Health Canada OKs Imbruvica for Treating Chronic Graft-Versus-Host Disease

lymphomanewstoday.com/2017/10/31/janssen-inc-announces-imbruvica-ibrutinib-as-the-first-approved-treatment-for-chronic-graft-versus-host-disease-cgvhd-granted-by-health-canada-priority-review/

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Janssen's Imbruvica (ibrutinib) has been approved by Health Canada for treating chronic graft-versus-host disease (cGVHD), a life-threatening condition that some patients develop after a stem cell transplant.

Following a priority review, Health Canada approved the drug as an oral, once-daily therapy for patients with steroid dependent or resistant cGVHD. The U.S. Food and Drug Administration approved Imbruvica for the same purpose in August.

Imbruvica is a first-in-class Burton's tyrosine kinase (BTK) inhibitor. Health Canada's decision was based on results from the ongoing PCYC-1129 Phase 1b/2 trial (NCT02195869) showing that the drug is safe and efficacious in treating the condition.

"Symptoms related to cGVHD can have a significant impact on a patient's quality of life, and for most they come after an already long and difficult battle with a life-threatening disease such as leukemia or lymphoma," Andrew Daly, MD, director of the Alberta Blood and Marrow Transplant Program said in a press release. Daly also is clinical associate professor at the Cumming School of Medicine, University of Calgary. "Physicians have had a real challenge finding options with compelling clinical data to treat cGVHD safely and effectively. This approval provides a much-needed new approach for patients who fail initial therapy, as data shows treatment with Imbruvica resulted in improved patient outcomes," Daily said.

cGVHD is a life-threatening condition. It is a complication of stem cell transplants that happens when a donor's immune cells attack the patient's body, and occurs in 30 to 70 percent of patients who receive stem cells from a partially matched donor (a sibling, for example). But current therapies involve corticosteroids, which damped the immune system and make patients more susceptible to infections or cancer progression.

The Phase 1b/2 trial (NCT02195869) of Imbruvica included 42 patients with steroid dependent or refractory cGVHD, whose first line corticosteroid therapy had failed. Their ages ranged from 19 to 74 years.

The most common malignancies that led to transplantation were acute lymphocytic leukemia (ALL), acute myeloid leukemia (AML), and chronic lymphocytic leukemia (CLL).

Of the 42 patients, 21 percent achieved complete responses while 45 percent showed partial responses. Doses of steroids were reduced over the course of the study, with five patients completely discontinuing corticosteroids.

"Lymphoma and leukemia patients are among those who may be able to get a stem cell transplant and achieve a potential cure. The procedure also comes with a high risk of cGVHD, which can have a severe impact on a patient's ability to work and go about their day-to-day life," said Robin Markowitz, CEO, Lymphoma Canada. "To date, many patients have had to rely on immunosuppressants and high-dose steroids to treat their cGVHD symptoms, and these come with significant issues. It is great news that patients finally have an approved treatment option."

Pharmacyclics, AbbVie, and Janssen Biotech are all involved in the development and commercialization of Imbruvica.