

## **CURRENT MULTIPLE SCLEROSIS TRIALS THAT ARE RECRUITING PATIENTS**

**PRINCIPAL INVESTIGATOR:** DR KARYN BOUNDY  
**PLACE:** NEUROLOGY DEPARTMENT, TQEH  
**STUDY COORDINATOR:** PETER CHEUNG. PHONE: 8222 8161

**Type:** Relapsing Remitting Multiple Sclerosis (RRMS)  
**Sponsor:** Sanofi-Aventis  
**Protocol/Title:** COPERNICUS GLATI\_L 04209 Study  
**Trial Drug:** Not applicable

### **Details:**

- Prospective, parallel-group, observational study of patients using Copaxone, Interferons and placebo
- Assessing EDSS (a detailed neurological assessment), fatigue, cognition and quality of life
- 6 monthly visits over 2 years
- 256 patients. Australia only

### **Inclusion criteria**

- Age 18-65
- Diagnosed within last 6 years.
- On the same MS medication for last 3 months or treatment naïve.
- EDSS score of 0 - 3.
- English language proficient.
- Not exposed to mitoxantrone.
- Not had immunosuppressive agents, cytotoxic therapy, total body irradiation, monoclonal antibodies or any MS investigational drug in the last 6 months.
- Not had corticosteroids in last 30 days.
- Not a diabetic.
- No significant medical conditions or other neurodegenerative conditions.
- Not sensitive to mannitol.
- Not pregnant and willing to use reliable & acceptable contraception.

### **Known Major Potential Adverse Effects**

Not applicable

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**Type:** Relapsing Remitting Multiple Sclerosis (RRMS)  
**Sponsor:** Novartis  
**Protocol/Title:** CFTY720D2316 4-month Safety & Tolerability Study  
**Trial Drug:** Fingolimod 0.5mg capsule – 1 capsule a day

- It traps the T-cells in the lymphoid system, reducing their role in systemic inflammation
- Has been shown in 2 large Phase III studies (FREEDOMS and TRANSFORMS) to significantly reduce relapse rate and brain lesions

### **Details:**

- Phase IIIb, open-label with 0.5mg Fingolimod daily, in RRMS patients
- To evaluate safety & tolerability in a broader 'real world' patient population
- Particularly looking at slow and abnormal ECG events & macular oedema of the eyes
- 6 visits over 4 months. Three 2-weekly visits followed by 3 monthly visits
- 1850 patients worldwide
- Long term open label extension study following that

### **Inclusion criteria**

- Age 18-65. EDSS score of 0 – 6.5
- No other chronic immune system disorder. Not pregnant.
- Does not have moderate to severe diabetes.
- No macula oedema at screening.
- Not have the following cardiovascular conditions/findings:
  - ❖ history of cardiac arrest, angina due to coronary spasm, Raynaud's phenomenon
  - ❖ Myocardial infarction (heart attack) in the previous 6 months
  - ❖ unstable or severe ischaemic heart disease or moderately severe cardiac failure
  - ❖ history or presence of heart blocks
  - ❖ receiving Class Ia and III anti-arrhythmic drugs
  - ❖ resting pulse of <45 bpm, heart rate of less than 30 by holter monitoring
  - ❖ uncontrolled high blood pressure
- Not had corticosteroids within 1 month prior to baseline.
- Not on disease-modifying drugs(DMDs) (No washout period is needed for current DMDs).
- Not exposed to mitoxantrone, cladribine, cyclophosphamide or Fingolimod at any time.
- Not exposed to azathioprine, methotrexate, IVI immunoglobulin, monoclonal antibodies within 3 months of baseline.
- Positive for varicella-zoster virus IgG at screening. Not immunised with live vaccines.
- No significant abnormal kidney, liver and other lab values.
- Not have active systemic bacterial, viral or fungal infections or positive to AIDS, HIV, Hepatitis B, C, active or latent TB.
- Not participated in a clinical trial in previous 6 months.

### **Known Major Potential Adverse Effects**

- Slow heart rate – transient decrease in mean heart rate of 8bpm ± AV blocks.
- Symptomatic bradycardia in 0.5% of 0.5mg fingolimod patients.
- Macula oedema - 0.4% of clinical trial patients on fingolimod 0.5mg
- Opportunistic infections - 2 fatal herpes infections in fingolimod 1.25mg group.

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**Type:** RRMS.  
**Sponsor:** PRA/Biogen Idec  
**Protocol/Title:** DECIDE 205MS301 Study  
**Trial Drug:** Daclizumab – subcutaneous (s/c) injection

- Daclizumab (Zenepax) is the first humanised monoclonal antibody approved by the FDA for acute renal transplantation rejection
- Reduces survival of activated T cells
- Tested in a phase II study of patients who have failed to respond to Interferons. A total of 11 patients received seven doses each, the first two doses were given fortnightly and then every 4 weeks. Daclizumab resulted in a 78% reduction in new lesion formation & an 80% reduction in relapse rate.

### **Details:**

- Phase III, 2-arms, randomised, double-blinded, active-controlled (Avonex) study of Daclizumab monotherapy in RRMS patients
- Monthly visits. Total length of 2-3 years
- Daclizumab 150mg s/c every 4 weeks or Avonex 30mcg IM once weekly
- 1500 patients worldwide

### **Inclusion criteria**

- Age 18-55. EDSS score of 0 - 5.0
- 2 or more documented relapses in previous 3 years with 1 or more in the year before randomisation; OR 1 or more relapses AND 1 or more new MRI lesion within the previous 2 years with at least 1 event in the year prior to randomisation.
- No relapse in last 50 days
- Not known intolerance, contraindication to, or non-compliance with Avonex.
- Not participated in a clinical trial in previous 6 months.
- Not had prior treatment with natalizumab (Tysabri) within 1 year.
- Not had corticosteroids, Copaxone within 30 days prior to randomisation. (No washout period for Interferons)
- Not exposed to Daclizumab or other anti-CD25 monoclonal antibody, mitoxantrone, cladibrine.
- Not exposed to azathioprine, methotrexate, IVI immunoglobulin within 6 months.
- Not immunised with live vaccines within 4 weeks of randomisation.
- No significant abnormal kidney, liver and other laboratory values.
- No severe viral infections within last 6 weeks.
- Not positive to HIV, Hepatitis B, C, active or latent TB.
- Not pregnant or have any significant concurrent illness that may affect interpretation of clinical efficacy or safety data.
- No history of seizure or suicidal ideation in the last 6 months

### **Known Major Potential Adverse Effects**

Opportunistic infections