

You are invited to the Biogen Idec & Elan Symposia:

Thursday 10th September 2009, 19:15 to 20:15, Main Auditorium

Redefining Success in MS:
Advancing a New Treatment Paradigm

and

Friday 11th September 2009, 12:45 to 13:45, Main Auditorium

Redefining Success in MS:
Challenging Treatment Expectations



Thursday 10th September 2009, 19:15 to 20:15, Main Auditorium

Redefining Success in MS: Advancing a New Treatment Paradigm

Welcome and Introduction

Prof. Ralf Gold, Germany

Defining a Practical Treatment Algorithm for MS

Dr. Norman Putzki, Germany

Applying the Evidence: Case Study Exploration

Prof. Per Soelberg Sorensen, Denmark

Emerging Therapies:

Where Might They Fit in our Treatment Algorithm?

Prof. Ralf Gold, Germany

Q&A Session



Friday 11th September 2009, 12:45 to 13:45, Main Auditorium

Redefining Success in MS: Challenging Treatment Expectations

Welcome and Introduction

Prof. Hans-Peter Hartung, Germany

Optimizing Efficacy From the Start

Dr. Mar Tintoré, Spain

Disability Improvement as a Treatment Outcome?

Prof. Frederick Munschauer, United States

Connecting Clinical Trial Data with Real World Experience

Prof. Patrick Vermersch, France



Prescribing information: AVONEX® (interferon beta-1a)

Please refer to the Summary of Product Characteristics for further information.

Indication: For the treatment of patients with relapsing multiple sclerosis or patients who have experienced a single demyelinating event with an active inflammatory process who are determined to be at high risk of developing clinically definite multiple sclerosis. **Dosage and Administration:** 30 µg injected IM once a week. **Contraindications:** Initiation of treatment in pregnancy. Patients with a history of hypersensitivity to any of the constituents. Patients with severe depression and/or suicidal ideation; **Warnings & Precautions:** Use with caution in patients with previous or current depressive disorders - depression and suicidal ideation are known to occur in increased frequency in the multiple sclerosis population in association with interferon use. Administer with caution to patients with a history of seizures, or receiving treatment with anti-epileptics, particularly if their epilepsy is not adequately controlled with anti-epileptics. Used with caution and monitor closely in patients with cardiac disease, severe renal or hepatic failure or severe myelosuppression. Routine periodic blood chemistry and haematology tests are recommended during treatment. Development of neutralizing antibodies to AVONEX may decrease efficacy. **Pregnancy & lactation:** Initiation of treatment is contraindicated during pregnancy. Women of child bearing potential should take appropriate contraceptive measures. If the patient becomes pregnant or plans to become pregnant, or breast feeding while taking AVONEX, discontinuation of therapy should be considered. **Drug interactions:** No formal interaction studies have been conducted with AVONEX in humans. Corticosteroids or ACTH can be given during relapses. Caution should be exercised in combining AVONEX with products with a narrow therapeutic index and dependent on cytochrome P450 for clearance. **Side Effects:** The most commonly reported symptoms are of the flu-like symptoms: myalgia, fever, chills, asthenia, headache and nausea. Other common events include: decreased lymphocyte, white blood cell, and neutrophil counts; decreased haematocrit and increased blood potassium and blood urea nitrogen. Nervous system disorders: muscle spasticity, hyposthesia. Respiratory, thoracic and mediastinal disorders: rhinorrhoea. Gastrointestinal disorders: vomiting, diarrhoea, nausea. Skin and subcutaneous tissue disorders: rash, increased sweating, contusion. Musculoskeletal and connective tissue disorders: muscle cramp, neck pain, myalgia, arthralgia, pain in extremity, back pain, muscle stiffness, musculoskeletal stiffness. Metabolism and nutrition disorders: anorexia. Vascular disorders: flushing. General disorders and administration site conditions: flu-like symptoms, pyrexia, chills, sweating, injections site pain, injection site erythema, injection site bruising, asthenia, pain, fatigue, malaise, night sweats. Psychiatric disorders: depression, insomnia.

Legal Classification: Medicinal product subject to medical prescription. **Pack Size:** Box containing four or twelve injections. **Package Quantities:** Lyophilised Powder: 1 box containing four trays. Each tray contains a 3 ml glass vial with BIO-SET device containing a 30µg dose of Interferon beta-1a per vial, a 1 ml pre-filled glass syringe of solvent and one needle. Pre-filled Syringe: 1 box containing four or twelve trays. Each tray contains a 1 ml pre-filled syringe made of glass containing 0.5 ml of solution (30µg dose of Interferon beta-1a) and one needle. **Product Licence Numbers:** EU/1/97/033/002-004. **Product Licence Holder:** Biogen Idec Ltd, Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom.

Date of last revision of Prescribing Information: December 2008.

The opinions and views expressed by the speakers are their own and do not necessarily represent the views of Biogen Idec and/or Elan Pharmaceuticals.

MULTI-PAN-25067

AVONEX™
(interferon beta-1a)

TYSABRI™
(natalizumab)

biogen idec

elan

biogen idec
neurology **MS™**

Prescribing information: TYSABRI® (natalizumab)

Please refer to the Summary of Product Characteristics for further information.

Indications: single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following patient groups: patients with rapidly evolving severe relapsing remitting multiple sclerosis or patients with high disease activity despite treatment with a beta-interferon. **Dosage and Administration:** The recommended dosage is 300 mg administered by intravenous infusion once every 4 weeks. The diluted solution is to be infused intravenously over 1 hour at a rate of approximately 2ml/minute and patients are to be observed during infusion and for 1 hour after the completion of the infusion for signs and symptoms of hypersensitivity reactions. TYSABRI therapy is to be initiated and supervised by a specialised physician with experience in the diagnosis and treatment of neurological conditions, in centres with resources for management of hypersensitivity reactions and timely access to MRI. Continued therapy must be carefully reconsidered in patients who show no evidence of therapeutic benefit beyond 6 months. Patients treated with TYSABRI must be given the Patient Alert Card. **Contraindications:** Hypersensitivity to natalizumab or to any of the excipients, progressive multifocal leukoencephalopathy (PML); patients with increased risk of opportunistic infections, including immunocompromised patients (including those currently receiving immunosuppressive therapies or those immunocompromised by prior therapies, e.g. mitoxantrone or cyclophosphamide); combination with beta-interferons or glatiramer acetate; known acute malignancies; children and adolescents. **Special Warnings and Precautions;** **CNS:** Use of TYSABRI has been associated with increased risk of progressive multifocal leukoencephalopathy (PML). Before initiation of treatment with TYSABRI, a recent (usually within 3 months) Magnetic Resonance Image (MRI) of the patients should be available. Patients must be monitored at regular intervals for any new or worsening neurological symptoms or signs suggestive of PML. If new neurological symptoms occur, further dosing should be suspended until PML has been excluded. If the symptoms are suggestive of PML, or if any doubt exists, further evaluation, including MRI scan preferably with contrast (compared with pre-treatment MRI), CSF testing for JC viral DNA and repeat neurological assessments should be considered. Once PML has been excluded (if necessary, by repeating clinical, imaging and/or laboratory investigations if clinical suspicion remains), dosing of TYSABRI may resume. The physician should be alert to symptoms suggestive of PML that the patient may not notice (e.g. cognitive or psychiatric symptoms). If patients develop PML, the dosing of TYSABRI must be permanently discontinued. **Other Opportunistic Infections:** Other opportunistic infections have been reported with use of TYSABRI. If an opportunistic infection is suspected, dosing with TYSABRI is to be suspended until such infection can be excluded through further evaluation. **Educational Guidance:** All physicians who intend to prescribe TYSABRI must be familiar with the Physician Information and Management Guidelines. **Hypersensitivity:** hypersensitivity reactions have been associated with TYSABRI, including serious systemic reactions. These reactions usually occur during the infusion or up to 1 hour after completion of infusion. The risk of hypersensitivity was greatest with early infusions and in patients re-exposed to TYSABRI following an initial short exposure (one or two infusions) and an extended period (three months or more) without treatment. If a hypersensitivity reaction occurs TYSABRI must be permanently discontinued. In post-marketing there have been reports of hypersensitivity reactions occurring with one or more of the following symptoms: hypotension, chest pain/discomfort, dyspnoea and angiodema. Immunogenicity: In the case of disease exacerbations or infusion related events the presence of antibodies should be evaluated. Treatment should be discontinued if persistent antibodies develop. **Hepatic Events:** Monitor patients as appropriate for impaired liver function and instruct them to contact their physician if signs and symptoms suggestive of liver injury occur. Discontinue in cases of significant liver injury. **Stopping Therapy:** If therapy is discontinued be aware that TYSABRI has pharmacodynamic effects for up to 12 weeks following the last dose. **Pregnancy and lactation:** If patients become pregnant while taking TYSABRI, discontinuation of TYSABRI should be considered. Patients receiving TYSABRI should not breastfeed their infant. **General:** Physicians must discuss the benefits and risks of TYSABRI therapy with the patient and provide them with a Patient Alert Card. Patients should be instructed that if they develop any infection they should inform their physician that they are being treated with TYSABRI. **Drug interaction:** Combination with beta-interferons or glatiramer acetate is contraindicated. The safety and efficacy of TYSABRI in combination with other immunosuppressive and antineoplastic therapies have not been fully established. Concurrent use of these agents with TYSABRI may increase the risk of infections including opportunistic infections. No formal interaction studies have been conducted with TYSABRI in humans. **Undesirable Effects:** The most commonly reported symptoms are: **Infections and infestations:** urinary tract infection, nasopharyngitis. **Immune system disorders:** urticaria. **Nervous system disorders:** headache, dizziness. **Gastrointestinal disorders:** vomiting, nausea. **Musculoskeletal and connective tissue disorder:** arthralgia. **General disorders and administration site conditions:** rigors, pyrexia, fatigue. Other less common events include: hypersensitivity reactions, infusion reactions, PML, other opportunistic infections, immunogenicity. Spontaneous cases of serious liver injuries have been reported during the post marketing phase. For further information regarding adverse events please refer to the Summary of Product Characteristics.

Legal Classification: Medicinal product subject to medical prescription. **Package Quantities:** 300mg/100ml. **Product Licence Number:** EU/1/06/246/001. **Product Licence Holder:** Elan Pharma International Ltd, Monksland, Athlone, County Westmeath, Ireland.

Date of last revision of Prescribing Information: January 2009