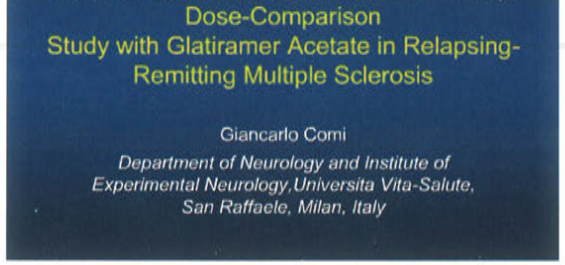
1.



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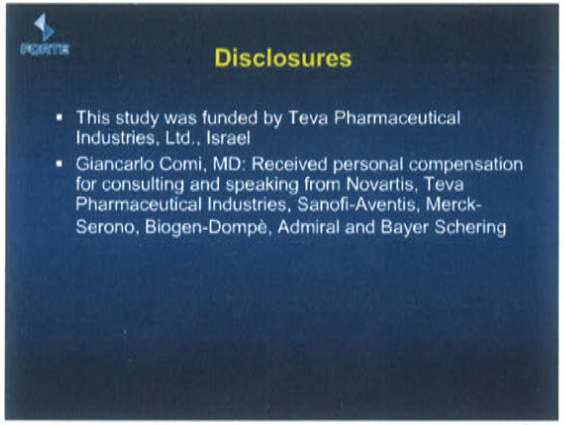

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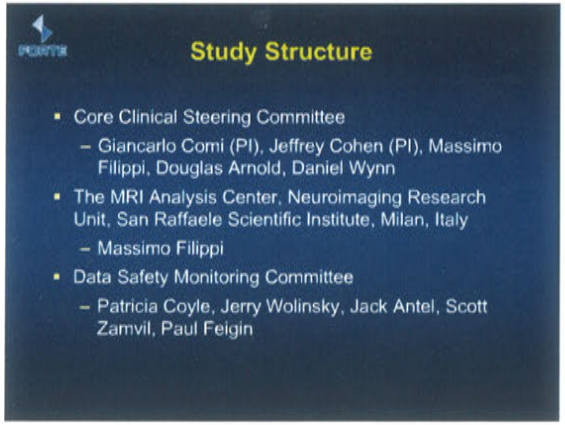

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Ashley Soevyn, CSR No. 1201
Date 10/22/
Witness: GREE

[1] Available from;
http://www.multiwebcast.com/wctrims/2008/msmontreal/2448/chair.giancarlo.comi.results.from.a.phase.iii.one-year.randomized.double-blind.html

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4.

L Velkova. *Spain*: A. Rodriguez -Antiguedad, T. Arbizu, R. Arroyo, J. Barcena, B. Casanova, O. Fernández, X. Montalban, L. Rami ó, A. Saiz -Hinarejos,; *UK*: B. Sharrack, E. Silber, C. Young; *USA*: M. Agius, G. Birnbaum, D. Campagnolo, K. Chaudhary, J. Cohen, C. Ford, E. Fox, A. Goodman, B. Green, A.Gupta, B. Hughes, A. Javed , D. Jeffery, L. Kasper, M. Kaufman, O. Khan, K. Kresa-Reahl, T. Leist, S. Lynch, C. Markowitz, D. Mattson, H. Moses, B. Parks, G. Parry, T. Phillips, M. Picone, K. Rammohan, S. Rizvi, W. Royal, S. Scarberry, C. Sheppard, V. Simnad, B. Thrower, R. Whitham, D.Wynn

5.

Background

- Three pivotal trials support the efficacy, tolerability, and safety of GA 20 mg dosing in RRMS patients
- Results from a phase II study showed that 40mg dose of glatiramer acetate (GA) was possibly more effective than the currently approved 20mg dose in reducing MRI activity and clinical relapses

6.

Study Objectives

A Multinational, Multicenter, Randomized, Parallel -Group, Double-Blind Study, to Compare the Efficacy, Tolerability and Safety of Glatiramer Acetate Injection 40 mg/ml to that of Glatiramer Acetate Injection 20 mg/ml Administered Once Daily by Subcutaneous Injection in Subjects with Relapsing Remitting (R-R) Multiple Sclerosis (MS)

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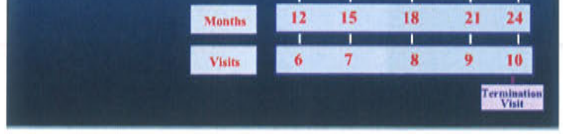

8.

Main Inclusion Criteria

- RRMS patients (revised McDonald criteria 2005)
- Age 18-55, inclusive
- EDSS score of 0-5
- Subjects must have experienced one of the following:
  - At least one documented relapse in the 12 months prior to screening, or
  - At least two documented relapses in the 24 months prior to screening, or
  - One documented relapse between 12 and 24 months prior to screening with at least one documented T1-Gd enhancing lesion in an MRI performed within 12 months prior to screening

9.

Main Exclusion Criteria

- Previous treatment with immunomodulators within the last 2 months
- Previous treatment with immunosuppressive treatments within the last 6 months
- Previous use of GA
- Previous use of Natalizumab
- Relapse or steroid treatment within 30 days prior to screening
- Pregnancy or breastfeeding

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rate by 30% to 0.49

- Treatment with GA 40mg/day will further reduce annual relapse rate by 30%, compared to GA 20 mg/day to 0.343 relapses per year

10.

Primary Endpoint

The rate of confirmed relapses observed during the double-blind phase

Analysis methodology:

- Baseline-adjusted, quasi-likelihood (over dispersed) Poisson regression
- Covariates:
  - Baseline EDSS score
  - log of the prior 2-year number of relapses (+1)
  - Center/Country

11.

Secondary Endpoints

- Cumulative number of T1-Gd enhancing lesions at months 3, 6, 9 and 12 (Frequent MRI Cohort)
- Number of new T2 lesions at month 12 compared to baseline scan

12.

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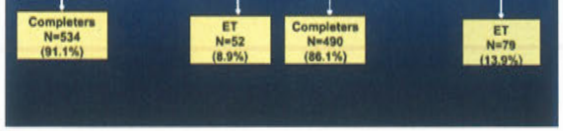

14.

Early Termination Reasons

	GA 20mg		GA 40mg	
	Number	Percent	Number	Percent
All	52	8.9%	79	13.9%
Adverse Events	28	4.8%	51	9.0%*
Subject Withdrew Consent	10	1.7%	12	2.1%
Failed to Return/Lost to Follow up	6	1.0%	5	0.9%
Request of Investigator	3	0.5%	6	1.1%
Pregnancy	3	0.5%	2	0.4%
Sponsor's Decision	1	0.2%	1	0.2%
Non-Compliance	1	0.2%	1	0.2%
Death	.	.	1**	0.2%

* Statistically significant compared to GA 20mg. The difference is mainly due to Injection Site Reactions
** Due to a motorcycle accident

15.

Baseline Characteristics

	GA 20 mg N=586	GA 40mg N=569
Age (years)	36.3 ± 9.0	36.3 ± 9.0
Gender (female)	71.8%	71.5%
Time from 1st Symptom (years)	6.3 ± 6.5	6.5 ± 6.7
Time from Diagnosis (years)	3.0 ± 4.0	3.3 ± 4.8
Number of relapses in the previous year	1.5 ± 0.7	1.4 ± 0.7
Number of relapses in the previous 2 years	2.0 ± 1.0	2.0 ± 1.0
Number of T1 Gd-Enhancing lesions	2.2 ± 6.9	2.2 ± 4.8
Volume of T2 lesions (ml)	9.7 ± 12.4	9.8 ± 10.4
Converted EDSS score	2.2 ± 1.2	2.1 ± 1.1

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