#### **CLINICAL REVIEW**

Application Type NDA **Application Number** 204063 Priority or Standard Standard

Submit Date 2-27-2012 Received Date 2-27-2012 PDUFA Goal Date 3-27-2013

Division / Office DNP/OND 1/ ODE 1

Reviewer Name Heather Fitter, M.D. Review Completion Date 11-08-2012

Established Name BG00012 (BG-12)

(Proposed) Trade Name Tecfidera

Therapeutic Class Dimethyl Fumarate

Applicant Biogen Idec

Formulation Oral

Dosing Regimen 240 mg bid

Indication

Relapsing forms of Multiple Intended Population

Sclerosis

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## **Table of Contents**

1	RE	COMMENDATIONS/RISK BENEFIT ASSESSMENT	7
	1.1 1.2 1.3 1.4	Recommendation on Regulatory Action	8 9
2	INT	RODUCTION AND REGULATORY BACKGROUND	9
	2.1 2.2 2.3 2.4 2.5	Product Information	10 13 13
3	ET	HICS AND GOOD CLINICAL PRACTICES	16
	3.1 3.2 3.3	Submission Quality and Integrity  Compliance with Good Clinical Practices  Financial Disclosures	17
4		SNIFICANT EFFICACY/SAFETY ISSUES RELATED TO OTHER REVIEW SCIPLINES	20
	4.3	Chemistry Manufacturing and Controls Preclinical Pharmacology/Toxicology Clinical Pharmacology 3.1 Mechanism of Action 3.2 Pharmacodynamics 3.3 Pharmacokinetics	21 23 23 23
5	so	URCES OF CLINICAL DATA	25
	5.2 F 5.3 E 5.3 5.3	Tables of Studies/Clinical Trials  Review Strategy Discussion of Individual Clinical Trials  3.1 Protocol C-1900 5.3.1.1. Efficacy Results Trial C-1900 5.3.1.1.1 Trial Population 5.3.1.1.2 Efficacy Analysis 3.2 Protocol 109MS301 5.3.2.1 Efficacy Results Trial 301 5.3.2.1.1 Trial Population 5.3.2.1.2 Efficacy Analysis	26 26 .27 .27 .28 30 .48
		3.3 Protocol 109MS302	64
	ţ	5.3.3.1 Efficacy Results Trial 302	.70

Clinical Review Heather Fitter, M.D. NDA 204063 BG-12

	5.3.4 Protocol 109MS303	87
	5.3.4.1. Efficacy Results Trial 303	88
	5.3.4.1.1 Trial Population	
	5.3.4.1.2 Efficacy Analysis	
6	REVIEW OF EFFICACY	90
	6.1 Indication	90
	6.1.1 Methods	90
	6.1.2 Demographics	90
	6.1.3 Subject Disposition	
	6.1.4 Analysis of Primary Endpoints	
	6.1.5 Analysis of Secondary Endpoints	
	6.1.5.1 Number of New or Newly Enlarging T2 Hyperintense Lesions	
	6.1.5.2 Number of Gd-enhancing lesions at 2 years	96
	6.1.5.3 New T1 hypointense lesions	
	6.1.5.4 Annualized relapse rate/proportion relapsing	
	6.1.5.5 Disability progression	
	6.1.6 Other Endpoints	
	6.1.7 Subpopulations	
	6.1.8 Analysis of Clinical Information Relevant to Dosing Recommendations .	
	6.1.9 Discussion of Persistence of Efficacy and/or Tolerance Effects	
	6.1.10 Discussion of the Presence of Withdrawal Effects	
	6.1.11 Additional Efficacy Issues/Analyses	108
7	REVIEW OF SAFETY	113
8	POSTMARKET EXPERIENCE	113
9	. APPENDICES	113
	9.1 Labeling Recommendations	113
	9.2 Advisory Committee Meeting	



Clinical Review Heather Fitter, M.D. NDA 204063 BG-12

## **Table of Tables**

Table 1: Table of currently available treatments for proposed indications	11
Table 2: Financial disclosure trial 301, earnings over \$100,000 and enrollmen	
Table 3: Financial disclosure trial 302, earnings over \$100,000 and enrollmen	
subjects, with one exception	20
Table 4: List of BG-12 trials that contributed to efficacy analysis	
Table 5: Study C-1900 summary of key efficacy results (efficacy evaluable po	
T.I. O.I. I	29
Table 6: Laboratory criteria requiring withholding or permanent discontinuation	
blinded study treatment	
Table 7: Blinded study treatment dosing regimen	
Table 8: Trial 301 study activities, visit 1-12, chart 1/3	
Table 9: Trial 301 study activities: visits 13-25, chart 2/3	
Table 10: Trial 301 study activities with premature study withdrawal visit and	
unscheduled relapse visit, chart 3/3	
Table 11: Disposition of subjects in trial 301	
Table 12: Summary of number of subjects and reasons for exclusion from the	
protocol population (trial 301)	
Table 13: Baseline MRI evaluation- MRI cohort Trial 301	
Table 14: Summary of the proportion of subjects relapsed (INEC confirmed re	
2 years -ITT	52
Table 15: Summary of proportion of subjects relapsed (INEC confirmed) at 2	
sensitivity analysis reassigning status of patients that reported an u	
1 1	53
Table 16: Results of sensitivity analyses of the primary endpoint (trial 301)	
Table 17: Number of new or newly enlarging T2 lesions at 2 years compared	
baseline-MRI cohort (trial 301)	
Table 18: Number of Gd enhancing lesions at 2 years-MRI cohort (trial 301).	
Table 19: Summary of ARR (INEC confirmed) at 2 years- ITT population	
Table 20: Summary of time to confirmed progression of disability as measure	
increase in EDSS (12 week confirmation)-ITT (trial 301)	
Table 21: Change of MSFC z score from baseline to 2 years- ITT (trial 301) .	59
Table 22: MSFC: Change of actual scores from baseline to 2 years- ITT population	
301)	
Table 23: Subgroup analyses (trial 301)	
Table 24: Key demographic and baseline characteristics- MRI cohort and nor	
cohort (trial 302)	
Table 25: Summary of ARR (INEC confirmed) at 2 years-ITT (trial 302)	
Table 26: MRI: Number of new or newly enlarging T2 lesions at 2 years comp	
baseline- MRI cohort (trial 302)	77
Table 27: Number of new T1 hypointense lesions at 2 years compared to bas	seline- MRI
cohort (trial 302)	
Table 28: Summary of time to confirmed disability progression at 2 years-pe	
population (trial 302)	81

Clinical Review Heather Fitter, M.D. NDA 204063 BG-12

_	
	MSFC: Change of raw scores from baseline to 2 years- ITT (trial 302)82
Table 30.	ARR with 95% CI for subjects randomized to placebo then active study treatment (trial 303)
Table 21:	treatment (trial 303)
Table 31.	groups91
Tahla 32:	Trial subject disposition
	Efficacy results of ARR and proportion relapsing- ITT (trials 301 and 302) 94
	Number of new and newly enlarging T2 hyperintense lesions at 2 years
Table 04.	compared to baseline (trial 301 and 302)96
Table 35	Number of Gd enhancing lesions at 2 years- MRI cohort (trials 301, 302) 97
	Number of new T1 hypointense lesions over 2 years- MRI cohort (trial 301
	and 302)
Table 37:	Disability progression in trial 301, 302 and pooled analysis
	Summary of ARR (INEC confirmed) at 2 years by EDSS score (trials 301 and
	302 pooled)
Table 39:	Summary of proportion of subjects relapsed (INEC confirmed) at 2 years by
	region- ITT (trial 301)
	Summary of ARR (INEC confirmed) at 2 years by region- ITT (trial 302) 105
Table 41:	Estimated proportion of relapsing patients based on the presence of the
T 11 40	adverse event of flushing (trial 301)
Table 42:	Estimated ARR based on the presence of the adverse event of flushing (trial
Tabla 40.	302)
Table 43:	Summary of proportion of subjects relapsed (INEC confirmed) at 2 years by
Tabla 44:	dose reduction/interruption status (trial 301)
i abie 44.	Summary of ARR (INCEC confirmed) at 2 years by dose reduction/interruption status (trial 302)
Tahle 45	Summary of the proportion of subjects relapsed (INEC confirmed) at 2 years
Table 40.	by the presence of minimum post baseline lymphocyte count <lln (trial="" 301)<="" td=""></lln>
Table 46:	Summary of ARR (INEC confirmed) at 2 years by the presence of minimum
	post baseline lymphocyte count <lln (trial="" 302)<="" td=""></lln>



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