

Ilaris® receives Health Canada approval as first of its kind treatment for rare, inflammatory disorder, adult-onset Still's disease

Apr 29, 2021

- The approval of Ilaris (canakinumab) in the treatment of adult-onset Still's disease (AOSD) brings hope for Canadians living with this rare, debilitating, and sometimes life-threatening inflammatory disorder.
- Ilaris, an interleukin-1 beta inhibitor, provides a new mode of treatment for this disease which previously had limited options.^{1,2}

Dorval, QC, April 29, 2021— Novartis Pharmaceuticals Canada Inc. is pleased to announce that Health Canada has approved Ilaris® (canakinumab) for the treatment of active Still's disease, including adult-onset Still's disease (AOSD)¹. AOSD is a rare form of inflammatory arthritis that can be a complex disease with variable presentation and potentially life-threatening complications².

This new indication follows the existing approval of Ilaris for Systemic Juvenile Idiopathic Arthritis (SJIA)¹, now allowing patients over the age of 16 to be treated. Characteristics of AOSD have considerable overlap with SJIA, which includes fever, arthritis, rash and elevated markers for inflammation, suggesting these as similar conditions under the same disease continuum but with different ages of onset³. AOSD is complex, multigenic, disruptive, and difficult to diagnose⁴. The disease can vary from an indolent chronic condition to a severe and highly symptomatic one from patient to patient^{2,4}.

The availability of Ilaris for the treatment of adult-onset Still's disease represents a significant advancement for Canadians currently suffering from this potentially life-threatening autoinflammatory condition, and also for the expansion of research in this field," said Dr. Derek Haaland, rheumatologist, clinical immunologist and allergist in Barrie, Ontario. "This development also brings with it much-needed awareness of AOSD and other related autoinflammatory disorders that are rare and too often don't receive the attention they deserve."

New treatments have been slow to develop for AOSD, in part because its rarity and complexity make it difficult for the scientific community to study⁴. While the clinical manifestations of AOSD are similar to other autoinflammatory diseases in some ways, including the characteristic of interleukin involvement, it is differentiated by the length and severity of flares, the occurrence of bone and cartilage destruction, and the apparent lack of genetic origin⁴. As such, the availability of a therapy for AOSD that inhibits interleukin-1 beta is significant.

"With rare autoinflammatory diseases like AOSD, we are especially eager to provide new treatment options for patients who too often have limited options," said Andrea Marazzi, Country Head, Novartis Pharmaceuticals Canada. "We are proud to announce this latest approval for Ilaris and are hopeful that it will open the door to reimagining care for adult Canadian patients."

Ilaris is a genetically engineered high-affinity human anti-human-interleukin-1 beta (IL-1β) monoclonal antibody, administered by subcutaneous injection every four weeks in the treatment of AOSD¹. As a targeted biological therapy, Ilaris is an entirely new mode of treatment for this disease, which has historically been

managed with corticosteroids and nonsteroidal anti-inflammatory drugs^{1,2}.

AOSD is estimated to affect less than one per 100,000 people³. First described in 1971, the disorder presents with high spiking fevers, skin rash, sore throat, abnormal liver function, and joint symptoms⁴.

In addition to AOSD and SJIA, Ilaris is also approved for a number of autoinflammatory Periodic Fever Syndromes, including Cryopyrin-Associated Periodic Syndrome (CAPS) in adults and children¹.

About Novartis Pharmaceuticals Canada

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. In 2020, the company invested \$45 million in research and development in Canada. Located in Dorval, Quebec, Novartis Pharmaceuticals Canada Inc. employs approximately 1,000 people in Canada and is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. For further information, please consult <https://www.novartis.com/ca-en/en/>

About Novartis

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Ilaris is a registered trademark.

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