

Notice of Compliance issued regarding Rezurock(TM) (belumosudil tablets)

TORONTO, March 21, 2023 /CNW/ - sanofi-aventis Canada Inc. (Sanofi Canada) is pleased to announce that Health Canada has issued a Notice of Compliance ("NOC") for Rezurock™ (belumosudil tablets), for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy.¹

Chronic GVHD is a complication that can occur following allogeneic stem cell transplantation, resulting in significant morbidity and mortality.² In Chronic GVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joint, liver, lung, esophagus and gastrointestinal tract.²⁻⁴



Dr. Kirk Schultz

MD, FCAHS, President, Cell Therapy Transplant Canada

"Chronic graft-versus-host disease is systemic, so it can negatively affect multiple organs in a person's body. This includes fibrosis, which can have a devastating impact on a patient's health and well-being. I welcome the approval of Rezurock™ in Canada because it brings a new treatment option to patients who are experiencing severe and life-threatening symptoms."

Dr. Corey Cutler

MD, MPH, FRCPC, Professor of Medicine at Harvard Medical School and Medical Director, Adult Stem Cell Transplantation Program at the Dana-Farber Cancer Institute

"Rezurock™ is adding to the existing therapeutic options. It was developed specifically for the treatment of chronic graft-versus-host disease and it has anti-fibrotic properties. If left untreated fibrosis can lead to hardening and scarring of organ tissue, which is one of the main causes of morbidity in people with chronic graft-versus-host disease."

Dr. Gizelle Popradi

MDCM, Assistant Professor, Department of Medicine, Division of Hematology, Faculty of Medicine and Health Sciences, McGill University

"The severe symptoms of chronic graft-versus-host disease, including fibrosis, can impose a heavy burden on patients and significantly impact their quality of life. With limited treatment options and high-mortality rates among patients, approval of Rezurock™ brings patients an additional treatment option after other lines of therapy have failed."

Ahmed Moussa

General Manager, General Medicines, Sanofi Canada

"At Sanofi, we are dedicated to addressing the unmet medical needs of the patients suffering from the debilitating effects of chronic graft-versus-host disease. The availability of Rezurock™ represents an advancement for patients who have undergone a stem cell transplant and require treatment for chronic graft-versus-host disease."

About Studies

The Rezurock™ product monograph includes data from Study KD025-208 and Study KD025-213, a phase 2 clinical trial evaluating the safety of Rezurock™ in patients with chronic GVHD. Please refer to the product monograph for more information.

About Rezurock™

Rezurock™ is an inhibitor of Rho-associated, coiled-coil containing protein kinase-2 (ROCK2) and ROCK1, with IC50 values of approximately 100 nM and 3 µM, respectively. Belumosudil downregulated proinflammatory responses via modulation of CD4+ T-cell activity and STAT3/STAT5 phosphorylation in ex vivo or in vitro human T cell assays. Belumosudil also inhibited pro-fibrotic signaling in vitro. In vivo, Rezurock™ demonstrated activity in animal models of chronic GVHD.¹

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment

options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

For more information about Rezurock™, refer to the [Canadian Product Monograph](#).

References

1. Rezurock™ Product Monograph, October 19, 2022.
2. Leukemia & Lymphoma Society of Canada. Graft-Versus-Host Disease. Available at: https://www.bloodcancers.ca/sites/default/files/2022-02/2022%20LLSC%20Fact%20Sheet-Disease-GVHD_Final_EN%20%28with%20logo%29.pdf. Accessed March 15, 2023.
3. Canadian Cancer Society. Graft-Versus-Host Disease. Available at: <https://cancer.ca/en/treatments/side-effects/graft-versus-host-disease-gvhd#:~:text=Graft%2Dversus%2Dhost%2Ddisease,identify%20and%20destroy%20cancer%20cells>. Accessed March 15, 2023.
4. Kitko CL, White ES, Baird K. Fibrotic and sclerotic manifestations of chronic graft-versus-host disease. Biol Blood Marrow Transplant. 2012 Jan; 18(1 Suppl): S46-52. doi: 10.1016/j.bbmt.2011.10.021. PMID: 22226112; PMCID: PMC3260451.

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