



**Indivior Announces New Drug Submission to Health Canada for SUBLOCADE™ (Buprenorphine Extended-Release) Injection for the Treatment of Moderate to Severe Opioid Use Disorder**

*Health Canada Grants Priority Review Designation for SUBLOCADE™*

**Slough, UK and Richmond, VA, 20 April 2018** – Indivior PLC (LON: INDV) today announced that it has filed a New Drug Submission (NDS) with Health Canada’s Therapeutic Drugs Directorate for SUBLOCADE™ (buprenorphine extended-release) injection, for subcutaneous use, for the treatment of moderate to severe opioid use disorder (OUD) as part of a complete treatment plan to include counseling and psychosocial support. Health Canada granted Priority Review status for SUBLOCADE on April 6, 2018<sup>1</sup>. If approved, SUBLOCADE will be marketed by Indivior Canada Ltd.

“The Priority Review designation is an important acknowledgment by Health Canada of the potential for SUBLOCADE to help address the current unmet needs for patients living with opioid use disorder,” said Shaun Thaxter, Chief Executive Officer of Indivior. “Indivior looks forward to working closely with regulatory authorities to ensure SUBLOCADE, if approved, will be available as soon as possible to the Canadian treatment community to help address the current opioid public health crisis<sup>2</sup>.”

In granting the Priority Review status for the SUBLOCADE NDS, Health Canada noted that OUD is a serious, potentially life-threatening disorder and that there is substantial evidence of the clinical efficacy of SUBLOCADE in the treatment of moderate to severe OUD<sup>1</sup>. Health Canada also acknowledged that SUBLOCADE has the potential to yield improved efficacy through enhanced adherence, due to its monthly administration<sup>1</sup>.

A Priority Review designation indicates Health Canada's goal to review the NDS within a shortened target of 180 calendar days<sup>3</sup>. Priority Review designation may be granted to drug submissions intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases or conditions for which there is substantial evidence that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

The NDS submission of SUBLOCADE to Health Canada follows approval of the drug by the U.S. Food and Drug Administration (FDA) on November 30, 2017.

**About SUBLOCADE™**

IN CANADA, SUBLOCADE IS AN INVESTIGATIONAL PRODUCT AND ITS SAFETY AND EFFICACY IS CURRENTLY UNDER REVIEW BY HEALTH CANADA.

In the U.S., SUBLOCADE is indicated for the treatment of moderate to severe OUD in adult patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days<sup>4</sup>. It should be administered only by healthcare providers and

should be used as part of a complete treatment program that includes counseling and psychosocial support<sup>4</sup>. SUBLOCADE has a BOXED WARNING in the U.S. and is available through restricted distribution under the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program<sup>4</sup>.

SUBLOCADE uses the ATRIGEL<sup>®</sup> delivery system, which consists of a polymeric solution of a biodegradable poly-(DL-lactide-co-glycolide) co-polymer dissolved in N-methyl pyrrolidone (NMP), a water-miscible biocompatible solvent. After subcutaneous injection, NMP diffuses out of the polymer matrix and the polymer precipitates, trapping the drug inside and forming an amorphous solid depot in situ. The depot releases buprenorphine over a one-month period by diffusion as the polymer biodegrades.

### **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 1,000 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 harbour 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 will or may 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 our financial guidance for 2018 and our medium- and long-term growth outlook, our operational goals, our 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; 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. Indivior Data on File.
2. Government of Canada. (2017). Government of Canada Actions on Opioids: 2016 and 2017. Retrieved from: <https://www.canada.ca/en/health-canada/services/publications/healthy-living/actions-opioids-2016-2017.html>. Accessed April 16, 2018.
3. Government of Canada. (2009). Guidance for Industry – Priority Review of Drug Submissions. Retrieved from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/priority-review/drug-submissions.html#a2>. Accessed April 16, 2018.
4. SUBLOCADE™ [U.S. Prescribing Information]. Indivior Inc., North Chesterfield, VA. April 2018.

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