

OPEXA THERAPEUTICS

Corporate Presentation
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Neil K. Warma
President & CEO

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Opexa: Leading in Development of Novel Cell Therapy Treatments

- **Tovaxin®**: entering phase III planning as first line treatment for Multiple Sclerosis
  - Phase IIb completed Aug. '08
- **Efficacy** : Exceeds most marketed therapies
  - Annualized relapse rate of 0.2 : lowest of most drugs currently on market
- **Safety** : setting new standards
  - No SAEs observed in three clinical trials
- **Compliance** : improved
  - 5 subcutaneous injections per year
- **Maximizes patient benefit** : therapy is tailored to each patient's disease profile

What is the urgency in MS? Where is the unmet need?

Based on comments from physicians and patients

- Safety
  - Side effects have plagued MS patients for years, e.g. recent PML cases
  - >50% patients are non-compliant after 2 years of treatment

- Administration
  - Cumbersome treatment (daily, 3X/wk injections, infusions)
  - Significant reason for non-compliance

- Efficacy
  - Still much room for improvement, many drugs demonstrate only moderate efficacy
  - Many treatments symptomatic, not attacking root cause of disease

Competitive Advantage of Tovaxin

Therapy	ARR	Safety	Admin	Revenues (2007)*
TOVAXIN*	.28	No SAEs to date Injection site Rx (25%)	5x/yr (SC)	N/A
Avonex**	.67	Flu symptoms (49%) Headache (58%)	Weekly (IM)	$1.86B
Betaseron**	.90	Flu symptoms (60%) Headache (57%)	Every other day (SC)	$1.11B
Copaxone**	.86	Inj. site Rx (66%) Infection (50%)	Daily (SC)	$1.67B
Rebif**	.86	Flu symptoms (56%) Headache (65%)	3x/wk (SC)	$1.46B
Tysabri**	.22	Infusion Rxns (22%) Infections (18%) Headache (35%) Deaths (PML)	1x/mo (IV)	191M

* Phase IIb data based on prospective analysis of patients with greater disease activity (ARR>1 at study entry)

** Source: package inserts

* Datamonitor report

TERMS Phase IIb Highlights

- **Clinical endpoints:** Favors Tovaxin
  - Tovaxin ARR lowest of any marketed or development therapy
  - (0.28 relapses/patient/year); 55% reduction over placebo

- **Disability Score :** Favors Tovaxin
  - Reduction in disability (EDSS) score with Tovaxin (p=0.045).
  - 28% of Tovaxin patients improved EDSS compared to 5% for placebo.

- **MRI data** : Favors Tovaxin
  - 88% reduction in brain atrophy favoring Tovaxin

- **Immunological & Epitope Data** : Favors Tovaxin
  - Tovaxin patients exhibit less myelin peptide reactivity, fewer driver clones, lower risk of relapse

- **Safety** : Favors Tovaxin
  - No SAEs related to Tovaxin treatment, mild to moderate injection site reactions only

MS Demographics

Region	Prevalence
USA	400,000
EU	350,000
Japan	10,000
Worldwide	**2,500,000**

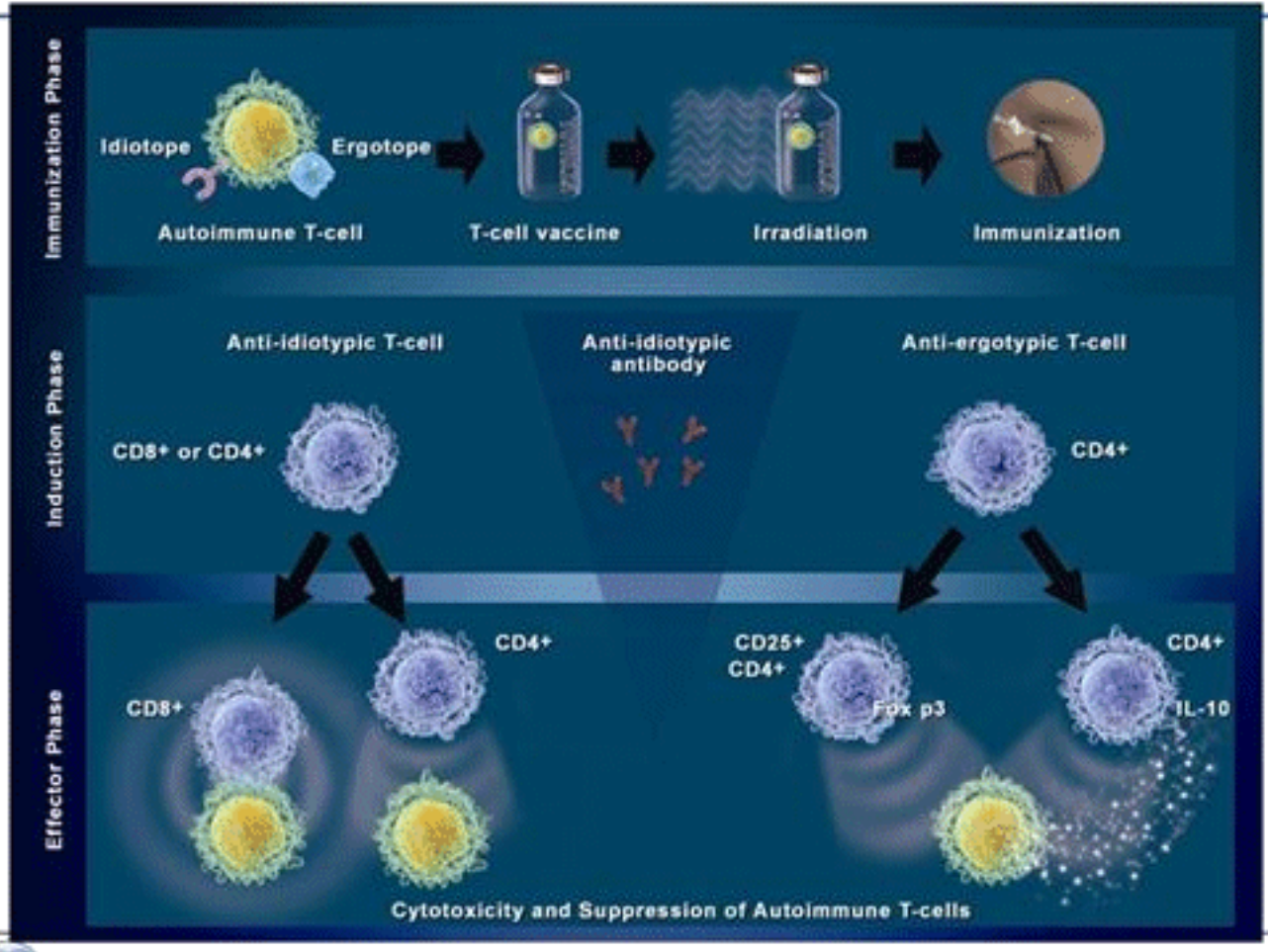
- Two-thirds of all cases occur in women
- Diagnosis occurs most often between the ages of 20-50
- Sales of MS drugs
  - Treatment cost : $20,000 - $28,000/patient/year
  - 2006 global sales: **$6 billion**

Tovaxin: T-Cell therapy for MS

Tovaxin: Description

- **Tovaxin is an autologous attenuated whole T-cell vaccine tailored to each patient's disease profile**
  - Manufactured by selecting Myelin Reactive T-Cells (MRTC) from a patient's blood and expanding the cells *ex-vivo* to a therapeutic dose
  - Reintroduction of attenuated T-cells via subcutaneous inoculation induces immune response against the MRTCs, triggering immune system to attack the pathogenic T-cells in the body.
- **Dual mechanism of action**
  - Anti-idiotypic response: results in depletion of Myelin Reactive T-cells
  - Anti-ergotypic response : restores immune regulatory balance
- **Tovaxin induces the depletion of circulating MRTC**
  - Does not eliminate or suppress other T-cells that are important for the proper functioning of the immune system
- **Tovaxin induces the restoration of immune regulatory balance**
  - Induction of Tregs suppresses function of autoreactive T cells

Tovaxin – Dual Mechanism of Action



Tovaxin: TERMS Phase IIB topline results

TERMS Study

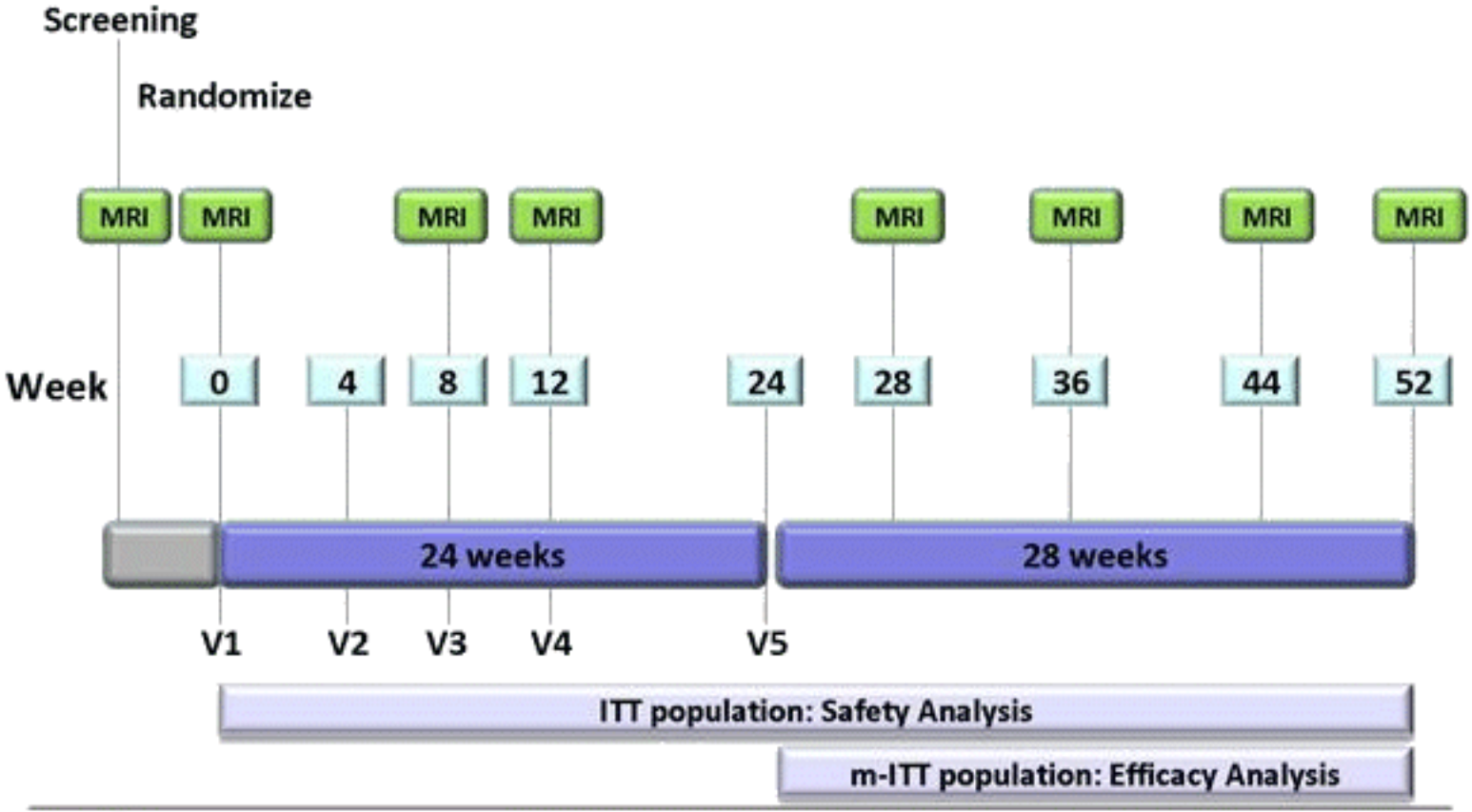
Study Design	Multi-center, randomized, double blind, placebo controlled trial in patients suffering from CIS or RRMS over 52 weeks in 33 sites in the U.S.
No. Patients	150 subjects with 2:1 randomization (100 Tovaxin:50 Placebo)
Treatment Regimen	Five sc injections of Tovaxin, 30-45x10^6 total cells in in 2ml dosage; administered 0, 4, 8, 12, and 24 weeks
Power	80% powered to show 50% reduction in cumulative Gad lesions

TERMS Endpoints

- **Primary endpoints:**
  - Cumulative number of gadolinium-enhancing lesions on T1-weighted brain MRI summed over the week 28, 36, 44, and 52 MRIs
  - Safety

- **Secondary endpoints:**
  - Annualized relapse rate at endpoint
  - Cumulative number of new gadolinium-enhancing lesions over weeks 28, 36, 44 and 52 MRIs
  - Change in T2-weighted lesion volume at 52 weeks

TERMS Study Design

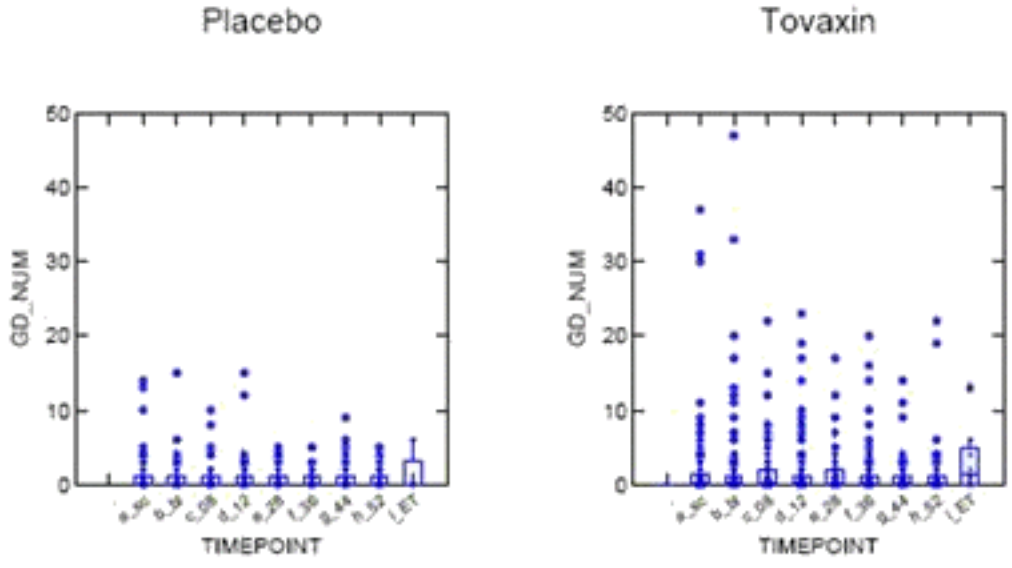


TERMS - Demographics Full ITT set

Baseline characteristics (n=150)

Characteristic	Tovaxin	Placebo
Total patients	100	50
Male	21%	30%
Female	79%	70%
Age (mean)	39.6	37.7
CIS	5%	6%
RRMS	95%	94%
MRI Gd+	39%	40%
MRI Gd-	61%	60%
Baseline MRI Gd+ lesions	2.3	1.0

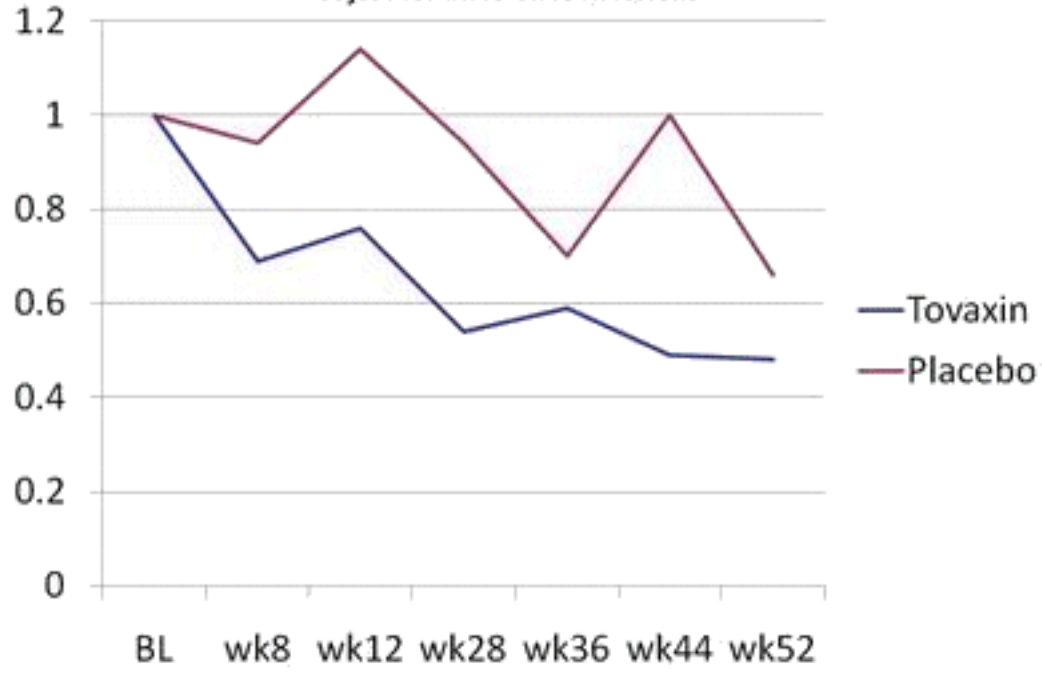
Randomization at Baseline



- Higher lesion count and lesion volume in Tovaxin arm at baseline compared to placebo
- As a result patients in placebo arm had much lighter severity of disease and disease burden as compared to patients in treatment arm

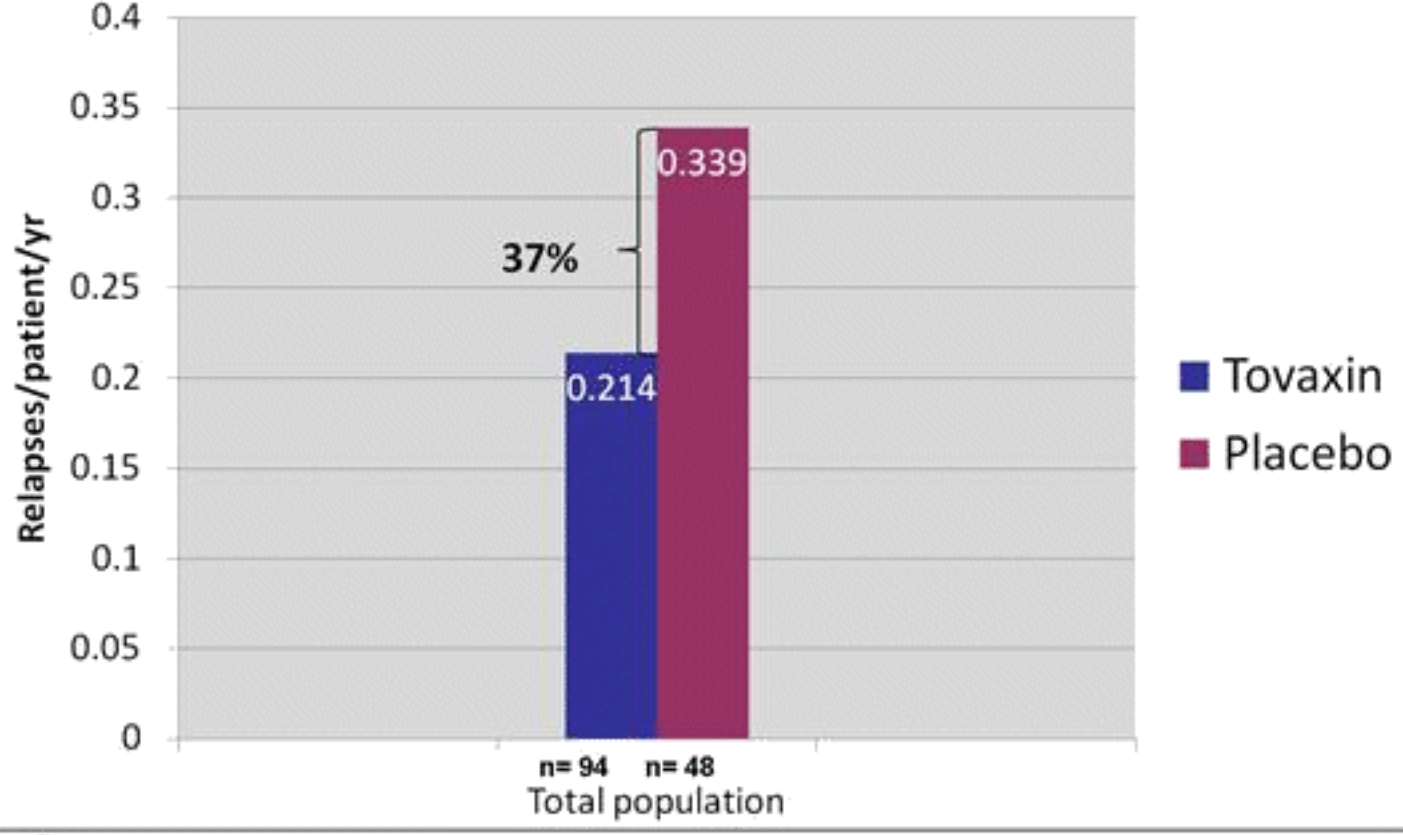
Study Results (mITT population n=132)

Primary endpoint:
Cumulative number of CEL in T-1 weighted MRIs at 28, 36, 44 and 52 weeks; normalized at baseline to adjust for imbalance in lesions



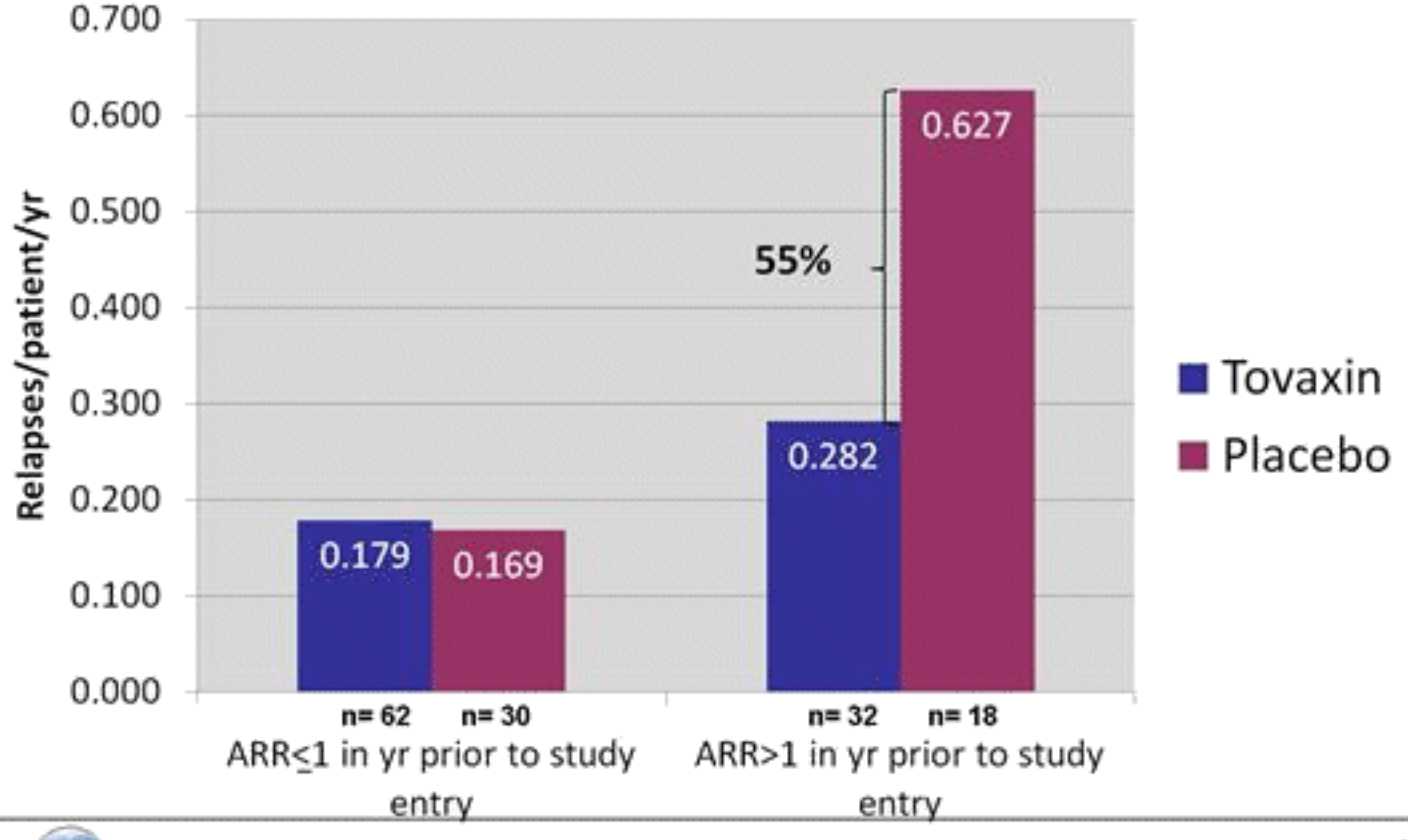
- With a much lighter disease burden than was anticipated in the placebo arm, it was difficult to show a significant treatment effect
- The primary endpoint showed no difference between the placebo and treatment arms

Annualized Relapse Rates (ARR): Positive trend favoring Tovaxin



Annualized Relapse Rates (ARR)

AAR ≤ and > 1 prior or study entry



Analysis of Patient Population with ARR>1 at Study Entry

Tovaxin demonstrates substantial improvement over placebo on all MRI and clinical endpoints

Primary and secondary efficacy endpoints	Tovaxin n=32	Placebo n=18	Difference
Annualized Relapse Rate (ARR) at 52 weeks	0.28	0.63	55%
Cumulative number of Gd lesions on T1-weighted brain MRI summed over the week 28, 36, 44, and 52 MRIs	3.91	5.17	24%
Cumulative number of new Gd lesions over weeks 28, 36, 44 and 52 MRIs	3.66	4.72	22%
Absolute change in T-2 lesion volume at week 52	0.42	1.03	59%

Primary safety endpoints	
Serious Adverse Events (SAEs)	• There were no SAEs associated with Tovaxin treatment
Most common adverse events	• Mild to moderate injection site reactions only

Analysis of Patient Population with ARR>1 at Study Entry

Statistically significant change in EDSS favoring Tovaxin
Substantial reduction in atrophy may indicate Tovaxin's neuroprotective effect

Additional efficacy endpoints	Tovaxin n=32	Placebo n=18	Difference
Absolute change in T-2 lesion volume at week 52	0.42	1.03	59%
Percent Brain Volume Change (Atrophy) at 52 weeks	-0.04	-0.32	88%
Change in EDSS score (disability score) -Improved -No change -Worsening	-0.17 9 (28.1%) 19 (59.4%) 4 (12.5%)	0.18 1 (5.6%) 14 (77.8%) 3 (16.7%)	Statistically significant improvement (p=0.045)
Timed 25 foot walk (fatigue)	0.14	-0.02	Improvement

TERMS – Safety

- **Treatment safe and well tolerated**
  - No SAEs were related to study treatment
  - No deaths in the study population
  - Mild injection site reactions only

Immunology Data

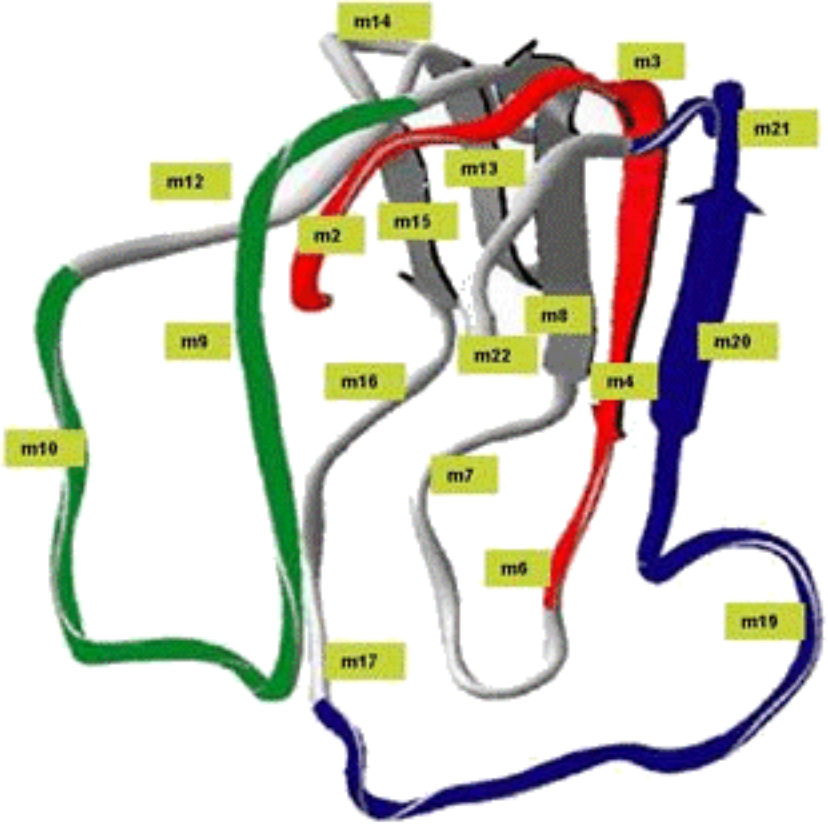
Epitope Analysis Assay (EAA)

Profiles

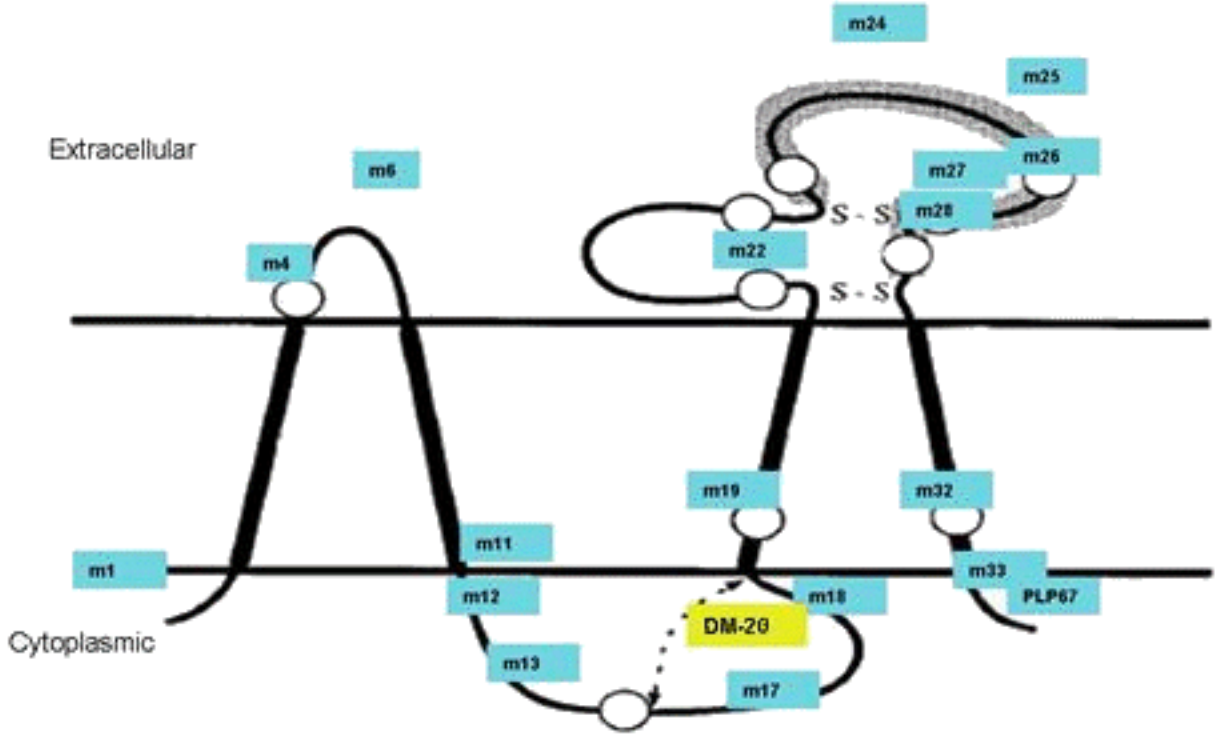
Epitope Analysis Assay (EAA)

- The EAA is used to analyze blood samples for their reactivity to peptides
- The read out of the assay provides the following advantages:
  - Determination of the profile unique to the individual
  - Ability to monitor epitope shift: the natural movement of epitope specificity over time
  - The enrichment of clinical studies for subjects amenable to T-cell vaccination
- The assay screens against 109 peptides from all three key myelin proteins

Protein Maps
Myelin Basic Protein (MBP)



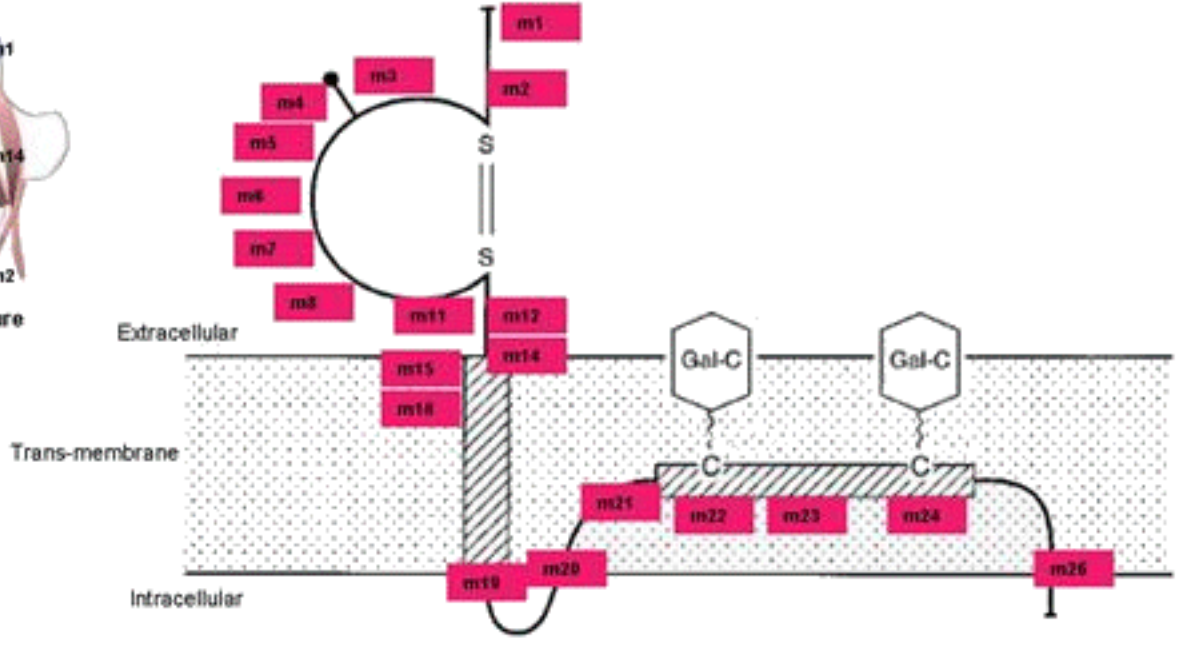
Protein Maps
Myelin Proteolipid Protein (PLP)



Protein Maps
Myelin Oligodendrocyte Glycoprotein (MOG)



Extracellular 3-D structure



Risk/Benefit: Primary Consideration for FDA Approval

- **Tovaxin Benefit: Maximum**
  - Opexa is pre-selecting patients based on presence of reactive T-cells and manufacturing a vaccine specific to patient's epitope (disease profile)

- **Tovaxin Risk: Minimal**
  - There have been no adverse events associated with Tovaxin treatment to date

- Opexa is confident Tovaxin risk/benefit profile will represent a benchmark for MS moving forward

Next steps

- Secure strategic partner for Phase III development and commercialization
- Phase IIB close out meeting with FDA: 1H '09
- Scale up manufacturing to support Phase III development
- Finalize analysis of data from TERMS Phase IIb trial

Summary of Opportunity

- Large markets with high unmet need
  - Current MS therapies surpass $5B sales annually
  - 50% of patients are non-compliant due to side effects of current therapies

- Tovaxin well positioned to enter MS market
  - Favorable safety profile to date: no SAEs associated with treatment
  - Lowest ARR of most marketed drugs
  - Personalized therapy targeting specific root cause of MS
  - Patient compliant: 5 sc injections/year – addresses patient compliance concerns
  - Significant improvement in disability and reduction in brain atrophy suggests a neuroprotective effect