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### **BRENZYS® (etanercept injection) now indicated for the Treatment of Plaque Psoriasis, Psoriatic Arthritis and Juvenile Idiopathic Arthritis**

- BRENZYS® is a biosimilar biologic drug authorized based on its similarity to ENBREL®, which is already approved for use in Canada.<sup>1</sup>
- Approximately one million people in Canada live with psoriasis,<sup>2</sup> and between 10 and 30% of people with psoriasis will develop psoriatic arthritis.<sup>3</sup>

**KIRKLAND, QC – September 15, 2020** - Merck Canada Inc., an affiliate of Merck & Co., Inc., known as MSD outside the United States and Canada, announced today that Health Canada has approved BRENZYS®, a TNF-inhibitor, for four new indications:

- Adult patients with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
- Pediatric patients ages 4 to 17 years with chronic severe PsO who are candidates for systemic therapy or phototherapy
- Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis and improving physical function in adult patients with psoriatic arthritis (PsA)
- Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients aged 4 to 17 years who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).<sup>4</sup>

BRENZYS® is a type of protein called a tumour necrosis factor (TNF) blocker that blocks the action of a substance the body makes called TNF-alpha. TNF-alpha is made by the body's immune system.<sup>5</sup> People with immune diseases like JIA, PsA and PsO have too much TNF-alpha in their bodies, which can cause inflammation and lead to painful, swollen joints and raise thick, red, scaly patches ("psoriatic skin lesions") that can appear anywhere on the body.<sup>6</sup> It can reduce the amount of TNF in the body to normal levels, helping to treat joint damage and psoriatic skin conditions.<sup>7</sup>

An estimated one million Canadians live with psoriasis,<sup>8</sup> and between 10 and 30% of these patients will develop psoriatic arthritis.<sup>9</sup> Plaque Psoriasis is an inflammatory disease that affects the skin and can cause psoriatic skin lesions that can appear anywhere on the body.<sup>10</sup> About 80% to 90% of people with psoriasis have plaque psoriasis, the most common type of psoriasis.<sup>11</sup> PsA is usually seen in patients with PsO and affects both the joints and the skin.<sup>12</sup> JIA is an inflammatory disease that affects the joints in the body and is the most common type of arthritis in children under the age of 16.<sup>13</sup> Approximately 10,000 children and teens live with arthritis in Canada.<sup>14</sup>

"Merck is committed to providing Canadians with more therapeutic choices for patients and their

treaters,” says AnnA Van Acker, President, Merck Canada. “BRENZYS® adds to Merck’s portfolio of treatments for dermatological and inflammatory immune diseases and can help improve quality of life for patients living with psoriasis, psoriatic arthritis or juvenile idiopathic arthritis, as well as rheumatoid arthritis and ankylosing spondylitis.”

### **About BRENZYS®**

BRENZYS® is a biosimilar biologic drug (biosimilar)<sup>15</sup> and authorized based on its similarity to ENBREL®, which is already approved for use for PsO, PsA and JIA in Canada.<sup>16</sup> A biosimilar is a biologic drug that is highly similar to a biologic drug already authorized for sale.<sup>17</sup> Biosimilars are assessed and approved by Health Canada against the same meticulous standards used to ensure the quality, efficacy and safety of all other biologic drugs.<sup>18</sup> Biosimilars provide patients more treatment options to help manage their disease and symptoms.

In addition to its use for the treatment of JIA, PsO and PsA, BRENZYS® was first approved by Health Canada in 2016 for the treatment of moderate-to-severe rheumatoid arthritis (RA) in adults and ankylosing spondylitis (AS).<sup>19</sup> It is administered by an injection under the skin and should be used under the guidance and supervision of a physician.<sup>20</sup>

Clinical efficacy and safety studies have been conducted in patients with rheumatoid arthritis to demonstrate clinical comparability between BRENZYS® and ENBREL®. The extrapolation of these data to support uses of BRENZYS® in ankylosing spondylitis 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 BRENZYS® to Enbrel® in patients with psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, juvenile idiopathic arthritis and pediatric psoriasis.<sup>22</sup>

The most common expected adverse reactions with BRENZYS® are infections, injection site reactions and headaches. It should not be administered to patients with or at risk of sepsis. BRENZYS® contains a Boxed Warning to alert health care professionals and patients about an increased risk of serious infections including tuberculosis and infections caused by bacteria, viruses or fungi that have spread throughout their body. The Boxed Warning also notes that malignancies, sometimes fatal, have been reported in children and teenage patients who started using TNF-blocking agents, including etanercept, at less than 18 years of age.<sup>26</sup>

### **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 BRENZYS® (etanercept injection) at:

[https://www.merck.ca/static/pdf/BRENZYS-PM\\_E.pdf](https://www.merck.ca/static/pdf/BRENZYS-PM_E.pdf)

### **References**

<sup>1</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.

<sup>2</sup> Psoriasis. Canadian Dermatology Foundation. 2020.

<sup>3</sup> Psoriatic Arthritis. Arthritis Society. 2020. [https://arthritis.ca/about-arthritis/arthritis-types-\(a-z\)/types/psoriatic-arthritis](https://arthritis.ca/about-arthritis/arthritis-types-(a-z)/types/psoriatic-arthritis)

<sup>4</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.

<sup>5</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.

<sup>6</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.

<sup>7</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.

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- <sup>8</sup> Psoriasis. Canadian Dermatology Foundation. 2020.
- <sup>9</sup> Psoriatic Arthritis. Arthritis Society. 2020. [https://arthritis.ca/about-arthritis/arthritis-types-\(a-z\)/types/psoriatic-arthritis](https://arthritis.ca/about-arthritis/arthritis-types-(a-z)/types/psoriatic-arthritis)
- <sup>10</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.
- <sup>11</sup> Symptoms. Canadian Association of Psoriasis Patients. 2014. [canadianpsoriasis.ca/index.php/en/psoriasis/81-english/psoriasis/94-symptoms#:~:text=About%2080%25%20to%2090%25%20of,with%20silvery%20scales%20on%20top](http://canadianpsoriasis.ca/index.php/en/psoriasis/81-english/psoriasis/94-symptoms#:~:text=About%2080%25%20to%2090%25%20of,with%20silvery%20scales%20on%20top)
- <sup>12</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.
- <sup>13</sup> <https://www.mayoclinic.org/diseases-conditions/juvenile-idiopathic-arthritis/symptoms-causes/syc-20374082>
- <sup>14</sup> 6 facts about Juvenile Idiopathic Arthritis. Montreal Children's Hospital. 2020. <https://www.thechildren.com/health-info/conditions-and-illnesses/6-facts-about-juvenile-idiopathic-arthritis>
- <sup>15</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.
- <sup>16</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.
- <sup>17</sup> Biosimilar Biologic Drugs in Canada: Fact Sheet. Government of Canada. August 27, 2019.
- <sup>18</sup> Biosimilar Biologic Drugs in Canada: Fact Sheet. Government of Canada. August 27, 2019.
- <sup>19</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.
- <sup>20</sup> BRENZYS® Product Monograph. Merck & Co. Inc. August 19, 2020.