



## **Indivior Receives Complete Response Letter from FDA Not Approving Naloxone Nasal Spray New Drug Application for Opioid Overdose**

**Slough, UK, [November 24, 2015]** – Indivior Inc., a subsidiary of Indivior PLC (LON: INDV), today announced that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application for naloxone nasal spray, an intranasal naloxone product candidate for the emergency treatment of known or suspected opioid overdose.

The FDA's response was principally focused on clinical pharmacology that found the early stage uptake of naloxone nasal spray did not fully meet the FDA's threshold as determined by the reference product (0.4 mg naloxone by intramuscular injection).

Indivior is evaluating the FDA's comments to determine our next steps to address FDA's findings.

"We are closely reviewing the FDA's response," said Shaun Thaxter, Chief Executive Officer, Indivior PLC. "Our commitment to improving patient outcomes remains steadfast, and as part of this, our work with stakeholders across communities will continue."

As the rate of opioid prescription painkiller and heroin abuse and dependence has escalated in recent years, so has the number of overdose deaths. Between 1999 and 2013, the total deaths involving opioid pain relievers per year increased fourfold. More than 24,000 people in the United States succumbed to opioid prescription painkiller or heroin overdose in 2013.

### **About Indivior**

Indivior is a global specialty pharmaceutical company with a 20-year legacy in patient advocacy, health policy and evidence-based best practice models that have helped to advance modern addiction treatment. The name is the fusion of the words individual and endeavor, and the tagline

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“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 opioid dependence portfolio, Indivior has a pipeline of product candidates designed to both expand on its heritage in this category and address other chronic diseases of addiction – including opiate overdose, alcohol use disorders and cocaine intoxication. It also is pursuing novel product candidates in related mental health disorders such as schizophrenia. Headquartered in the United States in Richmond, Va., Indivior employs more than 700 individuals globally and its portfolio 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 forward-looking statements. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior products and any future 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 litigation relating to 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.

Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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