Bristol-Myers Squibb

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 Healthcare Professional:

The purpose of this letter is to inform 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 transplant 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.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of NULOJIX outweigh the risks of post-transplant lymphoproliferative disorder (PTLD) and progressive multifocal leukoencephalopathy (PML), both of which can be fatal.

Boxed Warning Includes Increased Risk of PTLD

- Patients treated with NULOJIX are at an increased risk for developing PTLD, predominantly involving the central nervous system (CNS)

Increased Risk of PML

- PML has been reported in patients receiving NULOJIX at higher than recommended doses as part of an immunosuppressant regimen

Contraindications

- **NULOJIX is contraindicated in transplant recipients who are EBV seronegative or with unknown serostatus**
- Be sure to verify the patient's EBV status before initiating therapy with NULOJIX

This letter is not intended as a complete description of the benefits and risks associated with the use of NULOJIX. For a more complete description about the risks including PTLD and PML, please see the enclosed NULOJIX® Fact Sheet, and full Prescribing Information, included with this letter.

ENLiST Registry

BMS established the ENLiST Registry to further evaluate the safety profile of NULOJIX. The primary objective of ENLiST is to determine the incidence of PTLD, CNS PTLD, and PML in US adult EBV seropositive kidney transplant recipients treated with NULOJIX. ENLiST is intended to enroll all adult kidney transplant patients who are treated with NULOJIX.

Data collection will include the patients' EBV and CMV serostatus as well as when NULOJIX was initiated relative to time of transplant. BMS encourages your center to participate in the ENLiST Registry. For more information on how to enroll in ENLiST and answers to other questions regarding the registry, please call 1-800-321-1335. Find out more about the protocol at www.clinicaltrials.gov

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.

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

Sincerely,

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

Enclosure: NULOJIX® Fact Sheet, full Prescribing Information and Medication Guide

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