Indivior receives approval for SUBUTEX® prolonged release solution for injection, 100mg and 300mg for substitution treatment of opioid dependence in Sweden

Slough, UK, 6 May 2020 – Indivior PLC (LON: INDV) announced today that the Swedish Medical Products Agency (MPA) has approved Subutex® prolonged release solution for injection, 100 and 300mg for substitution treatment of opioid dependence in adults and adolescents over 16 years of age within a framework of medical, social and psychological treatment.[1] This marks the first approval of Indivior's monthly long acting buprenorphine treatment for opioid dependence in Europe.

"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 Subutex® prolonged release solution for injection in Sweden is an important step, and we look forward to continuing to partner with the local treatment community to help those with opioid use disorder."

Subutex® prolonged release solution for injection contains buprenorphine with the Atrigel® Delivery System, which is to be subcutaneously injected monthly in the abdominal area.[2] It was designed to deliver consistent and sustained plasma levels of buprenorphine over the entire monthly dosing interval, resulting in an occupancy of greater than 70% of the mu-opioid receptors for control of disease symptoms.[2,3]

"This will provide patients with OUD, a chronic brain disease, an additional buprenorphine treatment option. The expanded variety of treatments addresses the need to tailor the right treatment for the right patient, which can help improve treatment retention. The effectiveness of buprenorphine is dose-dependent, which we know correlates with plasma concentration and brain mu-opioid receptor occupancy. Accordingly, this new treatment which delivers a stable dose of at least 2ng/mL of buprenorphine over a full month provides a chance for long-term stability." says Professor Markus Heilig, Linköping's University Hospital

The approval is based on safety and efficacy data from a development programme, which included clinical data of up to 12 months of treatment, in patients with opioid dependence.[1]

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This medicine was first approved by the U.S. Food and Drug Administration (FDA) in November 2017 under the name SUBLOCADE® for the treatment of moderate to severe opioid use disorder. It is currently commercially available in the U.S., Australia, and Canada and has been recently approved in Israel under the same name.

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About Subutex® prolonged release solution for injection

This medicine contains buprenorphine, a partial-opioid agonist, and is a treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Subutex® prolonged release injection is indicated in adults and adolescents aged 16 years and older, who have agreed to be treated for opioid addiction. It must only be administered subcutaneously in the abdominal region by a healthcare professional and must not be administered intravenously or intramuscularly. [1]

Subutex® prolonged release solution for injection is available in 100mg and 300mg dosage strengths and the recommended dosing regimen, following a minimum 7 day induction period with a transmucosal buprenorphine-containing product (8-24mg/day), is two initial doses of 300mg one month apart followed by monthly doses with 100mg.[1]

Subutex® prolonged release solution for injection was evaluated in a a pivotal phase III, double-blind, placebo-controlled randomized study including 504 patients and was shown to be superior to placebo in achieving more illicit opioid-free weeks ($p<0.0001$).[4] The most common adverse events were withdrawal symtoms (e.g. insomnia, headache, nausea and hyperhidrosis) as well as pain. The safety profile was consistent with other buprenorphine products for treatment of opioid use disorder, except for injection-site reactions, which were reported in more than 5% of patients, but were mostly mild and not treatment-limiting.[4]

About Opioid Use Disorder

Opioid use disorder (OUD) is a chronic, relapsing disease which causes neurobiological changes in the brain. There are three key drivers of the disease that underlie these changes, characterised as: positive reinforcing effects of drug taking; withdrawal and the need to offset symptoms of withdrawal; craving, relating to an intrusive want to use a drug.[5] People with OUD may experience a loss of control of intake of opioids as a result of these drivers despite the associated harms. Obtaining, using and recovering from opioid use can be all consuming and at the expense of other important activities, which can result in neglect of obligations at work, school or home. These features of OUD become more prominent in more severe cases of the disease.[6]

OUD is a growing global crisis with rising opioid-related morbidity and mortality resulting in a major public health burden.[7] In Europe, there are an estimated 1.3 million high-risk opioid users, with heroin being the most commonly used drug that results in emergency hospital visits.[8] 40 - 60% of patients relapse within a year,[9] and patients who use opioids have a risk of death of up to 10 times higher than the general population. The importance of reducing the health burden of OUD is widely recognised.[8]

Up to 29,000 people in Sweden suffer from OUD[10] and only 4,468 patients were estimated to be in structured Opioid Agonist Treatment (OAT) according to EMCDDA.[8] The estimated drug-induced mortality rate among adults (aged 15-64 years) was 92 deaths per million in 2017, which is higher than in most other European countries.[8]

About Indivior

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat addiction and serious mental illnesses. 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 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. 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 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 2020 and its medium- and longterm 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.

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