To: Karelia Stetz-Waters
From: Melanie J. Bone
Date: February 19, 2008
Subject: Proposal for determining the safety of the drug natalizumab (tysabri)

Introduction

The Food and Drug Administration (FDA) is always conducting tests and trials on new drugs that manufacturers are developing. The FDA is the final seal of approval before the drug hits the market and the approval process takes anywhere from five to ten years. Sometimes drugs get approved without knowing the long term effects that it has on some patients. Natalizumab (Tysabri) is a monoclonal antibody that has showed promise in treating patients with multiple sclerosis (MS) and Crohn's disease.

Tysabri was released on to the market in 2001 and was given to patients with MS. Most patients showed significant improvement after receiving the drug. After about three weeks on the market, some patients who had received Tysabri developed an extremely rare infection of the brain called progressive multifocal leukoencephalopathy (PML) and were killed because of the infection. PML generally kills patients in three to six months after the onset of the infection.

Statement of Problem

Tysabri showed great promise in its clinical trials for helping patients with MS and Crohn's disease, yet for those patients that develop PML, it is a guaranteed death in less than a year. There is no cure for PML, and by the time it is discovered in most patients, they only have a few months left to live. Although Tysabri has shown great promise in aiding those with MS and Crohn's disease, it is only in relieving the symptoms and not a cure for the disease itself. Patients who get Tysabri are generally not going to die from the disease alone in the next three to six months so by getting Tysabri, they are potentially shortening their life.

Proposed Solution

One solution to this problem would be to pull Tysabri off the market and have the manufacturers do more laboratory tests and clinical trials using different combinations of drugs with Tysabri or changing the molecular formula all together. Some chemotherapeutic products, which Tysabri is classified under, show less side effects and increased treatment of the disease when given with a combination of drugs. Further studies need to be conducted on those patients that develop PML to find out if certain circumstances enabled them to be more susceptible to PML than other patients, and if that is conclusive, how to prevent it from happening.

Scope

To determine the safety of Tysabri, I will look at the following categories:

1) How effective is Tysabri in the treatment of MS and Crohn's disease?
2) What percentages of patients that receive Tysabri develop PML?
3) What are the long-term outcomes for patients with MS and Crohn's disease without receiving Tysabri?
4) Are there any other drugs that can treat MS and Crohn's disease with fewer side effects?
5) What is the manufacturer doing to prevent patients from developing PML?

My Qualifications

I myself have prepared this drug for some patients that receive it at the infusion center where I work. I am also a nationally and state certified pharmacy technician with six years of experience in the sterile preparations of chemotherapeutic products. I am familiar with Tysabri and patients that receive the drug, and I have also talked extensively with pharmacists and doctors who know about the drug as well.

Conclusion

Undoubtedly, there is something that needs to be done in order to ensure the patients safety while getting Tysabri. By further researching Tysabri myself, and addressing the five categories listed above, I believe I can determine a proper course of action that needs to be taken with this drug. With your support I will begin more extensive research into Tysabri.

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