



## **French Regulatory Agency ANSM Approves Marketing Authorisation for Indivior's NALSCUE® (Naloxone Hydrochloride) Nasal Spray for the Emergency Treatment of Characterized or Suspected Opioid Overdose**

### ***Ready-to-use, Needle-free Device Can Temporarily Reverse Characterized or Suspected Opioid Overdose Within Minutes<sup>1</sup>***

**Slough, UK, 31 July 2017** – Indivior Inc., a subsidiary of Indivior PLC (LON: INDV), today announces that l'Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) has approved a Marketing Authorisation (MA) in France for Indivior's NALSCUE® Nasal Spray for the emergency treatment of characterized or suspected opioid overdose, evidenced by respiratory depression, pending treatment in a medical department. NALSCUE® has been provided in France under a Temporary Authorisation for Use (Autorisation Temporaires d'Utilisation or ATU) since July 2016.

NALSCUE® is a ready-to-use, needle-free, disposable delivery system that is designed to deliver a dose of naloxone through the nasal mucosa of an opioid overdose victim and allows for rapid administration of the rescue medication. NALSCUE® is supplied as a preassembled device that requires minimal training so that a layperson can administer treatment to a characterized or suspected opioid overdose victim prior to the arrival of the emergency medical services.<sup>1,2</sup>

Naloxone is an opioid receptor antagonist that effectively reverses the effects of natural and synthetic opioids for a period of time.<sup>2</sup> Naloxone, through injectable administration, has been used for opioid overdose treatment for over 40 years. It is widely used by hospitals and emergency medical service personnel.<sup>3,4</sup> NALSCUE® is the first MA approved intranasal naloxone product for the emergency treatment of characterized or suspected opioid overdose in France.

In France, there are 220,000 individuals with opioid use disorder as reported in 2013.<sup>5</sup> Moreover, recent studies conducted by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) have noted that between 10% and 23% of mortality among those aged 15 to 49 could be attributed to opioid use.<sup>6</sup>

“As opioid overdoses continue to have a profound impact on communities within France, NALSCUE® may help make every second count by potentially allowing anyone, not just medical professionals, to administer life-saving treatment at the scene of an overdose,” said Ponni Subbiah, MD, MPH, Chief Medical Officer of Indivior.

### **About NALSCUE® Nasal Spray**

NALSCUE® (naloxone hydrochloride) Nasal Spray is indicated for the emergency treatment of characterized or suspected opioid overdose in adults and children older than 1 month, evidenced by respiratory depression and pending treatment in a medical department.

The use of NALSCUE® is not a substitute for emergency care by a medical department.

NALSCUE® is an emergency treatment and it should be ensured that the patient understands the importance of medical management after the use of this medication. Patients at risk for opioid overdose and his/her family who may administer NALSCUE® must receive clear instructions on the use of the medication. The emergency services should be called immediately as a matter of course before administering NALSCUE® and the patient should be monitored until the emergency services arrive.

The duration of some opioids may be longer than that of naloxone leading to a probable risk of recurrence of respiratory depression, even after an initial improvement in symptoms. In subjects who have consumed opioids, the sudden and complete reversal of their effects by naloxone may trigger the onset of major withdrawal syndrome. This emphasizes the continued need for medical management even after administration of NALSCUE®.

The following side effects have been reported after the administration of NALSCUE®: Changes to taste, headache, tactile sensitivity disorders, change to sense of smell and nasal congestion.

### **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 co-occurring disorders of addiction including alcohol use disorder and schizophrenia. Headquartered in the United States in Richmond, VA., Indivior employs more than 900 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 2017 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.

### **Media Contacts**

US  
IndiviorMediaContacts@indivior.com  
+1 804-594-0836

UK  
Tulchan Communications  
+44 207 353 4200

### **Investor Contact**

Jason Thompson, Indivior  
Vice President, Investor Relations  
+1 804-423-8916

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