GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

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Direct Health Care Professional Communication on BENLYSTA® (belimumab)

Title:

Two Post Marketing Reports, One Fatal, of Progressive Multifocal Leukoencephalopathy (PML) in Patients with Systemic Lupus Erythematosus (SLE)

Dear Health Care Professional:

Summary:

- Cases of JC virus-associated PML resulting in neurological deficits, including fatal cases, have been reported in patients with SLE receiving immunosuppressants, including Benlysta.
- A causal relationship between PML and Benlysta has not been established.
- Healthcare providers should consider the diagnosis of PML in any patient presenting with new onset or deteriorating neurological signs and symptoms and consult with a neurologist or other appropriate specialist as clinically indicated. This may include deficit or deterioration in cognition, speech or ocular functions, and/or motor and gait disturbances, seizures may also occur. In patients with confirmed PML, consider stopping immunosuppressant therapy, including Benlysta.
- If PML is suspected it should be urgently investigated by a neurologist or other appropriate specialist. Where appropriate, immunosuppressant medications including BENLYSTA® should be withheld until PML is excluded.

Further information on the safety concern:

GlaxoSmithKline would like to advise you of important new safety information relating to the use of Benlysta. The safety information is relevant to all healthcare providers who treat patients with Benlysta for SLE. Please refer to the indication statement and "limitations of use" which appear below in the section titled "Action Taken by GlaxoSmithKline."

Key Information Regarding the Risk of PML with Benlysta

• Two post-marketing cases of PML have been reported in patients receiving Benlysta, mycophenolate mofetil (MMF) and steroids for the treatment of SLE. One case was fatal.

• Risk factors for PML include treatment with immunosuppressant therapies and impairment of immune function.

• GlaxoSmithKline has updated the labelling for Benlysta given the risk of PML in SLE patients and the importance of making the correct diagnosis and appropriate medical intervention quickly. Please refer to the indication statement and "limitations of use" which appear below in the section titled "Action Taken by GlaxoSmithKline." Also refer to the accompanying Full Prescribing Information and Medication Guide.

• A causal relationship between PML and Benlysta has not been established.

Supporting Information

Two spontaneous post-marketing reports of PML have been reported in patients receiving Benlysta where the estimated post-marketing exposure is over 15,000 SLE patients.

Recommendations to healthcare professionals:

• Maintain a heightened awareness of the risk of PML in patients with SLE receiving Benlysta.

• Continue to monitor for signs and symptoms of PML, including but not limited, to visual disturbances, ocular movements, ataxia, aphasia, and mental status changes such as disorientation or confusion.

• Consider the diagnosis of PML in any patient presenting with new onset or deteriorating neurological signs and symptoms and consult with a neurologist or other appropriate specialist as clinically indicated. In patients with confirmed PML, consider stopping immunosuppressant therapy, including Benlysta.

• Advise patients to contact you or their healthcare professional if they experience new or worsening neurological symptoms such as memory loss, confusion, dizziness or loss of balance, difficulty talking or walking, or vision problems.

• Share this letter with relevant health care personnel under your supervision

About Benlysta™:

BENLYSTA® (belimumab) is indicated for the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.

Limitations of Use: The efficacy of BENLYSTA has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. BENLYSTA has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of BENLYSTA is not recommended in these situations.

The letter is sent in agreement with the Saudi Food and Drug Authority

Further Information

GlaxoSmithKline will continue to monitor the safety of Benlysta™ and update SFDA of any serious adverse event for evaluation. You can assist us in monitoring the safety of Benlysta™ by reporting adverse reactions to GlaxoSmithKline Fax: +966 12 6536660 or by email: faisal.m.shujrah@gsk.com or to the National Pharmacovigilance and Drug Safety Center at Fax: +966 11 2057662 or by email to: npc.drug@sfda.gov.sa or through online reporting system: http://ade.sfda.gov.sa/

If you have any question about the new information, please contact GSK medical information department at GlaxoSmithKline Saudi Arabia by phone: +966 12 6536666 or fax: +966 12 6536660.

Best regards;

Nauman Rashid

Country Medical Director

GlaxoSmithKline

Saudi Arabia

Reference:

Molloy ES, Calabrese LH. Progressive multifocal leukoencephalopathy: a national estimate of frequency in systemic lupus erythematosus and other rheumatic diseases. Arthritis Rheum 2009;60:3761–3765.