

June 2011

## IMPORTANT DRUG WARNING

### **Subject: Increased Risk of Post-transplant Lymphoproliferative Disorder (PTLD), predominantly involving the Central Nervous System (CNS), and Progressive Multifocal Leukoencephalopathy (PML) with NULOJIX® (belatacept)**

Dear Infusion Specialist:

This letter informs you of important safety information for NULOJIX® (belatacept), a selective T-cell costimulation blocker recently approved by the Food and Drug Administration (FDA) for prophylaxis of organ rejection in adult patients receiving a kidney transplant. NULOJIX is to be used in combination with basiliximab induction, mycophenolate mofetil (MMF), and corticosteroids. NULOJIX is indicated for use only in patients who are Epstein-Barr virus (EBV) seropositive. Use of NULOJIX for the prophylaxis of organ rejection in other transplanted organs has not been established.

#### **Important information you should know about NULOJIX:**

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of NULOJIX outweigh the risks, including:

- Post-Transplant Lymphoproliferative Disorder (PTLD)**, a type of malignancy. Patients treated with NULOJIX have a higher risk of getting PTLD, predominantly involving the central nervous system (CNS). PTLD can cause death
- Progressive Multifocal Leukoencephalopathy (PML)**, a rare, serious brain infection. This rare brain infection has been reported in patients treated with NULOJIX. PML can cause death

#### **You play an important role by:**

- 1) educating the patient about these risks,**
- 2) identifying any concerning signs and symptoms associated with these risks, and**
- 3) alerting the prescriber about any concerning signs and symptoms reported to you.**

To help identify patients who are experiencing new, changed, or worsened neurological, cognitive, or behavioral signs and symptoms, a **PRE-INFUSION CHECKLIST** is available. For every patient, complete the enclosed **PRE-INFUSION CHECKLIST** before each infusion. Transplant and infusion centers should develop a systematic way to evaluate all patients treated with NULOJIX before each NULOJIX infusion is administered.

- **To download the PRE-INFUSION CHECKLIST**, go to [www.NULOJIX.com/REMS.aspx](http://www.NULOJIX.com/REMS.aspx). The checklist is available as an editable PDF file for easier incorporation into electronic medical record systems
- **To order tear pads of the Checklist**, call Bristol-Myers Squibb at 1-800-321-1335

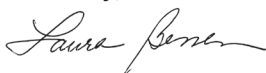
#### **Reporting Adverse Events**

For any adverse event with the use of NULOJIX, healthcare professionals should contact Bristol-Myers Squibb at 1-800-721-5072 and/or the FDA MedWatch program by phone at 1-800-FDA-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

This letter is not intended as a complete description of the benefits and risks associated with the use of NULOJIX. Please refer to the enclosed complete Prescribing Information and Medication Guide.

All REMS materials, including a NULOJIX® REMS webinar, are accessible at [www.NULOJIX.com/REMS.aspx](http://www.NULOJIX.com/REMS.aspx). For additional information, please call Bristol-Myers Squibb at 1-800-321-1335 or visit [www.NULOJIX.com](http://www.NULOJIX.com).

Sincerely,



Laura Bessen, MD  
Bristol-Myers Squibb  
Vice President, US Medical, Immunoscience and Neuroscience

Enclosure: NULOJIX® (belatacept) Pre-Infusion Checklist, full Prescribing Information and Medication Guide