



Indivior PLC Announces FDA Acceptance of Naloxone Nasal Spray New Drug Application With Priority Review

Product Candidate Has Potential to Be First Nasal Naloxone Product to Treat Opioid Overdose in United States

Slough, UK, 29 July 2015 – Indivior PLC (LON: INDV) today announced that the New Drug Application (NDA) for naloxone nasal spray was accepted and received Priority Review by the U.S. Food and Drug Administration (FDA) for the treatment of opioid overdose. This naloxone nasal spray comes as a pre-filled device that contains naloxone specially formulated for optimal absorption into the nasal mucosa.¹ The device has been designed to require minimal training so individuals may be better equipped to help an opioid overdose victim.

Naloxone nasal spray is expected to be the first FDA-approved intranasal naloxone product indicated to treat opioid overdose in the United States. Naloxone nasal spray is designed to deliver naloxone through the nasal mucosa of an overdose victim.

Naloxone, which is an opioid receptor antagonist that effectively binds to the opioid receptors in the brain to reverse the effects of natural and synthetic opioids, is the standard treatment for an opioid overdose.² Currently, only needle-based formulations of naloxone are FDA approved.

The number of unintentional overdose deaths involving opioid pain relievers in the United States has increased four-fold between 1999 and 2009.³ Opioid and heroin overdoses cause more than 25,000 deaths in the US every year.⁴ Between 50% to 80% of patients who died from a prescription opioid overdose had a history of chronic pain.⁵

“As the rate of opioid overdoses and their profound impact on communities nationwide continues to rise, naloxone nasal spray may help make every life-saving second count by potentially allowing anyone—be they layperson, trained healthcare personnel or first responders—to administer treatment at the scene of an overdose,” said Tim Baxter, M.D., Chief Medical Officer at Indivior. “We look forward to continuing to work closely with the FDA through the review process to make this vital treatment option widely available.”

The FDA's Priority Review status accelerates the review time from 10 to 6 months from the day of NDA acceptance and is given to medications that may offer significant advances in treatment effectiveness or may provide a treatment where no adequate therapy exists.⁶ At this time, the FDA's response to the NDA for naloxone nasal spray is expected late in the fourth quarter of 2015.

About Opioid Overdose

In addition to creating the feeling of euphoria that drug users seek, opioids cause sedation and slowed breathing. When taken in large doses, opioids can cause breathing to stop, resulting in a fatal overdose.⁷ Prescription opioids cause more overdose deaths than all other drugs combined, including heroin and cocaine.^{8,9}

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 "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 including SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet, and SUBUTEX® (buprenorphine) Sublingual Tablet, 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 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 SUBOXONE Tablet, SUBOXONE Film, SUBUTEX Tablet 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 the SUBOXONE Film patent litigation relating to the two 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.

Media Contacts

Amir Khan
Biosector 2
+1 212-845-5656
akhan@inventivhealth.com

Beth Keshishian
Biosector 2
+1 212-229-8417
bkeshishian@inventivhealth.com

Investor Contact

Tom Corran
Indivior, Director, Investor Relations
+44(0)175 321 780

References

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<<http://www.businesswire.com/news/home/20130920005500/en/Naloxone-Nasal-Spray-Development-Fast-Track-Emergency#.VZK7uvlVhBc>>.

² Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

³ Calcaterra S, Glanz J, Binswanger I. National Trends in Pharmaceutical Opioid Related Overdose Deaths Compared to other Substance Related Overdose Deaths: 1999-2009. Published in final edited form as: Drug Alcohol Depend. 2013 August 1; 131(3): 263–270.

⁴ ASAM. Opioid addiction disease 2015 facts and figures. American Society of Addiction Medicine. Chevy Chase, MD; 2015:1-2. <<http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>> Accessed July 2015.

⁵ Paulozzi J. Prescription drug overdoses: a review. Journal of Safety Research. 2012; 43: 283-289.

⁶ U.S. Food and Drug Administration. Priority Review.

<<http://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm>> Accessed July 1, 2015.

⁷ Center for Disease Control and Prevention. National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. Policy Impact: Prescription Painkiller Overdoses. Atlanta, GA: Centers for Disease Control and Prevention; 2011. Accessed July 2015.

⁸ NIDA DrugFacts Prescription and Over-the-Counter Medications.

<<http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications>> Accessed July 2015.

⁹Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999–2008. Morbidity and Mortality Weekly Report. < <http://www.cdc.gov/mmwr/index2011.html>> Vol 60 (43), November 4, 2011.

