Yervoy (ipilimumab): Risk Evaluation and Mitigation Strategy (REMS) - Severe Immune-Mediated Adverse Reactions

U.S. Food & Drug Administration

AUDIENCE: Hematology-Oncology

ISSUE: Bristol-Myers Squibb informed healthcare professionals about the risk evaluation and mitigation strategy (REMS), developed in collaboration with FDA, that is required to ensure that the benefits of Yervoy outweigh the risks of severe and fatal immune-mediated adverse reactions. The Yervoy REMS consists of a Communication Plan to inform healthcare professionals of the serious risks of Yervoy, to facilitate early identification of these risks, and an overview of recommended management of patients with moderate or more severe immune-mediated adverse reactions.

BACKGROUND: Yervoy was approved March 2011 with the Prescribing Information including a Boxed Warning stating that use of the product can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of Yervoy.

RECOMMENDATION: Healthcare providers were advised to read the boxed warning and accompanying full Prescribing Information for a complete description of these risks and their management and were advised to discuss the risks that may be associated with therapy with patients and their caregivers. Clinicians were advised to:

- permanently discontinue Yervoy and initiate systemic high dose corticosteroid therapy for indentified severe immune-mediated reactions.
- assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy and endocrinopathy and evaluate clinical chemistries including liver function tests and thyroid function tests at baseline and before each dose.

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

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] 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

[March 2011 - Dear Healthcare Professional Letter [3] - BMS]
[03/25/2011 - Prescribing Information [4] - BMS]
[03/25/2011 - Medication Guide [5] - BMS]

SOURCE [6]

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Links:
[1] http://www.fda.gov/MedWatch/report.htm
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