RXADVANCE
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CLINICAL UPDATE

Brand Name	Hemady™
Generic Name	dexamethasone
Drug Manufacturer	Acrotech Biopharma, LLC

Clinical Update

Clinical Update: FDA Approves Hemady™ 20 mg tablet (dexamethasone) in combination with other antimyeloma products for the treatment of adults with multiple myeloma.

FDA approval date: October 3, 2019

Overview

Dexamethasone has been routinely used for the treatment of multiple myeloma for over 30 years and has been included as part of the backbone regimen for numerous FDA-approved anti-myeloma therapies. Dexamethasone is also included in multiple treatment protocols in the national comprehensive cancer network (NCCN) guidelines for multiple myeloma. The efficacy and safety of dexamethasone for the treatment of patients with multiple myeloma is well established.

Efficacy

The NDA provided a new strength of dexamethasone (20 mg tablet) and a new indication, as the reference listed drug included an indication for neoplastic disease.

The Applicant conducted a clinical pharmacology study in healthy subjects (Study 160458) to compare the bioavailability of the proposed Hemady™ 20 mg tablet to the marketed tablet formulation. This study established a scientific bridge between the listed drug and Hemady™ and the dexamethasone drug products used in the literature to support the labeling recommendations. Additionally, the Applicant is relying on the FDA's previous findings of safety and efficacy for Decadron, Thalomid, Velcade, Revlimid, Pomalyst, Ninlaro, Farydak, and Kyprolis, as well as the published literature describing the results of clinical studies using dexamethasone in combination with these anti-myeloma drugs.