

July 8, 2011

## **FDA Safety Announcement: Nulojix (belatacept): Risk Evaluation and Mitigation Strategy (REMS)**

*\*Increased Risk of Post-transplant Lymphoproliferative Disorder (PTLD), predominantly involving the Central Nervous System (CNS), and Progressive Multifocal Leukoencephalopathy (PML)*



**AUDIENCE:** Transplantation, Nephrology

**ISSUE:** Bristol-Myers Squibb informed healthcare professionals about the REMS that is required for Nulojix to ensure that the benefits of Nulojix outweigh the risks of PTLD and PML, both of which can be fatal. Patients treated with Nulojix are at an increased risk for developing PTLD, predominantly involving the CNS. PML has been reported in patients receiving Nulojix at higher than recommended doses as part of an immunosuppressant regimen.

**BACKGROUND:** FDA may require a REMS from a manufacturer before approval or post approval to ensure that the benefits of a drug or biological product outweigh its risks. Nulojix is a selective T-cell costimulation blocker recently approved 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 in liver transplant patients is not recommended due to an increased risk of graft loss and death. Use of Nulojix for the prophylaxis of organ rejection in other transplanted organs has not been established.

**RECOMMENDATION:** Be sure to verify the patient's EBV status before initiating therapy with Nulojix. BMS established the ENLiST Registry to further evaluate the safety profile of Nulojix. BMS encourages your participation in the ENLiST Registry.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm262210.htm>

[www.kcercoalition.com/alerts.htm](http://www.kcercoalition.com/alerts.htm)