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FDA approves BMY therapy for previously treated Multiple Myeloma

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U.S. Food and Drug Administration Approves EmplicitiÂ® (elotuzumab) Plus Pomalidomide and Dexamethasone, a new Immunotherapy combination for certain patients with relapsed or refractory multiple myeloma



Bristol-Myers Squibb Company announced that the U.S. Food and Drug Administration (FDA) approved *Empliciti* (elotuzumab) injection for intravenous use in combination with pomalidomide and dexamethasone (EPd) for the treatment of adult patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.

In ELOQUENT-3, a randomized, open-label, Phase 2 trial, EPd demonstrated benefit in patients with relapsed or refractory multiple myeloma, doubling both median progression-free survival (PFS) and overall response rate (ORR) versus pomalidomide and dexamethasone (Pd).

"*Empliciti* plus pomalidomide and dexamethasone has been proven to extend the time that certain patients live without disease progression, giving health care professionals an effective new tool to tackle this relentless cancer," said Joseph E. Eid, M.D., senior vice president and head of Medical, Bristol-Myers Squibb. "Today's approval reinforces the importance of Immuno-Oncology in blood cancers and expands the role of *Empliciti* to address the needs of relapsed or refractory multiple myeloma patients."

***Empliciti* with pomalidomide and dexamethasone is associated with Warnings and Precautions related to: infusion reactions, infections, secondary primary malignancies, hepatotoxicity, interference with determination of complete response, pregnancy/females and males of reproductive potential and adverse reactions.**

"Relapse can be overwhelming and extremely challenging for multiple myeloma patients, particularly after they have already tried several therapies," said Paul Giusti, president and chief executive officer of the Multiple Myeloma Research Foundation. "*Empliciti*, in combination with pomalidomide and dexamethasone, is an exciting new option for patients with relapsed or refractory myeloma."

Bristol-Myers Squibb and AbbVie are co-developing *Empliciti*, with Bristol-Myers Squibb solely responsible for commercial activities.