Cladribine Tablets in Patients with RRMS and Active SPMS After Suboptimal Response to Prior DMD (MASTER-2 and CLICK-MS): Initial Baseline Demographics

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SUMMARY

Treatment switching is common in the management of MS. How patients with relapsing forms of MS will respond to cladribine tablets following suboptimal response to another DMD is unclear

Patient enrollment and data collection are ongoing. To date, baseline data (prior to receiving cladribine tablets) on disease characteristics, prior DMDs, PROs on health-related quality of life, and safety are representative of the US population with MS

MASTER-2 and CLICK-MS are 30-month Phase 4 studies in the US evaluating the effectiveness of cladribine tablets in patients with RRMS or active SPMS who had suboptimal response to prior DMD

With the ever increasing landscape of MS DMDs, real-world evidence in the US around switching, adherence, and PROs of DMDs will be critical in supporting the decision making process for MS treatment

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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BACKGROUND INFORMATION

- Numerous DMDs are available for treating MS
  - However, most patients with MS (>50%) experience suboptimal response to a DMD in at least one of the three key measures of efficacy outcomes: relapse, disability progression, and lesion activity on MRI[1]
    - Therefore, treatment switching is common in the management of MS. The rate of switching in the US (2015–2019) was 77% from first DMD, 17% from second DMD, and 6% from third or higher DMD[2]
- Cladribine tablets 10 mg (3.5 mg/kg cumulative dose over 2 years) are approved in >75 countries, including in the US, for treating relapsing-forms of MS, including RRMS and active SPMS
  - A retrospective follow-up study of 17 patients who transitioned from natalizumab to cladribine tablets reported no relapse and no increase in disability per EDSS scoring in any patients, and no new lesion activity on MRI in 15 patients during treatment with cladribine tablets[3]
  - However, how patients with relapsing forms of MS will respond to cladribine tablets following suboptimal response to other DMDs remains unclear

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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OBJECTIVE

To examine real-world effectiveness, safety, and PROs in patients with RRMS or active SPMS who transition to cladribine tablets after suboptimal response to:

- Prior **oral** or **infusion** DMDs (MASTER-2 study)
- Prior **injectable** DMDs (CLICK-MS study)

METHODS

MASTER-2 and CLICK-MS are single arm, observational, 30-month, Phase 4 trials in the US

Studies began in 2019 and are expected to end in 2023

~200 patients will be enrolled across **~50** sites per study

Main inclusion criteria

- ✓ Age ≥18 years
- ✓ Diagnosed with RRMS or active SPMS for ≥12 months
- ✓ Suboptimal response (investigator-assessed) to previous treatment with an **oral**, **infusion**, or **injectable** DMD
- ✓ Received last DMD ≥3 months ago
- ✓ Decision to initiate cladribine tablets treatment made during routine clinical care (i.e. before enrollment)

Main exclusion criteria

- ✗ Previous cladribine treatment (any dose or formulation)
- ✗ Decision to transition from previous DMD made for administrative reasons only (e.g. relocation)
- ✗ Have any clinical condition or medical history noted as a contraindication on the cladribine tablets USPI

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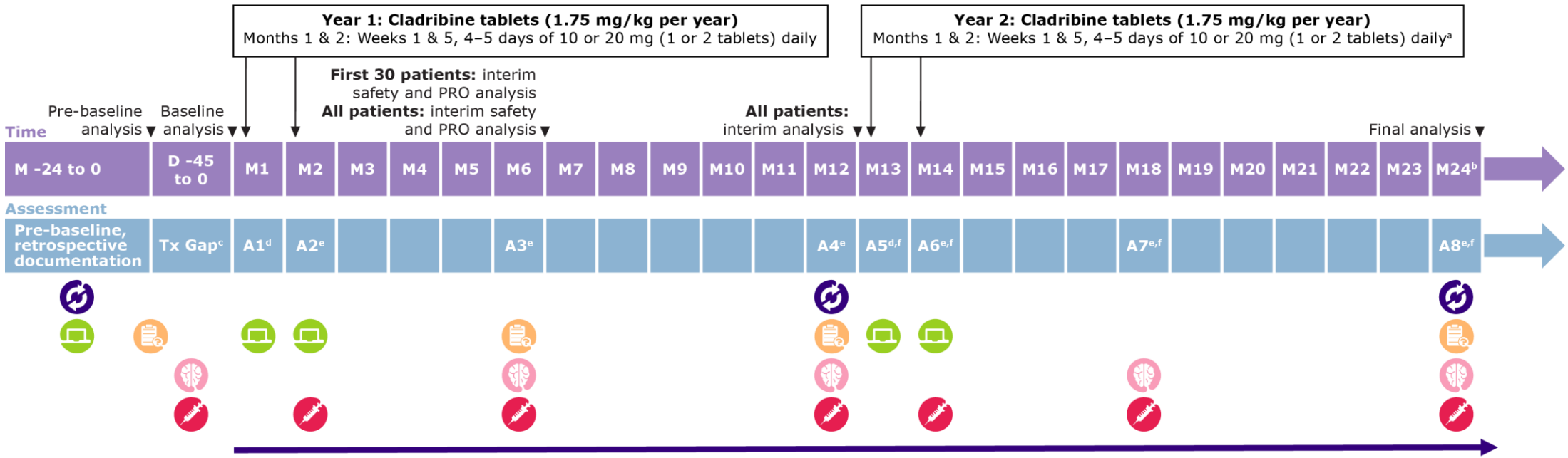
METHODS

Study design for both MASTER-2 (prior oral / infusion DMDs) & CLICK-MS (prior injectable DMDs)



- Relapse count (Pre-baseline: last 24 months)
- Treatment adherence: MS-TAQ, modified version (via online)
- Other PROs: TSQM, SF-36, MFIS-5, BDI-FS, WPAI-MS, PDDS (via eCRF)
- MRI data (as available as per routine practice, assuming documentation at baseline, Months 6, 12, 18, and 24)
- Blood samples (as available as per routine practice): expected time points based on required ALC testing as per USPI; additional assessments such as CBC, lymphocyte subsets, JCV status
- Parameters collected on an ongoing basis: AEs, concomitant medications (both for MS and overall)

Primary endpoint: ARR over 24 months

Patients will have visits and assessments as per routine clinical practice and in accordance with the USPI. All patients, including those who discontinue cladribine tablets treatment during the observation, will be followed up to Month 24 (or Month 30[a])

[a]Year 2 treatment may be delayed (up to 6 months) for some patients to allow recovery of ALC. [b]Follow-up can increase to up to 30 months depending on timing of Year 2 dose. [c]Duration between stopping previous oral, infusion, or injectable DMD and start of cladribine tablets is at the discretion of the investigator. [d]Assessment at home. [e]Assessment at the clinic. [f]Timing of assessment can be adjusted based on timing of Year 2 dose.

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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RESULTS

Baseline patient characteristics[a]

Patient demographics	MASTER-2: Prior oral DMD (N=38)	MASTER-2: Prior infusion DMD (N=14)	CLICK-MS: Prior injectable DMD (N=19)
Female, n (%)	27 (71.1)	12 (85.7)	15 (78.9)
Age (yrs)			
Mean (SD)	50 (10.3)	50 (11.7)	50 (13.5)
Min, Max	24, 69	30, 68	22, 67
Subject <65 yrs old, n (%)	36 (94.7)	13 (92.9)	18 (94.7)
Race, n (%)			
White	29 (76.3)	11 (78.6)	14 (73.7)
Black/African American	5 (13.2)	1 (7.1)	4 (21.1)
Other[b]	4 (10.5)	2 (14.3)	1 (5.3)

Disease characteristics	MASTER-2: Prior oral DMD (N=38)	MASTER-2: Prior infusion DMD (N=14)	CLICK-MS: Prior injectable DMD (N=19)
RRMS diagnosis, n (%)	36 (94.7)	11 (78.6)	17 (89.5)
Active SPMS diagnosis, n (%)	2 (5.3)	3 (21.4)	1 (5.3)
Missing diagnosis, n (%)	-	-	1 (5.3)
Elapsed time since diagnosis (yrs), mean (SD)	11.9 (8.2)	11.6 (6.6)	13.0 (8.1)[c]
Relapse in prior 24 months, n (%)			
0	25 (69.4)	9 (64.3)	10 (62.5)[d]
1	8 (22.2)	4 (28.6)	4 (25.0)[d]
2	2 (5.6)	1 (7.1)	2 (12.5)[d]
≥3	1 (2.8)	-	-
ARR in prior 24 months, mean (SD)	0.21 (0.37)[e]	0.21 (0.32)	0.25 (0.37)[d]
EDSS, mean (SD)	4.2 (1.9)[f]	4.5 (1.8)[g]	3.4 (3.0)[h]

[a]This presentation reports interim baseline data. Variable patient numbers for certain measures are due to ongoing data collection and cleaning.
[b]Asian, Puerto Rican, Filipino, unknown
[c]n=17; [d]n=16; [e]n=36; [f]n=6; [g]n=3; [h]n=7

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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RESULTS

Baseline satisfaction for most recent DMDs used[a]

MASTER-2

Prior oral DMD (N=38)[b]	
Prior DMD, n (%)	
Teriflunomide	12 (31.6)
Dimethyl fumarate	12 (31.6)
Fingolimod	10 (26.3)
TSQM-14[d] (for prior DMD), mean (SD); based on n=23	
Global satisfaction	50.0 (26.38)
Effectiveness	53.1 (25.94)
Side effects	83.7 (30.66)
Convenience	77.5 (17.84)

Prior infusion DMD (N=14)[b]	
Prior DMD, n (%)	
Ocrelizumab	7 (50.0)
Natalizumab	5 (35.7)
Alemtuzumab	1 (7.1)
TSQM-14[d] (for prior DMD), mean (SD); based on n=8	
Global satisfaction	52.7 (22.57)
Effectiveness	52.1 (26.22)
Side effects	88.3 (21.76)
Convenience	68.8 (20.34)

CLICK-MS

Prior injectable DMD (N=19)[c]	
Prior DMD, n (%)	
IFN beta-1a	7 (36.8)
Glatiramer acetate	5 (26.3)
Pegylated IFN beta-1a	2 (10.5)
TSQM-14[d] (for prior DMD), mean (SD); based on n=7	
Global satisfaction	41.8 (26.22)
Effectiveness	44.4 (17.57)
Side effects	100 (0)
Convenience	54.8 (25.95)

[a]This presentation reports interim baseline data. Variable patient numbers for certain measures are due to ongoing data collection and cleaning. [b]In the MASTER-2 study: 1 subject's prior DMD use is being confirmed; 4 subjects with no DMD in prior 2 years. [c]In the CLICK-MS study: 4 subjects' prior DMD use is being confirmed; 1 subject with no DMD in prior 2 years. [d]TSQM score range 0–100. Higher score = higher satisfaction

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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RESULTS

Baseline PROs before starting cladribine tablets[a]

	MASTER-2		CLICK-MS
	Prior oral DMD (N=38)	Prior infusion DMD (N=14)	Prior injectable DMD (N=19)
SF-36[b,c] mean (SD)			
Physical component summary scale	43.1 (11.16) n=30	75.5 (34.65) n=2	-[d]
Mental component summary scale	48.2 (9.78) n=30	54.5 (24.75) n=2	-[d]
WPAI-MS[e] mean (SD)			
Percent work time missed	6.6 (21.90) n=22	1.1 (2.91) n=7	7.6 (12.97) n=10
Percent impairment while working	23.5 (31.01) n=17	30.0 (35.59) n=4	30.0 (21.60) n=7
Percent overall work impairment	23.6 (31.28) n=17	30.0 (35.59) n=4	33.7 (23.57) n=10
Percent activity impairment	31.2 (28.18) n=25	41.4 (30.78) n=7	33.3 (24.49) n=9

	MASTER-2		CLICK-MS
	Prior oral DMD (N=38)	Prior infusion DMD (N=14)	Prior injectable DMD (N=19)
MFIS-5[f] mean (SD)	9.2 (5.03) n=28	7.9 (3.98) n=8	10.4 (5.81) n=9
BDI-FS[g] mean (SD)	1.5 (1.84) n=28	1.1 (1.25) n=8	4.4 (3.61) n=11
PDDS[h] mean (SD)	2.4 (2.20) n=32	3.6 (2.50) n=11	2.1 (1.35) n=14

[a]This presentation reports interim baseline data. Variable patient numbers for certain measures are due to ongoing data collection and cleaning. [b]Data not shown for the following measures: bodily pain, health transition item, mental health scale, general health scale, physical functioning, role-emotional scale, role physical scale, social functioning scale, and vitality scale. [c]SF-36 scores range 0–100 (higher score = better health). [d]SF-36 analysis has not yet been conducted for early data from the CLICK-MS study. [e]WPAI-MS scores are expressed as impairment percentages (higher percentage = greater impairment/less productivity). [f]MFIS-5 scores range 0–20 (higher scores = greater impact of fatigue). [g]BDI-FS scores range 0–21 (higher scores = greater symptom severity). [h]PDDS scores range 0–8 (higher scores = higher level of disability).

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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CONCLUSIONS

- **MASTER-2 and CLICK-MS will report real-world effectiveness and safety data of cladribine tablets in patients with RRMS or active SPMS with suboptimal response to prior oral, infusion, or injectable DMDs**
- **With the ever increasing landscape of MS DMDs, real-world evidence in the US around switching, adherence, and PROs of DMDs will be critical in supporting the decision making process for MS treatment**

Abbreviations: A, assessment; **AE**, adverse event; **ALC**, absolute lymphocyte count; **ARR**, annualized relapse rate; **BDI-FS**, Beck-Depression Inventory – Fast Screen; **CBC**, complete blood count; **D**, day; **DMD**, disease modifying drug; **eCRF**, electronic case report form; **EDSS**, Expanded Disability Status Scale; **IFN**, interferon; **JCV**, John Cunningham Virus; **M**, month; **MRI**, magnetic resonance imaging; **MFIS-5**, Modified Fatigue Impact Scale – 5-item version; **MS**, multiple sclerosis; **MS-TAQ**, MS Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PRO**, patient reported outcome; **SF-36**, 36-Item Short Form Health Survey; **TSQM**, 14-Item Treatment Satisfaction Questionnaire for Medication; **PRO**, patient reported outcome; **RRMS**, relapsing-remitting MS; **SD**, standard deviation; **SPMS**, secondary progressive MS; **USPI**, United States Prescribing Information; **WPAI-MS**, Work Productivity Activity Impairment – MS; **Yrs**, years

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