First New KS Treatment in Decades

The immune modulator Pomalyst led to remission in two thirds of people with AIDS-related Kaposi sarcoma.

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The Food and Drug Administration (FDA) has granted accelerated approval to Bristol Myers Squibb's Pomalyst (pomalidomide) as a treatment for AIDS-related Kaposi sarcoma (KS) in HIV-positive people whose virus is resistant to antiretroviral therapy as well as for KS in HIV-negative people.

"Pomalyst has shown positive results in Kaposi sarcoma patients, regardless of their HIV status," says Robert Yarchoan, MD, chief of the National Cancer Institute's HIV and AIDS Malignancy Branch. "Also, it provides a therapy that is taken orally and works by a different mechanism of action than the cytotoxic [toxic to cells] chemotherapy drugs generally used to treat Kaposi sarcoma."

Pomalyst boosts the body's natural immune system defenses against cancer cells while also suppressing cancer cell growth and blocking the development of blood vessels that feed tumors.

Pomalyst was evaluated in a Phase I/II clinical trial that included 18 HIV-positive and 10 HIV-negative people with KS, most of whom had advanced cases.

The participants received 5 milligrams of Pomalyst in pill form in three-weeks-on, one-week-off cyles that repeated until their KS progressed or they experienced unacceptable side effects. They also received daily aspirin to reduce the risk of blood clots. All the HIV-positive participants were taking antiretrovirals.

Two thirds of the HIV-positive participants and 80% of the HIV-negative participants saw their KS respond to the treatment. The median duration of such a response was about a year.

Eleven percent of the participants stopped Pomalyst due to side effects.

Drugs that receive accelerated approval based on early results are expected to undergo further testing in larger randomized trials.

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