



adolescent patients (12 to 17 years of age weighing  $\geq 30$  kg), who have not responded to conventional therapy (including systemic antibiotics).

- Treatment of adult patients with chronic moderate to severe plaque psoriasis (Ps) who are candidates for systemic therapy.
- Treatment of non-infectious uveitis (intermediate, posterior and panuveitis) in adult patients with inadequate response to corticosteroids or as corticosteroid sparing treatment in corticosteroid-dependent patients.
- Treatment of chronic non-infectious anterior uveitis in pediatric patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.<sup>7</sup>

HADLIMA<sup>®</sup> is a fully human monoclonal antibody that binds to a specific protein called tumor necrosis factor (TNF-alpha), which is made by the body's immune system. People with RA, PsA, AS, CD, UC, HS or psoriasis have too much of TNF-alpha in their bodies.<sup>8</sup> The presence of extra TNF-alpha in the body can attack normal healthy body tissues and cause inflammation, particularly in the bone, cartilage, joints, digestive tract and skin tissues. By binding to TNF-alpha, HADLIMA<sup>®</sup> decreases the inflammation process of these diseases.<sup>9</sup>

Approximately six million (one in five) Canadians are living with arthritis, making it Canada's most prevalent chronic health condition.<sup>10</sup> While there are many different subtypes of arthritis, inflammatory arthritis includes a group of conditions that impact the body's immune system. The most common forms of inflammatory arthritis are RA, AS and PsA.<sup>11</sup>

An estimated 270,000 Canadians live with inflammatory bowel disease (IBD), a group of disorders caused by inflammation in the intestines.<sup>12</sup> The main forms of IBD are CD and UC.<sup>13</sup> By 2030, the number of Canadians with IBD is expected to rise to 400,000 or approximately 1% of the population.<sup>14</sup>

It is estimated that over one million Canadians are currently living with HS, a chronic skin condition that causes lumps to appear in the folds of the skin.<sup>15</sup> Psoriasis, also a chronic skin condition, affects approximately one million Canadians, and Ps affects approximately 90% of this patient population.<sup>16</sup>

Uveitis, an inflammatory disease that causes damage to the eye, causes about 20% of legal blindness. Every year, approximately 2% of the Canadian population is newly diagnosed with uveitis.<sup>17</sup>

"HADLIMA<sup>®</sup> further expands Merck's portfolio of biosimilar treatments to address inflammatory and dermatological immune diseases," says Anna Van Acker, President, Merck Canada. "We are very proud to bring more solutions and therapeutic choices to help improve the lives of Canadians with these chronic conditions."

### **About HADLIMA<sup>®</sup>**

HADLIMA<sup>®</sup> is a biosimilar biologic drug (biosimilar) and authorized based on its similarity to HUMIRA<sup>®</sup>. A biosimilar is a biologic drug that is highly similar to a biologic drug already authorized for sale.<sup>18</sup> Biosimilars are assessed and approved by Health Canada against the

same rigorous standards used to ensure the quality, efficacy and safety as in any other biologic drug.<sup>19</sup> Biosimilars provide patients more treatment options to help manage their disease and symptoms.

Clinical efficacy and safety studies have been conducted in patients with RA to demonstrate clinical comparability between HADLIMA<sup>®</sup> and HUMIRA<sup>®</sup>. The extrapolation of these data to support uses of HADLIMA<sup>®</sup> in IBD is based on the demonstrated comparability, in terms of product quality, non-clinical, human pharmacokinetic and clinical characteristics. Randomized clinical trials have not been conducted to compare HADLIMA<sup>®</sup> to HUMIRA<sup>®</sup> in patients with JIA, PsA, AS, adult CD, UC, HS, Ps, and adult uveitis.<sup>22</sup>

The types, frequency and severity of adverse events were comparable between HADLIMA<sup>®</sup> and HUMIRA<sup>®</sup> in the RA clinical trial. The most common expected adverse reactions with HADLIMA<sup>®</sup> are injection site reactions and cough and cold symptoms. It should not be administered to patients with severe infections such as sepsis and tuberculosis. HADLIMA<sup>®</sup> contains a Boxed Warning to alert health care professionals and patients about an increased risk of hepatosplenic T-cell lymphoma (HSTCL), a rare, serious lymphoma that is often fatal, which has been identified in patients treated with adalimumab injection. The Boxed Warning also notes allergic reactions, other cancers, lupus-like symptoms, nervous system diseases, serious infections and blood problems.

The Merck Harmony Patient Program provides free confidential patient-assistance services to patients who have been prescribed HADLIMA<sup>®</sup> (adalimumab injection). To learn more visit [MerckHarmony.ca](http://MerckHarmony.ca).

## **About Merck**

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals — including cancer, infectious diseases such as HIV and Ebola and emerging animal diseases — as we aspire to be the premier research-intensive biopharmaceutical company in the world.

In Canada, Merck markets a broad range of vaccines, pharmaceutical and animal health products and is one of the top R&D investors in Canada, with investments totaling \$89 million in 2019 and more than \$1.3 billion since 2000. Based in Kirkland, Québec, Merck employs approximately 650 people across the country. For more information about our operations in Canada, visit [www.merck.ca](http://www.merck.ca) and connect with us on [YouTube](#) and [Twitter](#) @MerckCanada.

## **Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current

beliefs and expectations of the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

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Please see the product monograph for HADLIMA<sup>®</sup> (adalimumab injection) at: [https://www.merck.ca/static/pdf/HADLIMA-PM\\_E.pdf](https://www.merck.ca/static/pdf/HADLIMA-PM_E.pdf)

## References

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<sup>4</sup> The Canadian Skin Patient Alliance. Hidradenitis Suppurativa. Available at: [https://www.canadianskin.ca/hidradenitis-suppurativa#:~:text=Overview%20%2D%20What%20is%20HS,-Hidradenitis%20Suppurativa%20\(HS&text=Lumps%20that%20are%20close%20together,out%20a%20dermatologist%20for%20help](https://www.canadianskin.ca/hidradenitis-suppurativa#:~:text=Overview%20%2D%20What%20is%20HS,-Hidradenitis%20Suppurativa%20(HS&text=Lumps%20that%20are%20close%20together,out%20a%20dermatologist%20for%20help). Accessed on February 16, 2021.

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<sup>7</sup> HADLIMA<sup>®</sup> Product Monograph. Merck & Co. Inc. November 2020.

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- <sup>8</sup> HADLIMA® Product Monograph. Merck & Co. Inc. November 2020.
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