Participant Flow

Recruitment Details	
Pre-Assignment Details	

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years	Total (Not public)
▼ Arm/Group Description	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.	
Period Title: **Overall Study**							
Started	86 [1]	84 [2]	86 [3]	86 [4]	88 [5]	87 [6]	517
Completed	74	75	76	74	77	70	446
Not Completed	12	9	10	12	11	17	71
Reason Not Completed							
Adverse Event	2	1	3	2	1	6	15
Consent Withdrawn	6	3	4	6	6	5	30
Investigator Decision	2	0	1	0	0	0	3
Subject Non-compliance	0	0	0	0	0	1	1
Death	0	0	0	0	1	0	1
Not Specified	2	5	2	4	3	5	21
(Not Public)	Not Completed = 12 Total from all reasons = 12	Not Completed = 9 Total from all reasons = 9	Not Completed = 10 Total from all reasons = 10	Not Completed = 12 Total from all reasons = 12	Not Completed = 11 Total from all reasons = 11	Not Completed = 17 Total from all reasons = 17	

[1] number randomized and dosed
[2] number randomized and dosed
[3] number randomized and dosed
[4] number randomized and dosed
[5] number randomized and dosed
[6] number randomized and dosed

Baseline Characteristics

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years	Total
▼ Arm/Group Description	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for	

	subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	13 doses.	every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	a total of 13 doses.	every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	a total of 13 doses.	
Overall Number of Baseline Participants	86	84	86	86	88	87	**517**
▼ Baseline Analysis Population Description [Not specified]							
Age, Continuous Mean (Standard Deviation) Units: years	38.2 (9.78)	37.8 (7.98)	36.8 (8.76)	36.2 (9.30)	36.2 (9.03)	36.0 (7.60)	36.9 (8.77)
Age, Customized Measure Type: Number Units: participants							
18 to 19 years	0	0	0	0	1	1	2
20 to 29 years	19	13	19	25	20	16	112
30 to 39 years	26	37	29	28	35	41	196
40 to 49 years	29	28	33	27	24	25	166
50 to 55 years	11	6	5	6	7	3	38
> 55 years	1	0	0	0	1	1	3
Gender, Male/Female Measure Type: Number Units: participants							
Female	53	54	59	53	59	48	326
Male	33	30	27	33	29	39	191

Outcome Measures

1. Primary Outcome

Title:	Number of Participants With Treatment-emergent Adverse Events (AEs)
▼ Description:	Treatment-emergent AE: any untoward medical occurrence after the first dose of study treatment that did not necessarily have a causal relationship with this treatment. Serious AE (SAE): any untoward medical occurrence that at any dose: resulted in death; in the view of the Investigator, placed the subject at immediate risk of death (a life-threatening event); required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity; resulted in a congenital anomaly/birth defect. An SAE could also have been a medically significant event that, in the opinion of the Investigator, jeopardized the subject or required intervention to prevent one of the other outcomes listed in the definition above.
Time Frame:	Up to 72 weeks
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Safety population: all randomized participants who received study treatment. Participants who discontinued study treatment due to an AE and/or withdrew from the study due to an AE that started prior to 205MS202 (NCT00870740) and that was treatment-emergent under 205MS201 (NCT00390221) are included in this summary.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who previously received	Participants who previously received	Participants who previously received DAC	Participants who previously received DAC	Participants who previously received DAC	Participants who previously received DAC

	placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	86	84	86	86	88	87
Measure Type: Number Units: participants						
Participants with an AE	61	57	70	57	61	62
Participants with a moderate or severe AE	37	33	45	41	35	35
Participants with a severe AE	1	3	3	2	4	4
Participants with a possibly/definitely related AE	18	12	24	13	22	22
Participants with an SAE	15	11	18	15	15	11

2. Primary Outcome

Title:	Number of Participants With Abnormalities in Vital Signs
▼ Description:	For participants who took DAC HYP during 205MS201 (NCT00390221) the baseline is defined as the baseline from 205MS201, and for participants who took placebo during 205MS201 the baseline is defined as the baseline from 205MS202 (NCT00870740). All post-baseline data are taken after first dose in 205MS202 only. SBP=systolic blood pressure; DBP=diastolic blood pressure; bpm=beats per minute; ↑ BL=increase from baseline; ↓ BL=decrease from baseline.
Time Frame:	Up to Week 72
Safety Issue?	No

Outcome Measure Data

▼ Analysis Population Description

Safety population: all randomized participants who received study treatment; n=number of subjects who had a baseline assessment and at least one post-baseline assessment for that vital sign.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	86	84	86	86	88	87
Measure Type: Number Units: participants						
SBP >180 mmHg w/>40 mmHg ↑ BL; n=86,84,85,85,88,87	0	0	0	0	0	0
SBP <90 mmHg w/>30 mmHg ↓ BL; n=86,84,85,85,88,87	1	1	0	0	1	0
DBP >120 mmHg w/>20 mmHg ↑ BL; n=86,84,85,85,88,87	0	0	0	0	0	0
DBP <50 mmHg w/>20 mmHg ↓ BL; n=86,84,85,85,88,87	1	0	0	0	0	0
Pulse >120 bpm w/>20 bpm ↑ BL; n=86,84,85,85,88,87	0	0	0	0	0	0
Pulse <50 bpm w/>20 bpm ↓ BL; n=86,84,85,85,88,87	0	1	1	1	1	0
Temperature >38C w/≥1C ↑ BL; n=86,84,85,84,88,87	0	0	0	0	0	0

3. Primary Outcome

Title:	Number of Participants With Potentially Clinically Significant Hematology Laboratory Abnormalities

Description:	Hematology parameters evaluated include: white blood cells, lymphocytes, neutrophils, red blood cells (RBC), hemoglobin, and platelets.
Time Frame:	Up to 72 Weeks
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Number of participants in the safety population (all randomized participants who received study treatment) with at least one post-baseline value.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	85	84	85	85	88	87
Measure Type: Number Units: participants						
White Blood Cell Count <3.0*10^9 cells/L	0	3	3	4	3	2
White Blood Cell Count ≥16.0*10^9 cells/L	4	2	1	1	3	1
Lymphocytes <0.8*10^9 cells/L	5	4	6	3	2	5
Lymphocytes <0.5*10^9 cells/L	1	0	1	1	1	0
Lymphocytes >12*10^9 cells/L	0	0	0	0	0	0
Neutrophils ≤1.0*10^9 cells/L	0	0	1	0	0	1
Neutrophils <1.5*10^9 cells/L	0	4	2	2	5	2
Neutrophils ≥12*10^9 cells/L	4	3	2	1	4	2
RBC Count ≤3.3*10^12 cells/L	0	0	0	0	0	0
RBC Count ≥6.8*10^12 cells/L	0	0	0	0	0	0
Hemoglobin ≤100 g/L	1	5	3	3	3	3
Platelet Count ≤100*10^9 cells/L	0	0	0	0	0	1
Platelet Count ≥600*10^9 cells/L	0	2	1	0	1	0

4. Primary Outcome

Title:	Number of Participants With Abnormalities in Blood Chemistry Laboratory Data
Description:	For each abnormality a subject can be counted once. If a subject has more than one occurrence of the same abnormality the highest toxicity grade is counted. ALT=alanine aminotransferase; AST=aspartate aminotransferase; ALP=alkaline phosphatase; GGT=gamma-glutamyl transferase; TSH=thyroid stimulating hormone, ULN=upper limit of normal.
Time Frame:	Up to 72 Weeks
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Safety Population: all randomized participants who received study treatment; n=number of participants whose baseline value for 205MS202 (NCT00870740) was normal (i.e. not high or low) and who had at least one post-baseline value during the study.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	86	84	86	86	88	87
Measure Type: Number Units: participants						
ALT ≤ULN; n=84,81,78,81,83,79	65	62	61	62	60	55
ALT >1 to <3 ULN; n=84,81,78,81,83,79	18	17	16	19	20	20
ALT 3 to 5 ULN; n=84,81,78,81,83,79	0	1	0	0	0	3
ALT >5 to 10 ULN; n=84,81,78,81,83,79	1	1	1	0	2	0
ALT >10 to 20 ULN; n=84,81,78,81,83,79	0	0	0	0	1	1
ALT >20 ULN; n=84,81,78,81,83,79	0	0	0	0	0	0
AST ≤ULN; n=85,81,81,84,85,84	72	66	71	63	68	62
AST >1 to <3 ULN; n=85,81,81,84,85,84	13	14	9	20	14	18
AST 3 to 5 ULN; n=85,81,81,84,85,84	0	1	1	1	2	2
AST >5 to 10 ULN; n=85,81,81,84,85,84	0	0	0	0	0	2
AST >10 to 20 ULN; n=85,81,81,84,85,84	0	0	0	0	0	0

AST >20 ULN; n=85,81,81,84,85,84	0	0	0	0	1	0
ALP ≤ULN; n=84,84,84,84,86,86	76	83	80	80	81	82
ALP >1 to 2.5 ULN; n=84,84,84,84,86,86	8	1	4	4	5	4
ALP >2.5 to 5 ULN; n=84,84,84,84,86,86	0	0	0	0	0	0
ALP >5 to 20 ULN; n=84,84,84,84,86,86	0	0	0	0	0	0
ALP >20 ULN; n=84,84,84,84,86,86	0	0	0	0	0	0
GGT ≤ULN; n=81,79,81,82,84,82	74	71	74	74	73	73
GGT >1 to 2.5 ULN; n=81,79,81,82,84,82	5	8	5	6	8	9
GGT >2.5 to 5 ULN; n=81,79,81,82,84,82	2	0	2	2	2	0
GGT >5 to 20 ULN; n=81,79,81,82,84,82	0	0	0	0	1	0
GGT >20 ULN; n=81,79,81,82,84,82	0	0	0	0	0	0
Total Bilirubin ≤ULN; n=81,79,83,81,85,80	74	73	81	76	78	75
Total Bilirubin >1 to 1.5 ULN; n=81,79,83,81,85,80	5	6	2	4	4	5
Total Bilirubin >1.5 to 3 ULN; n=81,79,83,81,85,80	2	0	0	1	2	0
Total Bilirubin >3 to 10 ULN; n=81,79,83,81,85,80	0	0	0	0	0	0
Total Bilirubin >10 ULN; n=81,79,83,81,85,80	0	0	0	0	1	0
TSH-3rd Gen Abnormal; n=79,79,74,77,79,79	2	1	2	2	2	2
Free Thyroxine (T4) Abnormal; n=78,80,73,73,80,79	4	4	5	4	4	3
Total Thyroxine (T4) Abnormal; n=76,80,74,72,80,79	3	10	6	4	9	9

5. Primary Outcome

Title:	Number of Participants With Development of Anti-DAC Antibodies (ADAb) and Neutralizing Antibodies (NAb) Post-baseline
▼ Description:	Number of participants positive and negative for ADAb and NAb, based on all post-baseline immunogenicity assessments during treatment period and follow-up. Participants are stratified differently in this Outcome Measure as per the pre-specified statistical analysis plan.
Time Frame:	Up to 72 weeks
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

All participants in the Safety Population (all randomized participants who received study treatment) with a post-baseline ADAb assessment.

Arm/Group Title	Placebo + DAC HYP	DAC HYP + Washout	DAC HYP for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg or 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg or 300 mg SC, respectively, every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 received DAC HYP 150 mg or 300 mg SC, respectively, every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	169	171	170
Measure Type: Number Units: participants			
ADAb Positive	7	21	3
ADAb Negative	162	150	167
NAb Positive	4	4	1
NAb Negative	165	167	169

6. Secondary Outcome

Title:	Adjusted Annualized Relapse Rate
▼ Description:	Relapses are defined as new or recurrent neurological symptoms not associated with fever or infection, lasting at least 24 hours, and accompanied by new objective neurological findings upon examination by the Independent Neurology Evaluation Committee (INEC). Relapse rate is calculated as: (Total number of relapses that occurred during the 205MS202 [NCT00870740] treatment phase divided by the total number of days followed in the treatment phase for 205MS202), multiplied by 365 days. Participants who received an alternative multiple sclerosis (MS) medication during 205MS201 (NCT00390221; Year 1) are not included in the summary of relapses and relapse rate for this study (Year 2). Participants are stratified differently in this Outcome Measure as per the pre-specified statistical analysis plan.
Time Frame:	Up to 72 weeks
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Per-protocol population: all randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 participants for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was 56 days or longer.

Arm/Group Title	Placebo + DAC HYP	DAC HYP + Washout	DAC HYP for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg or 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg or 300 mg SC, respectively, every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 received DAC HYP 150 mg or 300 mg SC, respectively, every 4 weeks for a total of 13 doses.

Number of Participants Analyzed	163	132	129
Number (95% Confidence Interval) Units: relapses per person-years	0.179 (0.123 to 0.261)	0.302 (0.215 to 0.423)	0.165 (0.105 to 0.259)

7. Secondary Outcome

Title:	Estimated Proportion of Participants With a Relapse
▼ Description:	Relapses are defined as new or recurrent neurologic symptoms not associated with fever or infection, lasting at least 24 hours, and accompanied by new objective neurological findings upon examination by the INEC. Estimated using Kaplan-Meier analysis where time to first relapse is calculated from date of first dose in the study to date of first confirmed relapse. Participants who received an alternative MS medication before the first relapse were censored at the time of taking the alternative MS medication.
Time Frame:	Up to 72 weeks
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Per-protocol population: all randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 participants for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was 56 days or longer.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC)	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.

	injection every 4 weeks for a total of 13 doses.		total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	of 13 doses.	of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	
Number of Participants Analyzed	84	79	64	65	68	64
Measure Type: Number Units: proportion of participants	0.186	0.166	0.249	0.160	0.235	0.111

8. Secondary Outcome

Title:	Mean Number of New Gadolinium-enhancing Lesions
▼ Description:	Evaluated by magnetic resonance imaging (MRI) by a central reader. Number of new Gd lesions since the previous scan (the previous scan for Week 20 was Week 52 of study 205MS201 [NCT00390221]). The number of Gd lesions may be imputed using last observation carried forward or using the mean value across all subjects within the treatment group. Baseline visits are not imputed. Participants are stratified differently in this Outcome Measure as per the pre-specified statistical analysis plan.
Time Frame:	Week 20, Week 52
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Per-protocol population: all randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 participants for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was 56 days or longer.

Arm/Group Title	Placebo + DAC HYP	DAC HYP + Washout	DAC HYP for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg or 300 mg SC injection every 4 weeks	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 (NCT00390221) underwent a washout period	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 (NCT00390221) received DAC HYP 150 mg or 300

	for a total of 13 doses.	(placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg or 300 mg SC every 4 weeks for a total of 8 doses.	mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	163	132	129
Mean (Standard Deviation) Units: lesions			
Week 20	0.3 (1.01)	1.1 (2.34)	0.2 (0.51)
Week 52	0.2 (0.80)	0.2 (0.64)	0.2 (1.21)

9. Secondary Outcome

Title:	Mean Number of New or Newly-enlarging T2 Hyperintense Lesions
▼ Description:	Lesions detected on T2-weighted sequences represent a range of histopathology related to MS, including edema, inflammation, demyelination, gliosis, and axon loss. Evaluated by MRI by a central reader. New or newly enlarging T2 lesions since baseline of study 205MS202 (NCT00870740). For post-baseline visits, the number of T2 lesions may be imputed using the mean value across all participants within the treatment group, if the participant has non-missing baseline data. Baseline visits are not imputed. Participants are stratified differently in this Outcome Measure as per the pre-specified statistical analysis plan.
Time Frame:	Baseline, Week 20, Week 52
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Per-protocol population: all randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 participants for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was 56 days or longer.

Arm/Group Title	Placebo + DAC HYP	DAC HYP + Washout	DAC HYP for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg or 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 (NCT00390221) underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg or 300 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg or 300 mg SC injection in study 205MS201 (NCT00390221) received DAC HYP 150 mg or 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants	156	126	128

Analyzed			
Mean (Standard Deviation) Units: lesions			
Baseline	46.0 (36.48)	41.1 (36.36)	39.8 (32.63)
Week 20	1.1 (2.26)	2.6 (6.33)	0.5 (1.28)
Week 52	2.1 (3.68)	3.3 (6.95)	1.2 (4.33)

10. Secondary Outcome

Title:	Mean Volume of New T1 Hypointense Lesions
▼ Description:	T1-weighted scans detect areas of hypointensity that represent a greater degree of tissue destruction and axon loss than T2 hyperintense lesions and are more highly correlated with clinical disability measures and neurological deficit. Evaluated by MRI by a central reader. Baseline is volume of new T1 hypointense lesions since baseline in study 205MS201 (NCT00390221). Scans at Week 20 and Week 52 in 205MS202 are relative to baseline in 205MS202 (NCT00870740). For post-baseline visits, the total volume of T1 lesions may be imputed using the mean value across all subjects within the treatment group. Baseline visits are not imputed.
Time Frame:	Baseline, Week 20, Week 52
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Per-protocol population: randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was ≥ 56 days; n=participants with measurement at given time point.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201	Participants who previously received placebo in study 205MS201	Participants who previously received DAC HYP 150 mg SC injection in study	Participants who previously received DAC HYP 150 mg SC injection in study	Participants who previously received DAC HYP 300 mg SC in study 205MS201	Participants who previously received DAC HYP 300 mg SC in study 205MS201

	(NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	(NCT00390221) received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	205MS201 (NCT00390221) underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	205MS201 (NCT00390221) received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	(NCT00390221) underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	(NCT00390221) received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	84	79	64	65	68	64
Mean (Standard Deviation) Units: mm^3						
Baseline; n=83, 79, 63, 64, 66, 64	232.13 (467.811)	228.90 (390.587)	126.50 (288.580)	94.20 (281.450)	52.26 (184.170)	44.92 (150.363)
Week 20; n=81, 74, 62, 65, 63, 63	36.17 (114.019)	62.76 (143.280)	161.98 (829.086)	6.29 (24.095)	12.37 (32.361)	4.66 (19.386)
Week 52; n=81, 74, 62, 65, 63, 63	88.46 (239.741)	109.42 (231.734)	142.31 (628.500)	17.18 (39.881)	43.60 (88.084)	21.42 (82.566)

11. Secondary Outcome

Title:	Mean Percentage Change From Baseline in Total Lesion Volume of T2 Hyperintense Lesions
▼ Description:	Lesions detected on T2-weighted sequences represent a range of histopathology related to MS, including edema, inflammation, demyelination, gliosis, and axon loss. Evaluated by MRI by a central reader. Baseline values = baseline for study 205MS202 (NCT00870740). For post-baseline visits, the total volume of T2 lesions may be imputed using the mean value across all subjects within the treatment group. Baseline visits are not imputed.
Time Frame:	Baseline, Week 52
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Per-protocol population (with a baseline and post-baseline assessment): randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation)

plus 75 for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was ≥ 56 days.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	Participants who previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	81	75	62	65	64	63
Mean (Standard Deviation) Units: percentage change in volume	-7.75 (21.952)	-8.44 (13.942)	-0.78 (22.243)	-4.90 (25.935)	-5.40 (16.672)	-8.98 (11.673)

12. Secondary Outcome

Title:	Mean Percentage Change From Baseline in Total Volume of Non-gadolinium (Gd)-Enhancing T1 Hypointense Lesions
▼ Description:	T1-weighted scans detect areas of hypointensity that represent a greater degree of tissue destruction and axon loss than T2 hyperintense lesions and are more highly correlated with clinical disability measures and neurological deficit. Evaluated by MRI by a central reader. Baseline values = baseline for study 205MS202 (NCT00870740). For post-baseline visits, the total volume of T1 lesions may be imputed using the mean value across all participants within the treatment group. Baseline visits are not imputed.
Time Frame:	Baseline, Week 52
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Per-protocol population (with a baseline and post-baseline assessment): randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was ≥ 56 days.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who	Participants who	Participants who	Participants who	Participants who	Participants who

	previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	previously received placebo in study 205MS201 received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	81	74	62	65	63	63
Mean (Standard Deviation) Units: percentage change in volume	-3.99 (35.543)	-7.15 (39.932)	-5.51 (49.970)	-13.89 (18.089)	-6.72 (22.721)	-16.59 (17.436)

13. Secondary Outcome

Title:	Rate of Percentage Change From Baseline in Mean Total Brain Volume
▼ Description:	Total brain volume was measured by MRI and analyzed by a central reader. Rate of percentage change from baseline calculated using an analysis of covariance adjusting for baseline normalized brain volume. Baseline values = baseline for study 205MS202 (NCT00870740). Missing values post-baseline were imputed using the average value across subjects in the treatment group.
Time Frame:	Baseline, Week 52
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Per-protocol population (with a baseline and post-baseline assessment): randomized participants who received study treatment, excluding 18 participants from a single site (protocol violation) plus 75 for whom the time between the last dose of study treatment in 205MS201 (NCT00390221) and the first dose in 205MS202 (NCT00870740) was ≥ 56 days.

Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description:	Participants who	Participants who	Participants who	Participants who	Participants who	Participants who

	previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	previously received placebo in study received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	previously received DAC HYP 150 mg SC injection in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.	previously received DAC HYP 150 mg SC injection in study 205MS201 received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	previously received DAC HYP 300 mg SC in study 205MS201 underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	previously received DAC HYP 300 mg SC in study 205MS201 received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.
Number of Participants Analyzed	79	76	61	64	63	62
Number (95% Confidence Interval) Units: rate of percentage change	-0.772 (-0.978 to -0.565)	-0.930 (-1.141 to -0.719)	-0.622 (-0.857 to -0.387)	-0.528 (-0.758 to -0.297)	-0.505 (-0.736 to -0.274)	-0.452 (-0.685 to -0.219)

Adverse Events

Time Frame	Study Entry Week 0 (Baseline; Week 52 Visit from study 205MS201 [NCT00390221]) through Week 72 ± 5 days or early termination.					
Additional Description						
Source Vocabulary Name	MedDRA 16.1					
Assessment Type	Systematic Assessment					
Arm/Group Title	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
▼ Arm/Group Description	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 150 mg subcutaneous (SC) injection every 4 weeks for a total of 13 doses.	Participants who previously received placebo in study 205MS201 (NCT00390221) received DAC HYP 300 mg SC injection every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 (NCT00390221) underwent a washout period (placebo SC every 4 weeks for a total	Participants who previously received DAC HYP 150 mg SC injection in study 205MS201 (NCT00390221) received DAC HYP 150 mg SC every 4 weeks for a total of 13 doses.	Participants who previously received DAC HYP 300 mg SC in study 205MS201 (NCT00390221) underwent a washout period (placebo SC every 4 weeks for a total of 5 doses) and then	Participants who previously received DAC HYP 300 mg SC in study 205MS201 (NCT00390221) received DAC HYP 300 mg SC every 4 weeks for a total of 13 doses.

			of 5 doses) and then received DAC HYP 150 mg SC every 4 weeks for a total of 8 doses.		received DAC HYP 300 mg SC every 4 weeks for a total of 8 doses.	

Serious Adverse Events

	Placebo + DAC HYP 150 mg	Placebo + DAC HYP 300 mg	DAC HYP 150 mg + Washout	DAC HYP 150 mg for 2 Years	DAC HYP 300 mg + Washout	DAC HYP 300 mg for 2 Years
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	15/86 (17.44%)	11/84 (13.1%)	18/86 (20.93%)	15/86 (17.44%)	14/88 (15.91%)	11/87 (12.64%)
Blood and lymphatic system disorders						
Anaemia † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Leukopenia † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Endocrine disorders						
Basedow's disease † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Hyperthyroidism † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Gastrointestinal disorders						
Colitis ulcerative † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
General disorders						
Influenza like illness † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Hepatobiliary disorders						
Autoimmune hepatitis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	1/88 (1.14%)	0/87 (0%)
Chronic hepatitis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Hepatic steatosis † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Jaundice † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	1/88 (1.14%)	0/87 (0%)
Immune system disorders						
Allergy to arthropod sting † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Drug hypersensitivity † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Infections and infestations						
Appendicitis † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Bronchitis † A	1/86 (1.16%)	1/84 (1.19%)	0/86 (0%)	0/86 (0%)	1/88 (1.14%)	0/87 (0%)
Cellulitis † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Infectious mononucleosis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Klebsiella infection † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Lung infection † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Meningitis aseptic † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Mycobacterium abscessus infection † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Pneumonia † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Pyelonephritis chronic † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Sinusitis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Tracheobronchitis † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Upper respiratory tract	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	1/88 (1.14%)	0/87 (0%)

infection bacterial † A						
Injury, poisoning and procedural complications						
Joint dislocation † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Musculoskeletal and connective tissue disorders						
Back pain † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Breast cancer † A	0/86 (0%)	1/84 (1.19%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Nervous system disorders						
Demyelination † A	0/86 (0%)	1/84 (1.19%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Haemorrhagic stroke † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Ischaemic neuropathy † A	0/86 (0%)	1/84 (1.19%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Multiple sclerosis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Multiple sclerosis relapse † A	9/86 (10.47%)	7/84 (8.33%)	12/86 (13.95%)	9/86 (10.47%)	12/88 (13.64%)	5/87 (5.75%)
Pregnancy, puerperium and perinatal conditions						
Abortion spontaneous † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	1/86 (1.16%)	0/88 (0%)	0/87 (0%)
Psychiatric disorders						
Mental disorder due to a general medical condition † A	0/86 (0%)	1/84 (1.19%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Renal and urinary disorders						
Glomerulonephritis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Mesangioproliferative glomerulonephritis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Nephrotic syndrome † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Reproductive system and breast disorders						
Adenomyosis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Breast inflammation † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Endometriosis † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Uterine haemorrhage † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Respiratory, thoracic and mediastinal disorders						
Pulmonary embolism † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	1/88 (1.14%)	0/87 (0%)
Pulmonary granuloma † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Skin and subcutaneous tissue disorders						
Dermatitis exfoliative † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)

Drug eruption † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Eczema † A	1/86 (1.16%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Pityriasis rubra pilaris † A	0/86 (0%)	0/84 (0%)	1/86 (1.16%)	0/86 (0%)	0/88 (0%)	0/87 (0%)
Urticaria † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	0/88 (0%)	1/87 (1.15%)
Vascular disorders						
Deep vein thrombosis † A	0/86 (0%)	0/84 (0%)	0/86 (0%)	0/86 (0%)	1/88 (1.14%)	0/87 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 16.1

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%					
	Placebo + DAC HYP 150 mg	**Placebo + DAC HYP 300 mg**	**DAC HYP 150 mg + Washout**	**DAC HYP 150 mg for 2 Years**	**DAC HYP 300 mg + Washout**	**DAC HYP 300 mg for 2 Years**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	43/86 (50%)	37/84 (44.05%)	47/86 (54.65%)	38/86 (44.19%)	45/88 (51.14%)	43/87 (49.43%)
Gastrointestinal disorders						
Diarrhoea † A	4/86 (4.65%)	4/84 (4.76%)	1/86 (1.16%)	5/86 (5.81%)	2/88 (2.27%)	1/87 (1.15%)
General disorders						
Fatigue † A	5/86 (5.81%)	1/84 (1.19%)	2/86 (2.33%)	3/86 (3.49%)	4/88 (4.55%)	3/87 (3.45%)
Pyrexia † A	2/86 (2.33%)	1/84 (1.19%)	2/86 (2.33%)	1/86 (1.16%)	6/88 (6.82%)	5/87 (5.75%)
Infections and infestations						
Nasopharyngitis † A	12/86 (13.95%)	8/84 (9.52%)	11/86 (12.79%)	10/86 (11.63%)	10/88 (11.36%)	15/87 (17.24%)
Oral herpes † A	5/86 (5.81%)	1/84 (1.19%)	6/86 (6.98%)	1/86 (1.16%)	6/88 (6.82%)	2/87 (2.3%)
Pharyngitis † A	5/86 (5.81%)	3/84 (3.57%)	4/86 (4.65%)	5/86 (5.81%)	2/88 (2.27%)	5/87 (5.75%)
Respiratory tract infection viral † A	3/86 (3.49%)	3/84 (3.57%)	5/86 (5.81%)	1/86 (1.16%)	4/88 (4.55%)	2/87 (2.3%)
Upper respiratory tract infection † A	6/86 (6.98%)	4/84 (4.76%)	7/86 (8.14%)	9/86 (10.47%)	6/88 (6.82%)	7/87 (8.05%)
Investigations						
Alanine aminotransferase increased † A	2/86 (2.33%)	2/84 (2.38%)	3/86 (3.49%)	4/86 (4.65%)	3/88 (3.41%)	5/87 (5.75%)
Musculoskeletal and connective tissue disorders						
Back pain † A	1/86 (1.16%)	7/84 (8.33%)	2/86 (2.33%)	2/86 (2.33%)	2/88 (2.27%)	3/87 (3.45%)
Nervous system disorders						
Headache † A	5/86 (5.81%)	4/84 (4.76%)	5/86 (5.81%)	4/86 (4.65%)	8/88 (9.09%)	6/87 (6.9%)
Multiple sclerosis relapse † A	16/86 (18.6%)	13/84 (15.48%)	25/86 (29.07%)	13/86 (15.12%)	17/88 (19.32%)	13/87 (14.94%)
Skin and subcutaneous tissue disorders						
Rash † A	3/86 (3.49%)	5/84 (5.95%)	5/86 (5.81%)	4/86 (4.65%)	3/88 (3.41%)	5/87 (5.75%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 16.1

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Our agreement is subject to confidentiality but generally the PI can publish, for noncommercial purposes only, results and methods of the trial, but no other Sponsor Confidential Information. PI must give Sponsor no less than 60 days to review any manuscript for a proposed publication and must delay publication for up to an additional 90 days thereafter if Sponsor needs to file any patent application to protect any of Sponsor's intellectual property contained in the proposed publication.

Results Point of Contact

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