



## **Indivior Announces Health Canada Approval of SUBLOCADE™ (Buprenorphine Extended-Release) Injection for Patients with Moderate to Severe Opioid Use Disorder**

*SUBLOCADE is the first and only once-monthly injectable buprenorphine formulation approved in Canada for the management of moderate to severe opioid use disorder*

**Slough, UK and Richmond, VA, 23 November 2018** – Indivior PLC (LON: INDV) today announced that Health Canada has approved SUBLOCADE™ (buprenorphine extended-release) injection for subcutaneous use, for the management of moderate to severe opioid use disorder (OUD) in adult patients who have been inducted and clinically stabilized on a transmucosal buprenorphine-containing product. SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support, and must only be administered once a month, subcutaneously in the abdominal region by a healthcare provider<sup>1</sup>. In Canada, SUBLOCADE will be marketed by Indivior Canada Ltd., and will be available by the second half of 2019.

“We are committed to helping the patients, families and communities impacted by the opioid epidemic around the world,” said Shaun Thaxter, Chief Executive Office of Indivior. “The approval of SUBLOCADE in Canada is an important milestone, and we look forward to continuing to partner with the Canadian treatment community to help those with opioid use disorder.”

Illicit opioid use in Canada is a national public health crisis that continues to grow, with 3,005 and 3,996 apparent opioid-related deaths in 2016 and 2017 respectively<sup>2</sup>. From January to March 2018, there were at least 1,036 apparent opioid-related deaths; of these deaths, 94% were accidental and 73% involved fentanyl or fentanyl analogues<sup>2</sup>. Despite this growing crisis, barriers such as stigma continue to prevent patients from accessing treatment<sup>3</sup>.

SUBLOCADE, in combination with counseling and psychosocial support, is a once-monthly medication-assisted treatment (MAT) that contains buprenorphine, a mu-opioid receptor agonist. It uses the ATRIGEL® Delivery System and solidifies on contact with bodily fluids to deliver buprenorphine over the one month period<sup>2</sup>.

In clinical trials, common adverse reactions (≥5% patients) included constipation, nausea, vomiting, headache, fatigue, insomnia, hepatic enzymes increased, and injection site pain and pruritus<sup>1</sup>. Injection site reactions were reported in 16% of the patients<sup>1</sup>. None of the injection site reactions were serious and one led to study treatment discontinuation<sup>1</sup>. SUBLOCADE has a SERIOUS WARNINGS AND PRECAUTIONS BOX. Serious harm or death could result if administered intravenously<sup>1</sup>.

This approval from Health Canada follows approval of SUBLOCADE by the U.S. Food and Drug Administration (FDA) on November 30, 2017.

### **About SUBLOCADE™**

In Canada, SUBLOCADE is indicated for the management of moderate to severe opioid use disorder in adult patients who have been inducted and clinically stabilized on a transmucosal buprenorphine-

containing product. SUBLOCADE should be used as part of a complete treatment plan that includes counselling and psychosocial support. SUBLOCADE must only be administered subcutaneously in the abdominal region by a healthcare provider.

Contraindicated in:

- Patients who are hypersensitive to this drug or any ingredient in the formulation, including any non-medicinal ingredient, or any component of the ATRIGEL® Delivery System.
- Patients with severe respiratory insufficiency: e.g., acute or severe bronchial asthma, chronic obstructive airway, status asthmaticus, acute respiratory depression and/or cor pulmonale.
- Patients with severe hepatic impairment.
- Patients with acute alcoholism or delirium tremens.
- Patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
- Patients with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis).
- Patients with severe central nervous system (CNS) depression, increased cerebrospinal or intracranial pressure, and head injury.
- Patients taking monoamine oxidase (MAO) inhibitors (or within 14 days of such therapy).
- Patients with convulsive or seizure disorders.
- Congenital Long QT Syndrome or QT prolongation at baseline.
- Uncorrected hypokalemia, hypomagnesemia, or hypocalcemia.

Consult the product monograph for important information about:

- Serious warnings and precautions regarding incorrect administration, limitations of use, addiction, abuse and misuse, use during pregnancy, interaction with alcohol, neonatal opioid withdrawal syndrome, interaction with other central nervous system depressants and cardiac.
- Other warnings and precautions regarding intravenous administration, risk of misuse, abuse or diversion, risk of tissue damage, adrenal insufficiency, hypotension, QTc prolongation, dependence and risk of withdrawal with discontinuation, driving hazardous machinery, circumstances when cerebrospinal pressure may be increased, effects in acute abdominal conditions, elevation of intracholedochal pressure, hepatitis and hepatic events, monitoring and laboratory tests, peri-operative considerations, risk of respiratory and central nervous system depression, serotonin syndrome, reproduction, function and fertility, general precautions, unintentional pediatric exposure, use in opioid-naïve patients, pregnancy, labour or delivery, nursing women and geriatrics.
- Conditions of clinical use, adverse reactions, drug interactions and dosing instructions.

### **About Indivior**

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment models that have revolutionized modern addiction treatment. Our vision is for all patients around the world to have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. The name is the fusion of the words individual and endeavor, and the tagline “Focus on you” makes the Company’s commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-occurring disorders of addiction, including alcohol use disorder and schizophrenia. Headquartered in the

United States in Richmond, VA, Indivior employs more than 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit [www.indivior.com](http://www.indivior.com) to learn more.

### **Forward-Looking Statements**

This press release contains certain statements that are forward-looking, and which should be considered, amongst other statutory provisions, in light of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that may or may not occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2018 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the ongoing investigative and antitrust litigation matters; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

This press release does not constitute an offer to sell or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

### **References**

1. SUBLOCADE™ [Canada Prescribing Information]. Indivior UK Limited.
2. Special Advisory Committee on the Epidemic of Opioid Overdoses. National report: Apparent opioid-related deaths in Canada (January 2016 to March 2018) Web-based Report. Ottawa: Public Health Agency of Canada; September 2018.
3. Government of Canada. Together, we can stop the cycle of stigma. Retrieved from: <https://www.canada.ca/en/health-canada/services/video/stop-the-cycle-of-stigma.html>. Accessed September 2018.

### **Media Contacts**

Jonathan Sibun  
Tulchan Communications  
+44 207-353-4200

U.S. Media Inquiries  
IndiviorMediaContacts@indivior.com  
+1 804-594-0836

**Investor Contact**

Jason Thompson, Indivior  
Vice President, Investor Relations  
Jason.Thompson@indivior.com  
+1 804-423-8916

SUBLOCADE is a trademark of Indivior UK Limited.

© Indivior PLC | INDIVIOR is a registered trademark of Indivior UK Limited | All rights reserved