of the study was:

- To evaluate, through survey methods, overall device satisfaction ratings among patients with MS self-administering KESIMPTA using the Sensoready® pen during the prior 12 months.

Secondary objectives of the study were:

- To understand demographic, clinical, and treatment characteristics of patients with MS receiving treatment with KESIMPTA using the Sensoready® pen,
- To evaluate overall device usability and convenience/flexibility for travel ratings among patients with MS self-administering KESIMPTA using the Sensoready® pen.
- To evaluate overall confidence and intention to continue use ratings among patients with MS self-administering KESIMPTA using the Sensoready® pen.
- To evaluate the impact of KESIMPTA injection on patient's daily activities and injection preparation activities ratings among patients with MS self-administering KESIMPTA using the Sensoready® pen.

To evaluate the overall average time required for KESIMPTA injections (removing drug out of refrigerator and injection to disposing pen in sharps container) among patients with MS administering KESIMPTA using the Sensoready® pen.

Test Product (s), Dose(s), and Mode(s) of Administration

Ofatumumab self-administered by a once-monthly subcutaneous autoinjector pen.

Statistical Methods

Descriptive results were reported using mean, median, range and standard deviation as measures of central tendency and variance for continuous variables. Cross tabulation in count (frequency) and percentage were used for categorical variables. The primary endpoint was summarized as proportion of patients rating satisfied/extremely satisfied. For variables with ordinal data (i.e., ratings), the data were presented as counts and percentages for each rating and overall mean score.

Sample size permitting, analysis of key endpoints was planned and stratified by time periods of treatment initiation (for example, within prior 6 to 12 months and less than 6 months prior) and Disease Modifying Therapies (DMT) naïve vs DMT experienced patients. No inferential analysis was performed for this study. No statistical tests or calculation of confidence intervals were conducted for these analyses.

Study Population: Key Inclusion/Exclusion Criteria

Patients with MS Inclusion Criteria:

- Adult aged eighteen (18) years of age or over at the time of the survey
- Prescribed KESIMPTA within the prior 12 months and currently self-administering treatment using the Sensoready® pen
- MS diagnosis based on 2017 McDonald criteria

Care Partner Inclusion Criteria:

- Adult aged eighteen (18) years of age or over
- Formal or informal care partner of patient with MS prescribed KESIMPTA within the prior 12 months
- Is currently administering KESIMPTA using the Sensoready® pen on their patient's behalf

Patients with MS Exclusion Criteria:

- Previously used injection as a part of inclusion in any ofatumumab (OMB) randomized clinical trial
- Active Hepatitis B virus (HBV)
- Cognitive impairment that would impact their ability to participate in a survey study

Participant Flow Table

Disposition/Reason	TOTAL N=105
Completed Study	105

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Baseline Characteristics

Table 10-1 Demographic characteristics of the study participants

Patient characteristics	Study participants (N=105)	
	N	%
Age (categories)		
18-24 years old	5	4.8%
25-34 years old	25	23.8%
35-44 years old	33	31.4%
45-54 years old	18	17.1%
55-64 years old	21	20.0%
65-74 years old	3	2.9%
Age (years)[1]		
Mean (SD)	42.5 (12.24)	
Median (Q1, Q3)	42.0 (33.0,54.0)	
Sex		
Male	37	35.2%
Female	67	63.8%
Prefer not to disclose	1	1.0%
Race/ethnicity[2]		
Caucasian	54	51.4%
African American	28	26.7%
Latino or Hispanic	14	13.3%
Others[3]	7	6.7%
Missing/unknown	7	6.7%

Q1: First quartile; Q3: Third quartile; SD: Standard Deviation.
[1] Current age (years) = ([survey completion date] – [date of birth] + 1) / 365.25.
[2] Can be more than one answer per patient.
[3] Includes Asians and Native Americans

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Primary Outcome Result(s)

Proportion of respondents in top two rating categories for device satisfaction on use of KESIMPTA Sensoready

	Overall (N=105)
Satisfied and extremely satisfied respondents, n (%)	91 (86.7)
Overall satisfaction score (category), n (%)	
n	105
1 Extremely dissatisfied	0 (0.0)
2 Dissatisfied	0 (0.0)
3 Neither satisfied nor dissatisfied	14 (13.3)
4 Satisfied	37 (35.2)
5 Extremely satisfied	54 (51.4)
Missing	0

Secondary Outcome Result(s)

Proportion of patients by US region of residence.

Patient characteristics	Study participants (N=105)	
	N	%
Geographic region		
West	4	3.8%
Midwest	4	3.8%
Northeast	76	72.4%

South	21	20.0%

Proportion of patients by educational level

Patient characteristics	Study participants (N=105)	
	N	%
Education level*		
Some high school to associate degree	61	58.1%
Bachelor's degree	32	30.5%
Masters or Professional degree	10	9.5%
Missing or unknown	2	1.9%

*No participant had a doctorate degree or education till 8th grade.

Patients Determined Disease Steps (PDDS)

Clinical characteristics	Study Participants (N=105)	
	N	%
PDDS measure of disability*		
0 Normal	16	15.2%
1 Mild disability	15	14.3%
2 Moderate disability	24	22.9%
3 Gait disability	28	26.7%
4 Early cane	16	15.2%
5 Late cane	3	2.9%
6 Bilateral support	2	1.9%
7 Wheelchair / scooter	1	1.0%

PDDS measure of disability (continuous)		
Mean (SD)	2.3 (1.5)	
Median (Q1, Q3)	2 (1.0, 3.0)	

* No participant in this category was bedridden or had missing information

General Health

Clinical characteristics	Study Participants (N=105)	
	N	%

General Health		
1 Poor	2	1.9%
2 Fair	21	20.0%
3 Good	41	39.0%
4 Very good	37	35.2%
5 Excellent	4	3.8%
General Health (continuous)		
Mean (SD)	3.2 (0.87)	
Median (Q1, Q3)	3 (3.0;4.0)	

Proportion of patients by Multiple Sclerosis Phenotype

Clinical characteristics	**Study Participants (N=105)**	
	N	**%**
MS Phenotype		
Relapsing-remitting MS (RRMS)	44	41.9%
Secondary progressive MS (SPMS)	15	14.3%
Primary progressive MS (PPMS)	35	33.3%
Responded as "I'm not sure"	11	10.5%

Proportion of patients with co-morbidities

Clinical characteristics	**Study Participants (N=105)**	
	N	**%**

Prevalent comorbid conditions*		
Anxiety	38	36.2%
High Cholesterol	28	26.7%
Hypertension	24	22.9%
Chronic Pain	21	20.0%
Depression	19	18.1%
Diabetes	14	13.3%
Inflammatory Bowel Disease	11	10.5%
Osteoarthritis	9	8.6%
Number of comorbid conditions per patient		
Mean (SD)	2.0 (1.35)	
Median (Q1, Q3)	2.0 (1.0;2.0)	

* Remaining comorbid conditions can be found in Appendix 2

Importance of healthcare provider (HCP) instructions for first injection, level of agreement of the statements

Patients feel essential to have a healthcare provider instruct them for the first injection:	
n	105
1 Strongly disagree	3 (2.9)
2 Disagree	9 (8.6)
3 Neither agree nor disagree	8 (7.6)
4 Agree	23 (21.9)
5 Strongly agree	62 (59.0)
Missing	0
Patients feel they need to have a healthcare provider watch them to administer the first injection:	
n	105
1 Strongly disagree	6 (5.7)
2 Disagree	10 (9.5)

3 Neither agree nor disagree	21 (20.0)
4 Agree	18 (17.1)
5 Strongly agree	50 (47.6)
Missing	0
Patients feel comfortable receiving instructions from healthcare providers in the clinic on for the first injection and did not need healthcare providers to be present:	
n	105
1 Strongly disagree	11 (10.5)
2 Disagree	13 (12.4)
3 Neither agree nor disagree	31 (29.5)
4 Agree	19 (18.1)
5 Strongly agree	31 (29.5)
Missing	0

Level of anxiety with injections, in general

Clinical characteristics	**Study Participants (N=105)**
Level of anxiety with injections (on a scale of 10)	
Mean (SD)	3.9 (2.4)
Median (Q1, Q3)	4.0 (2.0;6.0)

Proportion of patients performing preparation activities for injection

Time to take my KESIMPTA Sensoready® pen out of the refrigerator and allow it to reach room temperature prior to injection (minutes) (step A)	
n	105
Mean (SD)	19.0 (9.10)
Median	20.0
Q1; Q3	15.0; 25.0
Min; Max	2.0; 60.0
Missing	0
Time to perform the injection including picking up the Sensoready® pen, injecting and disposing in the sharps container (minutes) (step B)	
n	105
Mean (SD)	6.5 (4.38)
Median	5.0
Q1; Q3	4.0; 10.0
Min; Max	1.0; 25.0
Missing	0
Total time for the two steps A+B (minutes)	
n	105
Mean (SD)	25.5 (10.48)
Median	25.0
Q1; Q3	20.0; 33.0
Min; Max	3.0; 62.0
Missing	0

Proportion of participants by site of administration

Site of injection, n (%)	

n	105
Outer upper right arm	15 (14.3)
Outer upper left arm	20 (19.0)
Lower abdomen	30 (28.6)
Front of right thigh	25 (23.8)
Front of left thigh	15 (14.3)
Missing	0

Proportion of participants by individual medication as previous Disease Modifying Therapy (DMT)

Type of DMT for MS prior to KESIMPTA[2]		
Injectable therapy	27	41.5%
Infused therapy	26	40.0%
Oral therapy	20	30.8%
Type of injectable DMT prior to KESIMPTA[2,3] (N=27)		
Prefilled syringe	22	81.5%
Autoinjector	7	25.9%
Other	1	3.7%
The most recent injectable DMT prior to KESIMPTA[3] (N=22)		
Interferon beta-1a	18	81.8%
Interferon beta-1b	3	13.6%
Glatiramer acetate	1	4.5%
Overall satisfaction with injectable DMT prior to KESIMPTA[3] (on a scale of 5) (N=27)		
Mean (SD)	2.8 (0.93)	
Median (Q1; Q3)	3.0 (2.0; 3.0)	
The most recent oral DMT prior to KESIMPTA[4] (N=17)		
Aubagio® (teriflunomide)	6	35.3%
Tecfidera® (dimethyl fumarate)	3	17.6%
Gilenya® (fingolimod)	2	11.8%
Mavenclad® (cladribine)	2	11.8%
Vumerity® (diroximel fumarate)	2	11.8%
Mayzent® (siponimod)	1	5.9%
Zeposia® (ozanimod)	1	5.9%
The most recent infused DMT prior to KESIMPTA[5] (N=21)		
Ocrevus® (ocrelizumab)	11	52.4%
Tysabri® (natalizumab)	9	42.9%
Lemtrada® (alemtuzumab)	1	4.8%

DMT: Disease Modifying Therapy; MS: Multiple Sclerosis; Q1: First quartile; Q3: Third quartile; SD: Standard Deviation.
Percentages are calculated using non-missing values as denominator

[F] Can be more than one answer per patient.
[3] Among those who have used injectable DMT for MS prior to KESIMPTA; There were no patients with Peginterferon beta-1a
[4] Among those who have used oral DMT for MS prior to KESIMPTA
[5] Among those who have used infused DMT for MS prior to KESIMPTA.

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Proportion of patients who are DMT naïve or experienced.

Treatment characteristics	Study Participants (N=105)	
	N	%
DMT naïve patients	40	38.0
DMT experienced patients	65	61.9

Proportion of participants by reasons for starting KESIMPTA or switch from most recent therapy

Treatment characteristics	Study Participants (N=105)	
	N	%
Among DMT naïve patients (N=40)		
Main reason for starting KESIMPTA		
Patient likes the convenience of KESIMPTA	14	35.0%
Doctor had safety concerns with other DMTs	9	22.5%
Patient prefers to avoid infusion clinics	6	15.0%
Insurance didn't cover other DMTs, or patient couldn't afford the therapies	3	7.5%
The way the other DMTs are administered is not right for patient	2	5.0%
Patient has another medical condition and/or takes other medications which prevent him/her from being able to take other disease modifying therapies	2	5.0%
Other	4	10.0%
Among DMT experienced patients (N=65)		
Main reason for switching to KESIMPTA		

MS symptoms were not getting better when patient took the previous DMTs	19	29.2%
MS symptoms became worse	16	24.6%
Patient had side effects from the previous DMTs and/or doctor had safety concerns with the previous therapy	13	20.0%
Patient likes the convenience of KESIMPTA	7	10.8%
The way the previous DMTs are administered was not right for patient	3	4.6%
Insurance didn't cover the previous DMTs, or patient couldn't afford the therapy	3	4.6%
Patient had another medical condition and/or took other medications which stopped him/her from being able to take the previous DMTs	2	3.1%
Patient prefers to avoid infusion clinics	1	1.5%
Other	1	1.5%

Proportion of patients agreeing with the attributes of the device Usability Characteristics during self-administration

	Overall (N=105)
Overall ease of use (Overall, the KESIMPTA Sensoready® pen is easy and simple to use)	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)
2 Disagree	3 (2.9)
3 Neither agree nor disagree	8 (7.6)
4 Agree	42 (40.0)
5 Strongly agree	52 (49.5)
Missing	0
value	

n	105
Mean (SD)	4.4 (0.75)
Median	4.0
Q1; Q3	4.0; 5.0
Min; Max	2.0; 5.0
Missing	0
Device ergonomics (The KESIMPTA Sensoready® pen feels comfortable in my hand when I inject)	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)
2 Disagree	9 (8.6)
3 Neither agree nor disagree	16 (15.2)
4 Agree	39 (37.1)
5 Strongly agree	41 (39.0)
Missing	0
value	
n	105
Mean (SD)	4.1 (0.94)
Median	4.0
Q1; Q3	4.0; 5.0
Min; Max	2.0; 5.0
Missing	0
Ease of preparing device (It was easy to prepare the KESIMPTA Sensoready® pen for use)	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)
2 Disagree	1 (1.0)
3 Neither agree nor disagree	18 (17.1)
4 Agree	41 (39.0)

5 Strongly agree	45 (42.9)
Missing	0
value	
n	105
Mean (SD)	4.2 (0.77)
Median	4.0
Q1; Q3	4.0; 5.0
Min; Max	2.0; 5.0
Missing	0
Convenient/flexible to travel (I feel the KESIMPTA Sensoready® pen is convenient/flexible to travel with)	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)
2 Disagree	0 (0.0)
3 Neither agree nor disagree	28 (26.7)
4 Agree	33 (31.4)
5 Strongly agree	44 (41.9)
Missing	0
value	
n	105
Mean (SD)	4.2 (0.82)
Median	4.0
Q1; Q3	3.0; 5.0
Min; Max	3.0; 5.0
Missing	0
The ease of KESIMPTA's monthly dosing schedule	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)

2 Disagree	3 (2.9)
3 Neither agree nor disagree	8 (7.6)
4 Agree	35 (33.3)
5 Strongly agree	59 (56.2)
Missing	0
value	
n	105
Mean (SD)	4.4 (0.76)
Median	5.0
Q1; Q3	4.0; 5.0
Min; Max	2.0; 5.0
Missing	0
Time required to prepare the KESIMPTA Sensoready® pen (The amount of time required to prepare the KESIMPTA Sensoready® pen for use was reasonable)	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)
2 Disagree	0 (0.0)
3 Neither agree nor disagree	14 (13.3)
4 Agree	46 (43.8)
5 Strongly agree	45 (42.9)
Missing	0
value	
n	105
Mean (SD)	4.3 (0.69)
Median	4.0
Q1; Q3	4.0; 5.0
Min; Max	3.0; 5.0
Missing	0

Time required to administer KESIMPTA using the Sensoready® pen for use (Overall, the amount of time required to administer KESIMPTA using the Sensoready® pen was reasonable)	
category, n (%)	
n	105
1 Strongly disagree	0 (0.0)
2 Disagree	2 (1.9)
3 Neither agree nor disagree	8 (7.6)
4 Agree	45 (42.9)
5 Strongly agree	50 (47.6)
Missing	0
value	
n	105
Mean (SD)	4.4 (0.71)
Median	4.0
Q1; Q3	4.0; 5.0
Min; Max	2.0; 5.0
Missing	0

Patient Confidence

	Study participants (N=105)
Confidence to self-administer KESIMPTA using the Sensoready® pen for use*	
Mean (SD)	8.1 (2.07)
Median (Q1; Q3)	9.0 (7.0;10.0)
Intention to continue use of KESIMPTA Sensoready® pen**	
Mean (SD)	8.3 (1.96)
Median (Q1; Q3)	9.0 (7.0; 10.0)
Intention to recommend KESIMPTA to others**	
Mean (SD)	8.3 (2.08)
Median (Q1; Q3)	(7.0; 10.0)

*On scale of 0 (Not at all confident) to 10 (Extremely confident)
**On scale of 0 (Not at all likely) to 10 (Extremely likely)

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Overall device satisfaction by treatment duration

	6-12 months prior (N=38)	< 6 months prior (N=67)
Satisfied and extremely satisfied respondents, n (%)	25 (65.8)	66 (98.5)
Overall satisfaction score (category), n (%)		
n	38	67
1 Extremely dissatisfied	0 (0.0)	0 (0.0)
2 Dissatisfied	0 (0.0)	0 (0.0)
3 Neither satisfied nor dissatisfied	13 (34.2)	1 (1.5)
4 Satisfied	10 (26.3)	27 (40.3)
5 Extremely satisfied	15 (39.5)	39 (58.2)
Missing	0	0
Overall satisfaction score (value)		
n	38	67
Mean (SD)	4.1 (0.87)	4.6 (0.53)
Median	4.0	5.0
Q1; Q3	3.0; 5.0	4.0; 5.0
Min; Max	3.0; 5.0	3.0; 5.0
Missing	0	0

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Overall device satisfaction score of the study participants by DMT experience

	DMT naïve patients (N=40)	**DMT experienced patients (N=65)**
Satisfied and extremely satisfied respondents, n (%)	32 (80.0)	59 (90.8)
Overall satisfaction score (category), n (%)		
n	40	65
1 Extremely dissatisfied	0 (0.0)	0 (0.0)
2 Dissatisfied	0 (0.0)	0 (0.0)
3 Neither satisfied nor dissatisfied	8 (20.0)	6 (9.2)
4 Satisfied	21 (52.5)	16 (24.6)
5 Extremely satisfied	11 (27.5)	43 (66.2)
Missing	0	0
Overall satisfaction score (value)		
n	40	65
Mean (SD)	4.1 (0.69)	4.6 (0.66)
Median	4.0	5.0
Q1; Q3	4.0; 5.0	4.0; 5.0
Min; Max	3.0; 5.0	3.0; 5.0
Missing	0	0

Safety Results

There was no planned pharmacovigilance activity for this study. Any Adverse Events (AEs) were handled and reported by the patient's physician, as necessary, according to standard recording mechanisms and requirements. Because this was a patient survey study, clinical data was not collected throughout the study period; thus, any event occurring during the study period was handled by the patient's health care provider

Other Relevant Findings

Not Applicable

Conclusion:

In this first study in the US evaluating patient satisfaction with KESIMPTA Sensoready® injection pen, a very high satisfaction rate was observed among MS patients included in the study. Several device usability characteristics were highly rated by patients with positive intention to continue treatment and recommend to other patients. Patients valued convenience, ease of dosing schedule, reasonable time of administration and low interference with daily activities of KESIMPTA Sensoready® pen.

Date of Clinical Trial Report

12 February 2024