

May 29, 2013

Subject: Continuous Education Program and Patient Care with Tysabri® (CONNECT) about the risk of progressive multifocal leukoencephaloathy (PML).

Dear Health Care Professional,

Biologix and Biogen Idec would like to provide you with important information regarding the use of Tysabri®. Treatment with Tysabri® has been associated with an increased risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Because of the risk of PML, Biologix and Biogen Idec have developed a risk management program for the Middle East and North Africa called CONNECT (CoNtiNuous Education program and patient Care with Tysabri).

CONNECT is a program that supports neurologists and Tysabri® patients through:

- Continuously educating physicians, pharmacists, patients and nurses.
- Helping prescribers and patients to take decision regarding the use of Tysabri® in relapsing-remitting MS based on assessment of benefits and risks.
- Ensuring continuous vigilance aiming at PML early detection and eventual decrease in morbidity and mortality.

Information for Health Care Providers

The program seeks to achieve the following:

- Physicians and patients are fully informed about the benefits and risk of Tysabri® before initiating and while on therapy.
- Only appropriate patients are prescribed and infused with Tysabri®.
- Patients treated with Tysabri® are continuously monitored.

Further information:

- Tysabri® does not cure MS disease.
- Tysabri® has not been studied for use longer than 2 years.
- Tysabri® has not been studied in patients with chronic progressive MS.
- It is not known if patients older than 65 years have a different response to Tysabri®.
- Tysabri® is not approved for use in patients under age 18.

This information has been agreed with the Saudi Food and Drug Authority.

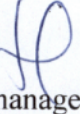
Call for reporting

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Email: Npc.drug@sFDA.gov.sa
- Biologix Pharmacovigilance and Risk Management Plan:
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Sincerely yours,
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