CLADQoL (CLADribine Tablets – Evaluation of Quality of Life) Study: Evaluating QoL 12 Months after Treatment Initiation with Cladribine Tablets

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Disclosures

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- **IKP** has received honoraria for speaking at scientific meetings, serving at scientific advisory boards and consulting activities from Adamas Pharma, Almirall, Bayer Pharma, Biogen, Celgene, Desitin, Sanofi-Genzyme, Janssen, Merck Serono GmbH, an affiliate of Merck KGaA, Darmstadt, Germany, Novartis, Roche, and Teva. She has received research support from the German MS Society, Celgene, Roche, Teva, and Novartis.
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- **JR, TW, BM, TB, APF** are employees of Merck Serono GmbH, an affiliate of Merck KGaA, Darmstadt, Germany.

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(DRKS German Register for clinical trials)

INTRODUCTION

- CLADQoL is a non-interventional study (NIS) in patients with relapsing multiple sclerosis (RMS) treated with cladribine tablets, focusing on quality of life (QoL).
- This is the first publication on the change in quality of life (examined by MSQoL-54) of patients treated with cladribine tablets in real world conditions at baseline and after 12 months.
- Recruitment started a few months after marketing authorization for cladribine tablets had been granted in Germany (Aug 22nd, 2017) and ended in April 2020.
  - Patient follow-up will continue and is planned for four years.

MSQoL-54, Multiple Sclerosis Quality of Life-54

OBJECTIVES

- **To evaluate changes in patients' quality of life (MSQoL-54 physical health and mental health composite scores) under therapy with cladribine tablets 12 months after treatment initiation.**
- **To describe the patient population, including pre-treatment and relapse rate.**

MSQoL-54, Multiple Sclerosis Quality of Life-54

METHODS

- Quality of life was evaluated from the patient subset where MSQoL-54 was available both at baseline and month 12.
- Safety analysis was performed on the overall study population.

MS patients were treated with **cladribine tablets** in accordance with the approved indication criteria in Germany.

Cut-Off date for analysis was **June 2nd, 2020***.

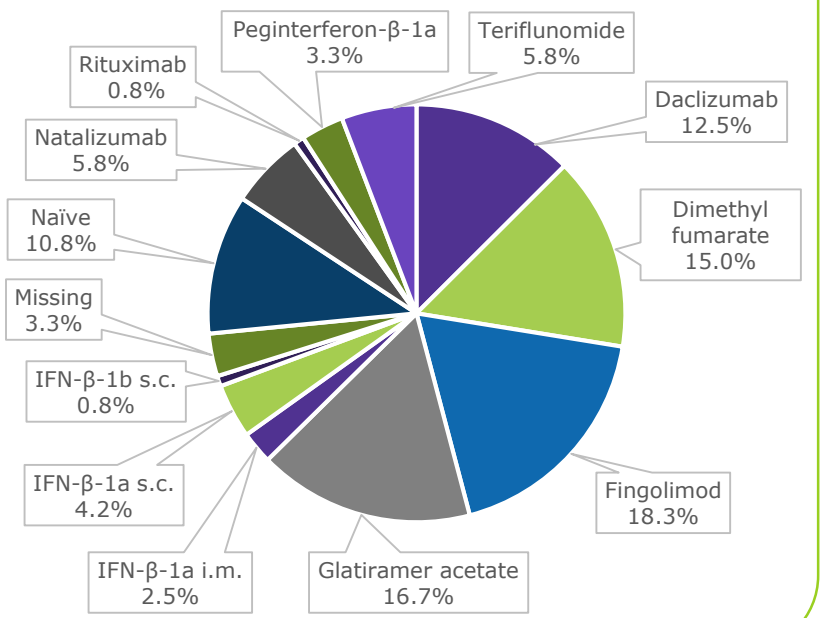
MSQoL-54, Multiple Sclerosis Quality of Life-54

RESULTS

Demographic and baseline data

Parameter	Study population	Subset with valid MSQoL-54 at baseline + 12 months
	N=289*	N=120**
Age, years (mean±SD)	38.3±10.0	37.6±10.0
Gender, % Female Male	 70.2 29.1	 76.7 23.3
Type of MS, % RRMS SPMS	 94.8 4.8	 93.3 6.7
Time since diagnosis, months (median [q1; q3])	80.2 [28.3; 147.2]	72.9 [28.3; 136.5]
Therapy-naïve, %	12.8	10.8

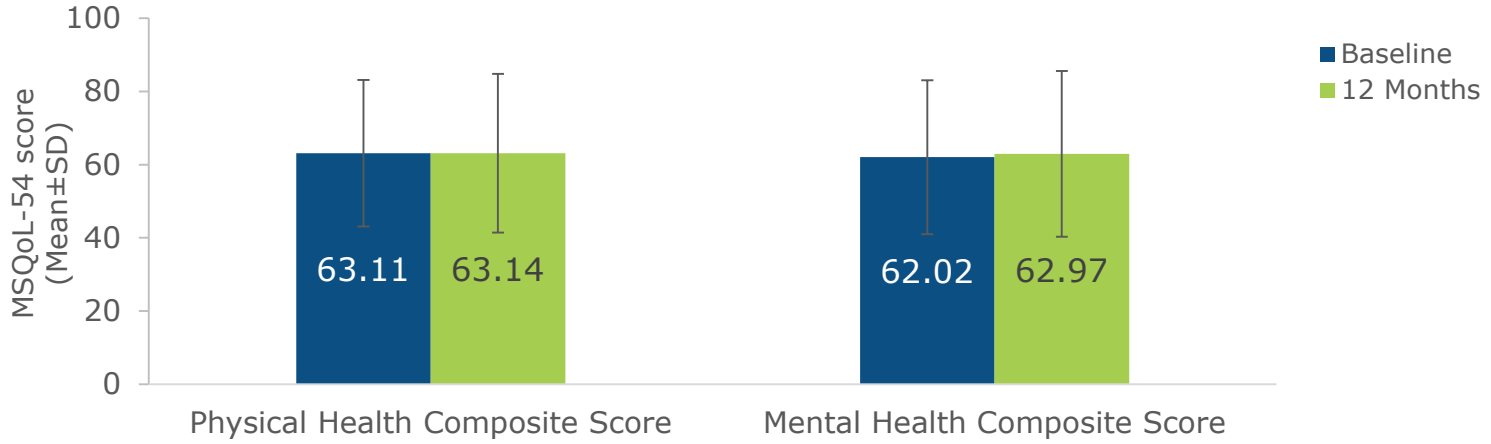
Last previous therapy (subset, N=120)#



* Missing/unknown data for some parameters: age (2), sex (2), type of MS (1),** 120 patients with valid MSQoL-54 at baseline and month 12 were documented at time of cut-off, out of 186 patients with due 12 month visit. The number of patients with complete MSQoL-54 is expected to increase at next data cut-offs; n=119 for time since MS diagnosis, # Subset with valid MSQoL-54 at Baseline + 12 months (N=120); Cut-off date: June 2nd, 2020; **SD**, standard deviation; **q1**, 1st quartile; **q3**, 3rd quartile; **RRMS,** relapsing-remitting MS; **SPMS**, secondary progressive MS

RESULTS

MSQoL-54 scores: Baseline vs 12 Months in subset (n=120)#

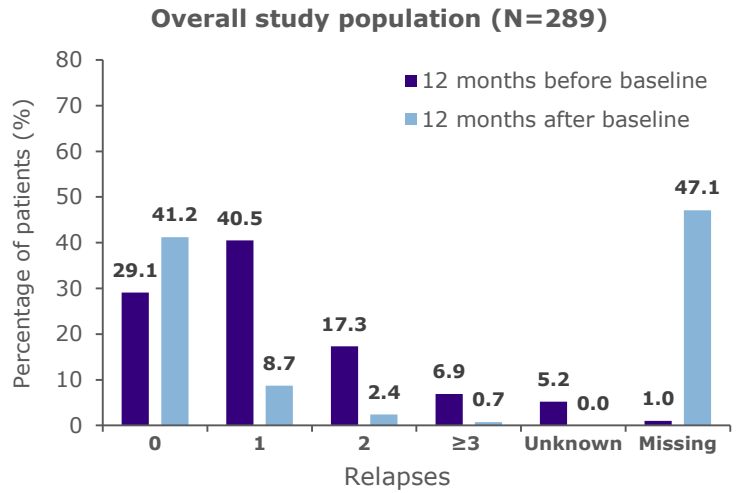


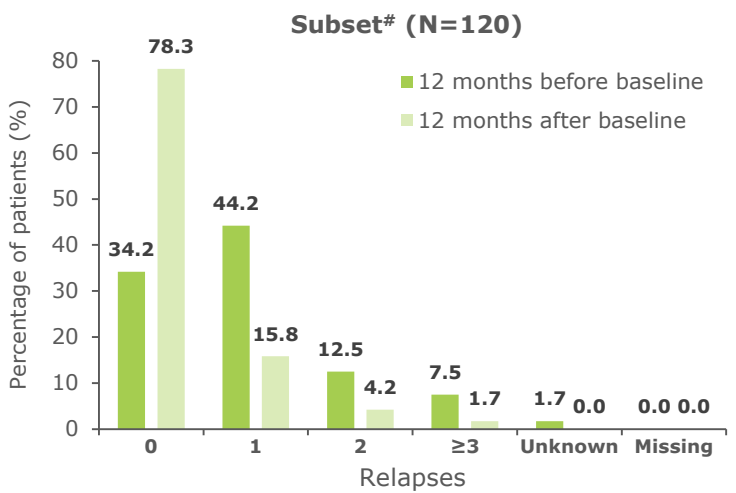
- High values indicate high Quality of Life.
- Mean (±SD) changes from baseline to month 12 were 0.04 ±14.06 and 0.95 ±17.05 for the Physical and Mental Health Composite Score, respectively*, measured in subset of 120 patients for whom both baseline and month 12 values were available. Changes were not statistically significant.

* Positive values indicate improvement; MSQoL: MS Quality of life; # Subset with valid MSQoL-54 at Baseline + 12 months (N=120); Cut-off date: June 2nd, 2020

RESULTS

Relapse before and after therapy with cladribine tablets*





- The mean number of relapses (±SD) before and after baseline was 1.1 ±1.0 and 0.3 ±0.7 in the overall population and 1.0 ±1.1 and 0.3 ±0.7 in the subset, respectively.

* Number of relapses per patient 12 months prior and 12 months after initiation of cladribine tablets; # Subset with valid MSQoL-54 at Baseline + 12 months (N=120); Cut-off date: June 2nd, 2020

RESULTS

Safety: overall study population (N=289)

Patients with adverse events	n (%)
≥1 AE	94 (32.5)
≥1 SAE	12 (4.2)
≥1 TRAE	46 (15.9)
≥1 serious TRAE	3 (1.0)
≥1 AESI	12 (4.2)*
≥1 serious AESI	0 (0)
≥1 (S)AE leading to death	0 (0)

Patients with (S)AE with suspected relation to cladribine tablets**		Number (% of total patient no)
Immune system	Lymphopenia (11)	11 (3.8)
Infections	Herpes zoster (4), infection (2), bronchitis (1), herpes ophthalmic (1), influenza (1), oral herpes (1)	9 (3.1)
Nervous system	**MS relapse** (4 AE, **1 SAE**), headache (4), dizziness (3), paraesthesia (1)	11 (3.8)
Gastrointestinal disorders	**Nausea** (4 AE, **1 SAE**), abdominal pain (1), abdominal upper pain (1), gastritis (1), vomiting (1), increased liver value (1)	6 (2.1)
Dermatological disorders	Alopecia (1), erythema (1), pruritus (1)	3 (1.0)
Cardiac & vascular	**Myocardial infarction (1, SAE),** flushing (1), haematoma (1)	3 (1.0)
Other	Facial pain (1), listlessness (1)**, asthenia (1, SAE),** influenza-like illness (1), malaise (1), **fatigue** (5 AE, **1 SAE**), Myalgia (1), **vision blurred (1, SAE)**	10 (3.5)

- 94 patients experienced at least one AE, of which 12 had ≥1 SAE and 46 had ≥1 TRAE.
- No severe opportunistic infections were reported.

***** All lymphopenia, all non-serious; ** Numbers in table may not add up as one patient may have more than one AE; **AE,** adverse event; **SAE,** serious adverse event; **TRAE,** treatment-related adverse event; **AESI,** adverse events of special interest. Definition according CLADQoL study protocol: Malignancies; severe and/or serious infections, that include 4 categories: severe and/or serious herpetic infections; severe and/or serious herpes zoster infection; severe and/or serious opportunistic infections (excluding herpetic infections), including progressive multifocal leukoencephalopathy (PML) and tuberculosis; other severe and/or serious infections; Severe lymphopenia (≥ grade 3); lymphopenia according to CTCAE criteria: >1,000 lymphocytes/µl

CONCLUSIONS

Within the first year of treatment with cladribine tablets in patients with relapsing MS **QoL remained stable**.

We observed a **decrease in relapses** and the safety results were in line with the known safety profile of cladribine tablets.

The non-interventional study is **ongoing** and the patients are being followed up.