

Kevzara® approved in Canada for the treatment of adults with polymyalgia rheumatica (PMR)

- The first monoclonal antibody in Canada indicated for the treatment of adult patients with polymyalgia rheumatica (PMR)
- Nearly tripled the remission rates (28.3% vs 10.3%) compared to placebo in adult PMR patients after one year.

Toronto, May 9, 2025. Health Canada has issued a Notice of Compliance (NOC) for Kevzara (sarilumab injection) for the treatment of adult patients with PMR, an inflammatory rheumatic disease, who have had an inadequate response to corticosteroids, or who have experienced a relapse during corticosteroid taper¹.

The approval is based on the SAPHYR trial demonstrating Kevzara's effectiveness in PMR by measuring sustained disease remission at one year, with treated patients achieving an almost three times higher remission rates (28.3% vs. 10.3%) compared to placebo in adult PMR patients.

Dr. Stephanie Garner

MD, FRCPC, Clinical Assistant Professor of Medicine, Division of Rheumatology, Department of Medicine University of Calgary

"I've seen firsthand the challenges of managing this condition with corticosteroids alone. The SAPHYR trial results demonstrate that Kevzara can help patients achieve sustained remission while significantly reducing their cumulative steroid exposure. This approval represents an important new option in our therapeutic arsenal that could fundamentally change our approach to treating PMR."

Stephanie Veyrun-Manetti

General Manager, Specialty Care and Country Lead Sanofi Canada

"The approval of Kevzara for polymyalgia rheumatica reflects our commitment to addressing significant unmet needs in inflammatory conditions for Canadians. We're proud to bring forward an innovative treatment option that offers these patients the possibility of sustained disease control while giving the possibility of sustained remission while potentially reducing their steroid burden—a balance that has been difficult to achieve until now."

This marks the second indication approved in Canada for Kevzara, following earlier approval in 2017 for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more biologic or non-biologic Disease-Modifying Anti-Rheumatic Drugs¹

About Polymyalgia Rheumatic (PMR)

PMR often initially presents with pain and stiffness around the neck, shoulder, and hip area and symptoms include fatigue, low-grade fever, and weight loss. Patients often experience flares during tapering of, or relapse after discontinuation of corticosteroid treatment. Patients with PMR report difficulty in carrying out everyday functions such as getting out of bed, standing up from a chair, or lifting their arms. PMR generally affects people who are 50 years and older.

About Kevzara

Kevzara (sarilumab) is a fully human IgG1 monoclonal antibody that binds specifically to both soluble and membrane-bound IL-6 receptors (sIL-6R α and mIL-6R α), and has been shown to inhibit IL-6-mediated signaling through these receptors.

IL-6 is an immune system protein produced in increased quantities in patients with rheumatoid arthritis and has been associated with disease activity, joint destruction and other systemic problems.

Sarilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

About Sanofi

Sanofi is an R&D-driven, AI-powered biopharma company guided by our purpose: we chase the miracles of science to improve people's lives. We apply our deep understanding of the immune system to advance breakthrough science and transform the lives of millions through innovative medicines and vaccines.

In Canada, we employ over 2,000 people and invest 20% of our revenue annually in biopharma research, representing \$1.2 billion CAD in R&D over the last decade, creating jobs, business, and opportunity throughout the country. We are on track to deliver over \$2 billion in new infrastructure investments by 2028, including two new vaccine manufacturing facilities at our Toronto Campus. We work in collaborative partnerships with a vast network of healthcare stakeholders and are committed to creating a healthier future in Canada.

2025 marks our 111th year dedicated to developing innovative health solutions for Canadians. What started as a small laboratory in May of 1914, recognized for having advanced some of the greatest contributions to public health, both nationally and globally, has evolved to become the largest biomanufacturing facility in Canada.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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¹ Kevzara Product Monograph
