Indivior Announces Validation of Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for SUBOXONE® (buprenorphine and naloxone) Sublingual Film

Slough, UK, 18 June 2019 – Indivior PLC (LON: INDV) (the 'Company'), a global specialty pharmaceutical company with a 20-year legacy of leadership in developing medicines to treat opioid use disorder (OUD), today announced that the European Medicines Agency (EMA) has completed formal validation of Indivior's Marketing Authorization Application (MAA) for SUBOXONE Film. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process.

SUBOXONE Film contains buprenorphine, a partial-opioid agonist, and naloxone, an opioid antagonist, and is an investigational substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. The SUBOXONE Film MAA was submitted to the EMA on March 8, 2019.

The EMA review of the MAA for SUBOXONE Film will be according to standard timelines, with an opinion of the Committee for Medicinal Products for Human Use (CHMP) expected by the end of the year, and European Commission final decision in Q1/2020.

"The validation of our MAA by the EMA represents an important step forward in our effort to expand access to evidence-based treatment for patients struggling to overcome opioid use disorder in the EU," said Shaun Thaxter, Chief Executive Officer of Indivior.

"The availability of Suboxone Film will enable us to enhance the management of opioid dependence. As healthcare resources remain a challenge, reduced dissolution time may lead to reduced supervision time and may help us improve our treatment capacity. " said Dr Kaarlo Simojoki, Med Dir A-Clinic Finland.

About SUBOXONE Film

SUBOXONE Film IS AN INVESTIGATIONAL PRODUCT THAT HAS NOT BEEN APPROVED BY THE EUROPEAN MEDICINES AGENCY FOR SAFETY AND EFFICACY.
The SUBOXONE sublingual film safety information is based upon findings obtained during the clinical development of buprenorphine/naloxone sublingual tablets. The most commonly reported treatment related adverse reactions reported during the pivotal clinical studies were constipation and symptoms commonly associated with drug withdrawal (i.e. insomnia, headache, nausea, and hyperhidrosis and pain).

SUBOXONE Film was first approved by the U.S. Food and Drug Administration (FDA) on August 30, 2010 for the treatment of opioid dependence. SUBOXONE Film is currently commercially available in the U.S., Australia, and Malaysia.

About Opioid Use Disorder

Opioid use disorder (OUD) is a chronic, relapsing disease characterized by compulsion to seek and take the drug, loss of control in limiting intake, and emergence of a negative emotional state reflecting a motivational withdrawal syndrome when access to the drug is prevented.[1]
In Europe, there are an estimated 1.3 million high-opioid risk users, with heroin being the the most commonly used drug that results in emergency hospital visits.[2]
Opioid deaths account for a substantial proportion of mortality associated with drug use [3]. Moreover, opioids are found in 84% of fatal overdoses which implies drug overdose continues to be a challenge in Europe [2].

About Indivior

Indivior is a global specialty pharmaceutical company working to change patient lives by pioneering life-transforming treatment for addiction and other serious mental health diseases. Our Vision is that all patients around the world will have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. 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 800 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

Forward-Looking Statements

This announcement contains certain statements that are forward-looking. By their nature, forward-looking statements involve risks and uncertainties 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 2019 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding

ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in this release): 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, if at all; 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 and the DOJ indictment; 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.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

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2. European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), *European Drug Report: Trends and Developments.* 2018.

3. European Monitoring Centre for Drugs and Drug Addiction. Perspectives on drugs: Preventing overdose deaths in Europe. Updated May 2016.