Bristol-Myers Squibb

August 1, 2019

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NCCN Guidelines® Panel: Hematopoietic Cell Transplantation

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed clinical data for ORENCIA® (abatacept) to the NCCN® Hematopoietic Cell Transplantation Panel for your consideration.

An oral presentation at the 2019 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR presented the results of the first phase 2 trial that evaluated T-cell co-stimulation blockage with abatacept for acute graft versus host disease (GVHD) prevention in human leukocyte antigen (HLA) matched and mismatched unrelated donor transplantation.

FDA Clearance of ORENCIA® (abatacept):

- moderately to severely active Rheumatoid Arthritis (RA) in adults. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists
- moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. ORENCIA® may be used as monotherapy or concomitantly with methotrexate
- active Psoriatic Arthritis (PsA) in adults
- should not be given concomitantly with TNF antagonists

The use of abatacept for prevention of acute GVHD in HLA matched and mismatched unrelated dolor transplant patients is considered investigational.

Rationale: These data are being submitted in response to a standing request from NCCN® for new data.

As part of this submission, the following resources are included for your review.

1. Watkins B, et al. T Cell Costimulation Blockade with CTLA4-Ig (Abatacept) for Acute GVHD Prevention in HLA Matched and Mismatched Unrelated Donor Transplantation. Oral presentation at: The Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR; February 18-23, 2019; Orlando FL.
2. Product Information, ORENCIA® (abatacept). Bristol-Myers Squibb Company, Princeton, NJ. July 2019

Thank you for your consideration.

Sincerely,

Awny Farajallah, MD, FACP
Vice President, Head US Medical
Bristol-Myers Squibb Company