RXADVANCE
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Pomalyst (pomalidomide) Capsules
Clinical Update

Clinical Update: U.S. Food and Drug Administration Approves Bristol Myers Squibb's Pomalyst (pomalidomide) for AIDS-Related and HIV-Negative Kaposi Sarcoma.
FDA approval date: May 14, 2020.

Pomalyst (pomalidomide) is a thalidomide analogue indicated for the treatment of patients with multiple myeloma and AIDS-related and HIV-negative Kaposi sarcoma. 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. The disease occurs at a rate of about 6 cases per million people each year in the United States, and mostly affects people who are immunocompromised. Boxed Warnings of the prescribing information, Pomalyst can cause fetal harm and is contraindicated in females who are pregnant. Pomalyst is only available through a restricted distribution program, Pomalyst REMS®. Deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke can occur in patients treated with Pomalyst and thromboprophylaxis is recommended.

U.S. Food and Drug Administration (FDA) approved Pomalyst (pomalidomide) for patients with AIDS-related Kaposi sarcoma whose disease has become resistant to highly active antiretroviral therapy (HAART), or in patients with Kaposi sarcoma who are HIV-negative. Pomalyst was granted accelerated approval, Breakthrough Therapy designation and Orphan Drug designation in these indications based on overall response rates observed in a Phase 1/2 open label, single-arm clinical trial (12-C-0047). Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. The approval of Pomalyst was based on the findings of a Phase 1/2 open-label, single-arm study conducted evaluating the safety, pharmacokinetics and efficacy of Pomalyst in patients with HIV-positive and HIV-negative symptomatic Kaposi sarcoma, the majority of whom had advanced disease. A total of 28 patients (18 HIV-positive, 10 HIV-negative) received 5 mg of Pomalyst, once daily for 21 of 28-day cycles, until disease progression or unacceptable toxicity. All HIV-positive patients continued concomitant highly active antiretroviral therapy (HAART). The trial excluded patients with symptomatic pulmonary or visceral Kaposi sarcoma, history of venous or arterial thromboembolism, or procoagulant disorders. The primary endpoint of the study was overall response rate (ORR), which included complete response (CR), clinical complete response (CCR) and partial response (PR), as assessed by investigators according to the AIDS Clinical Trial Group (ACTG) Oncology Committee response criteria for Kaposi sarcoma. For all patients, the ORR was 71% (95% CI: 51, 87) with 14% (4/28) of patients achieving CR and 57% (16/28) of patients achieving a PR, respectively. 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.