



## Court of Appeals for the Federal Circuit Denies Motion to Stay Issuance of the Mandate

February 12, 2019

**Slough, UK, and Richmond, VA, 12 February 2019** – Indivior PLC (LON: INDV) (“Indivior” or the “Company”) today announced that on February 11, 2019, the U.S. Court of Appeals for the Federal Circuit (CAFC) denied Indivior’s motion to stay issuance of the mandate following the CAFC’s ruling vacating the preliminary injunction (“PI”) granted against Dr. Reddy’s Laboratories (“DRL”) based on U.S. Patent No. 9,931,305.

In response, Indivior filed an emergency motion to stay the mandate pending resolution of its forthcoming application for an administrative stay to the Supreme Court of the United States. That stay, if granted, would have permitted the Supreme Court time to determine whether to administratively stay the CAFC mandate while it considered Indivior’s application to stay the mandate pending disposition of a petition for a writ of certiorari in this case. The CAFC denied that motion on February 11, 2019 and ordered that the mandate issue on February 19, 2019. Indivior will file a petition to stay the mandate with the Supreme Court of the United States.

After the mandate issues, DRL and Alvogen Pine Brook LLC (“Alvogen”) will no longer be prevented from selling, offering to sell, or importing their generic buprenorphine/naloxone sublingual film product. Indivior assumes that DRL and Alvogen will launch their generic buprenorphine/naloxone sublingual film products in the U.S. as soon as the mandate is issued by the CAFC. Any DRL and Alvogen generic product sales in the U.S. would be on an “at risk” basis, subject to the outcome of the appeal of the non-infringement judgments related to U.S. Patent No. 8,603,514, (and US 8,017,150 in the case of DRL), as well as ongoing litigation in the District of New Jersey asserting Orange Book-listed patents U.S. 9,931,305 and US 9,687,454.

SUBOXONE® Film is a prescription medicine indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

### **About Opioid Use Disorder (OUD)**

Opioid use disorder (OUD), sometimes referred to as opioid addiction, is a chronic disease<sup>1</sup>. According to DSM 5, “OUD is characterized by signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, they are used in doses greatly in excess of the amount needed for that medical condition<sup>2</sup>.” Based on 2016 data from the National Survey on Drug Use and Health report, approximately 11.8 million Americans (age 12+ years) engaged in misuse of opioids in the past year<sup>3</sup>. From 1999 to 2016, the rate of deadly prescription opioid overdoses increased five-fold<sup>4</sup>. In 2016, an average of 115 people died of opioid overdose each day in the United States<sup>5</sup>. In addition, in 2016, 935,000 adults used heroin and approximately 625,000 adults had a heroin use disorder<sup>3</sup>. In 2015, opioids accounted for 70 percent of the disease burden associated with drug use disorders worldwide.

### **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. The name is the fusion of the words individual and endeavour, 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 cooccurring 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](http://www.indivior.com) to learn more.

### **Forward thinking 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 2019 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.

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