



## PRESS RELEASE

### Health Canada Approves the Use of RINVOQ® (upadacitinib) for the Treatment of Adults and Adolescents with Moderate to Severe Atopic Dermatitis

- *Authorization is based on the results from three Phase 3 multicenter, randomized, double-blind, placebo-controlled registrational clinical trials evaluating the efficacy and safety of RINVOQ (upadacitinib) in monotherapy or in combination with topical corticosteroids.<sup>1</sup>*
- *RINVOQ demonstrated improvements in skin clearance and itch reduction compared to placebo.*
- *Milestone marks the third Health Canada-approved indication for RINVOQ<sup>1†</sup>*

**MONTREAL, QC, October 7, 2021** – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that Health Canada has approved RINVOQ® (upadacitinib), an oral, once-daily selective JAK inhibitor for the treatment of adults and adolescents 12 years of age and older with refractory moderate to severe atopic dermatitis (AD) who are not adequately controlled with a systemic treatment (e.g., steroid or biologic) or when use of those therapies is inadvisable. RINVOQ® can be used with or without topical corticosteroids.”

Atopic dermatitis (AD) is characterized by intense uncontrolled itching, dry skin, which becomes cracked, hardened, oozing and painful. It is estimated that up to 17% of Canadians will suffer from AD at some points in their lives.<sup>2</sup>

“Atopic dermatitis is a chronic inflammatory skin disease that impacts both patients and caregivers. As atopic dermatitis is common at all ages, it affects many Canadians. I have seen first-hand the debilitating impact of atopic dermatitis on patients through my research and my practice,” states Dr. Kim Alexander Papp, MD, PhD, FRCPC, Probitry Medical Research and K. Papp Clinical Research, Waterloo ON. “If we hope to improve patients’ overall quality of life, clinicians need more tools. Having access to advanced therapies allows us to better support patients and provide them with treatment outcomes that address their unmet needs.”

The Health Canada authorization is supported by data from a large registrational Phase 3 clinical trial program in atopic dermatitis including more than 2,500 adults and adolescents with moderate to severe disease.<sup>1</sup> These multicenter, randomized, double-blind, placebo-controlled registrational clinical trials evaluated the efficacy and safety of RINVOQ monotherapy (Measure Up 1 [MU1] and Measure Up 2 [MU2]) and with topical corticosteroids (AD Up [AU]) compared to placebo.<sup>1 3 4</sup> In all three studies, the co-primary endpoints were at least a 75 percent improvement in the Eczema Area and Severity Index (EASI 75) and validated Investigator's Global Assessment for Atopic Dermatitis (vIGA-AD) score of 0/1 (clear or almost clear) at week 16.<sup>1 3 4</sup>



Eczema Society of Canada's Executive Director Amanda Cresswell-Melville highlights the burden of atopic dermatitis. "The impacts of atopic dermatitis on quality of life for both patients and caregivers are often underestimated and misunderstood," says Cresswell-Melville. "Patients may be seeking additional options to address their unmet needs in the management of their condition. New treatment options bring hope to these patients."

Chronic inflammatory skin diseases go well beyond the surface and affect both physical and mental health. The exact cause of atopic dermatitis is unknown, but a combination of immune, genetic, and environmental factors is believed to be involved.<sup>3</sup>

"AbbVie is dedicated to the pursuit of innovation in life sciences and advancing the standards of care for patients," says Tracey Ramsay, Vice President and General Manager, AbbVie Canada. "We are proud of our strong heritage in dermatology and continue to deepen our understanding of the complex nature of serious inflammatory skin conditions. Through this milestone in atopic dermatitis, we remain committed to developing and delivering leading-edge therapies for patients who need them most."

### **About RINVOQ® (upadacitinib)**

RINVOQ is a once-daily oral medication in an extended-release tablet. It is a Janus kinase (JAK) inhibitor that interferes with the JAK-STAT signaling pathway, which is thought to play a role in inflammatory response.

RINVOQ is indicated for the treatment of adults and adolescents 12 years of age and older with refractory moderate to severe atopic dermatitis (AD) who are not adequately controlled with a systemic treatment (e.g., steroid or biologic) or when use of those therapies is inadvisable. RINVOQ can be used with or without topical corticosteroids.

For therapeutic and important safety information, please consult the RINVOQ Product Monograph at [www.abbvie.ca](http://www.abbvie.ca).

### **About AbbVie in Dermatology**

For more than a decade, AbbVie has worked to uncover new solutions and improve care for people with serious skin diseases. With a broad clinical trial program, we continue to actively research and adapt to the evolving needs of the dermatology community and advance our pipeline to help people achieve their treatment goals and live beyond their skin disease.

### **About AbbVie**

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at [www.abbvie.ca](http://www.abbvie.ca). Follow [@abbviecanada](https://twitter.com/abbviecanada) on Twitter or find us on LinkedIn.



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<sup>1</sup> RINVOQ (upadacitinib) Product Monograph. AbbVie Corporation. Available at [https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/RINVOQ\\_PM\\_EN.pdf](https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/RINVOQ_PM_EN.pdf).

<sup>2</sup> Canadian Dermatology Association. *Eczema* <https://dermatology.ca/public-patients/skin/eczema/>

<sup>3</sup> Guttman-Yassky E., et al. Once-daily upadacitinib versus placebo in adolescents and adults with moderate-to-severe atopic dermatitis (Measure Up 1 and Measure Up 2): results from two replicate double-blind, randomised controlled phase 3 trials. *Lancet*. 2021; 397(10290): 2151-2168. doi:10.1016/S0140-6736(21)00588-2.

<sup>4</sup> Reich K, Teixeira HD, Bruin-Weller, et al. Safety and efficacy of upadacitinib in combination with topical corticosteroids in adolescents and adults with moderate-to-severe atopic dermatitis (AD Up): results from a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2021; 397(10290): 2169-2181.

<sup>5</sup> Eczema Society of Canada. *What is eczema?* <https://eczemahelp.ca/about-eczema/>

<sup>†</sup> RINVOQ® is registered trademark of AbbVie Corporation.