Pomalyst® (pomalidomide) – New orphan indication

- On May 15, 2020, Bristol Myers Squibb announced the FDA approval of Pomalyst (pomalidomide), for the treatment of adult patients with acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failure of highly active antiretroviral therapy (HAART) and Kaposi sarcoma in adult patients who are human immunodeficiency virus (HIV)-negative.
    - This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Pomalyst is also approved, in combination with dexamethasone, for adult patients with multiple myeloma who have received at least two prior therapies including Revlimid® (lenalidomide) and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.
- Kaposi sarcoma is a rare form of cancer that usually presents as skin lesions, but can also develop in several other areas of the body including the lungs, lymph nodes and digestive system. Kaposi sarcoma is caused by Kaposi sarcoma-associated herpesvirus and most commonly arises in persons infected with HIV who are immunocompromised.
    - Kaposi sarcoma occurs at a rate of approximately 6 cases per million people each year.
- The approval of Pomalyst for the new indication was based on an open label, single center, and single arm study in 28 patients (18 HIV-positive, 10 HIV-negative) with Kaposi sarcoma. Patients received Pomalyst until disease progression or unacceptable toxicity. The major efficacy outcome measure was overall response rate (ORR), which included complete response, clinical complete response, and partial response.
    - In the overall population, the ORR was 71% (95% CI: 51, 87).
    - The median duration of response for all patients was 12.1 months (95% CI: 7.6, 16.8). Additionally, half (50%) of patients who responded maintained a response at more than 12 months with Pomalyst.
- Pomalyst carries a boxed warning for embryo-fetal toxicity and venous and arterial thromboembolism.
    - Pomalyst is only available through a restricted distribution program called Pomalyst REMS.
- The most common adverse reactions (≥ 30%) with Pomalyst use for treatment of Kaposi sarcoma were decreased absolute neutrophil count or white blood cells, elevated creatinine or glucose, rash, constipation, fatigue, decreased hemoglobin, platelets, phosphate, albumin, or calcium, increased alanine aminotransferase, nausea, and diarrhea.
- The recommended dosage of Pomalyst for Kaposi sarcoma is 5 mg orally once daily, with or without food, on days 1 through 21 of each 28-day cycle until disease progression or unacceptable toxicity.
    - HAART as HIV treatment should be continued in patients with AIDS-related Kaposi sarcoma.

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— Refer to the Pomalyst drug label for dosing in multiple myeloma.