Important Information on the Safe Use of Nulojix (belatacept)

Nulojix and INCREASED RISK of PTLD, CNS PTLD, and PML

FDA has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits outweigh the following risks:

Boxed Warning Includes Increased Risk of Post-Transplant Lymphoproliferative Disorder (PTLD)
- Patients treated with Nulojix are at an increased risk for developing PTLD, predominantly involving the central nervous system (CNS)

Increased Risk of Progressive Multifocal Leukoencephalopathy (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 Epstein-Barr virus (EBV) seronegative or with unknown serostatus
- Be sure to verify the patient’s EBV status before initiating therapy with Nulojix

Patient Monitoring and Counseling
- Monitor patients for new or worsening neurologic, cognitive, or behavioral signs or symptoms

ENLIST Registry—Evaluating Nulojix Long-Term Safety in Transplant
- BMS established the ENLIST Registry to further evaluate the safety profile of Nulojix
- ENLIST is intended to enroll all adult kidney transplant patients who are treated with 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
- 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

Nulojix Indication
Nulojix is a selective T-cell costimulation blocker indicated for the prophylaxis of organ rejection in adult patients receiving a kidney transplant. Use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. Nulojix is indicated for use only in patients who are EBV seropositive. Use of Nulojix for the prophylaxis of organ rejection in other transplanted organs has not been established.

Adverse events with the use of Nulojix should be reported to:
- Bristol-Myers Squibb at 1-800-721-5072 and/or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

This is not intended as a complete description of the benefits and risks associated with the use of Nulojix. For a more complete description, please see the full Prescribing Information which is available at www.Nulojix.com/REMS.aspx.

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