FDA Drug Safety Communication: FDA warns about case of rare brain infection PML with MS drug Tecfidera (dimethyl fumarate)

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FDA 提出警示，一位已有 18 年多發性硬化症病史的 54 歲女性患者，在服用 Tecfidera (dimethyl fumarate) 治療後，診斷出一種名為進行性多灶性白質腦病(progressive multifocal leukoencephalopathy，PML)的嚴重腦部感染症，並於患病後死亡。這名患者在服藥期間並未服用其他會影響免疫系統或可能導致 PML 的藥物。但在發展成 PML 之前，該名病人在服用 Tecfidera 期間具有嚴重淋巴球減少症（連續三年淋巴球數目小於 500 cells/μl）。目前此種罕見嚴重腦部感染的不良反應訊息已被要求加註於藥品仿單中。

建議

FDA 建議患者在服用 Tecfidera 期間若出現虛弱感、手腳不聽使喚、思考或視覺及平衡上的改變，必須馬上告知醫療人員。若患者疑似罹患多灶性白質腦病，醫師須停用 Tecfidera。

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AUDIENCE: Neurology, Pharmacy

ISSUE:

The U.S. Food and Drug Administration (FDA) is warning that a patient with multiple sclerosis (MS) who was being treated with Tecfidera (dimethyl fumarate) developed a rare and serious brain infection called PML and later died. As a result, information describing this case of PML, or progressive multifocal leukoencephalopathy, is being added to the Tecfidera drug label. The patient who died was not taking any other drugs that affect the immune system or drugs that are thought to be associated with PML. This is the only confirmed case of this rare and serious brain infection reported in patients taking Tecfidera.

BACKGROUND:

A 54-year-old patient with multiple sclerosis (MS) being treated with Tecfidera (dimethyl fumarate) in a clinical trial died after developing progressive multifocal leukoencephalopathy (PML). The patient, who had an 18 year history of MS, had no known medical conditions that would predispose her to the development of PML. She had no history of prior use of immunosuppressive medications or Tysabri, and was not taking any concomitant immunosuppressive or immunomodulatory medications. She had taken Copaxone (glatiramer acetate) for 3 years prior to being enrolled in a Tecfidera clinical trial. In the clinical trial, she had received placebo for two years followed by Tecfidera for approximately 4.5 years prior to developing PML. During Tecfidera treatment, she had severe lymphopenia, with lymphocyte counts consistently below 500 cells per microliter for 3.5 years before developing PML.

RECOMMENDATION:

Patients taking Tecfidera should contact their health care professionals right away if they experience symptoms that concern them, such as new or worsening weakness; trouble using their arms or legs; or changes to thinking, eyesight, strength or balance. Health care professionals should stop Tecfidera if PML is suspected.