



Statement of Indivior on Grand Jury Indictment

Company Believes U.S. Justice Department Is Fundamentally Wrong, Will Contest Charges Vigorously

Slough, UK and Richmond, VA, April 9, 2019 - Indivior PLC (LON: INDV) issued the following statement today in response to an indictment returned by a federal grand jury in the Western District of Virginia:

“We are extremely disappointed in this action by the Justice Department, which is wholly unsupported by either the facts or the law. Key allegations made by the Justice Department are contradicted by the government’s own scientific agencies, they are almost exclusively based on years-old events from before Indivior became an independent company in 2014, and they are wrong. The department has apparently decided it would rather pursue self-serving headlines on a matter of national significance than achieve an appropriate resolution, but we will contest this case vigorously and we look forward to the full facts coming out in court.

“Indivior’s top priority has always been the treatment of patients struggling with opioid addiction. The medications Indivior provides play an essential role in treating opioid use disorder and addressing the national opioid crisis. Indivior does not make pain pills in the U.S and is not a contributor to the opioid crisis. As acknowledged by government experts at the Food and Drug Administration (FDA) and Centers for Disease Control (CDC), we make a demonstrably effective treatment for opioid addiction. Indivior discovered buprenorphine, helped develop it as a leading evidence-based treatment for opioid dependence, and currently conducts approximately 75% of all private research into opioid addiction. No other company has done more to fight the opioid crisis, and we continue to be fully dedicated to helping patients, doctors, and communities dealing with opioid addiction.

“Indivior has never deliberately diverted its product. The government claims that the company aided the careless and clinically unwarranted prescribing by doctors of SUBOXONE® products to too many people or in too high doses. To the contrary, we have engaged in an extensive education campaign to teach doctors about recommended SUBOXONE® dosing limits and patient caps and have developed a process to identify concerning prescribers, going beyond what the law requires. Moreover, though it was under no legal obligation to do so, the company proactively reported the conduct of multiple physicians to the appropriate authorities, but the company’s risk manager was told by the Drug Enforcement Agency that there was no action the agency would take. We have worked aggressively to try to reduce the risk of diversion through extensive education of doctors and patients and by other means, including through the recent launch of a once-monthly injectable treatment for opioid use disorder, which must be administered by a healthcare provider, preventing direct distribution to a patient.

“Regarding the Justice Department’s allegations about SUBOXONE® film, the Centers for Disease Control itself has said that unit-dose packaging is likely to reduce the risk of pediatric exposure compared to bulk-bottle packaging. And a CDC study released in 2016 studying the rates of pediatric exposure before and after the introduction of Suboxone film found that emergency room visits due to accidental ingestion of buprenorphine/naloxone by children under six declined 65 percent after film was

introduced to the market. FDA officials have stated that ‘unit-dose packaging is a measure to reduce pediatric exposures,’ and encouraged the industry to move to unit-dose packaging. The Justice Department’s decision to indict a company for making claims that are in fact supported by the federal government’s own scientific research shows just how flawed its case is.

“Indivior has cooperated extensively with the Justice Department’s investigation for several years. We have turned over millions of pages of documents and spent extensive time explaining the company’s operations to the department. In the interest of resolving this matter and providing certainty to our shareholders, we have made numerous attempts to reach a settlement that went far beyond what we believe the facts of this case support. It is unfortunate the Justice Department decided to choose an alternative path, but we will fight these allegations on the facts and on the law in court, and we are confident of our position. In the meantime, we will not be distracted from our mission of helping patients struggling with opioid addiction.

“In terms of business going forward, the company does not anticipate any immediate change in its relationship with government providers due to today’s actions by the Justice Department.”

Indivior also released an open letter from Howard Pien, Chairman of the Board Directors, in which he writes:

“As you may know, the Department of Justice has taken the unusual step of indicting Indivior for events that date almost exclusively to before the company was formed in 2014. The Indivior Board of Directors, through a special committee of the board that I have chaired, has investigated the department’s allegations for several years, and the board believes they are flat wrong. The board has full confidence in the management of the company, and we will fight these charges on the facts and on the law in court.”

The full letter is available [here](#).

Specific Rebuttals to DOJ Claims:

On Pediatric Safety:

- Following the 2010 launch of SUBOXONE® film, data began to emerge from the Poison Control Centers showing far lower rates of pediatric exposure for film than for tablets. SUBOXONE® film is sold in unit-dose packaging, while SUBOXONE® tablets were sold in traditional bottles.
- Since that time, based on additional research, government agencies have repeatedly confirmed the safety benefits of unit-dose packaging. In August 2016, Dr. Daniel Budnitz, Director of the Medication Safety Program for the CDC, gave written testimony that he “consider[s] child-resistant, unit-dose packaging to be an engineering innovation likely to reduce the risk of pediatric exposure in comparison to child-resistant, bulk- bottle packaging.”
- In October 2016, the CDC published the results of its [study](#) of pediatric exposure rates before and after the introduction of Suboxone film in its unit-dose packaging to the market. The CDC found that when comparing the 2013-2015 period to the 2008-2010 period, the number of annual visits to the emergency department due to accidental ingestion of buprenorphine/naloxone by children under six years old declined 65.3 percent. The CDC

concluded that the reduction in emergency room visits “suggests that packaging/formulation changes might reduce accidental pediatric ingestions.”

- A [study](#) of poison center data published in the Journal of Pediatrics in June 2018 demonstrated that the industry shift from non-unit-dose packaging to unit-dose packaging of buprenorphine-naloxone products was associated with a 78.8 percent relative decrease in unintentional pediatric exposures reported to poison centers.
- In 2013, FDA noted that “child resistant unit-dose packaging could provide additional deterrence to accidental pediatric exposure.” FDA’s Office of Surveillance and Epidemiology (“OSE”) stated that “Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging.” OSE “suspect[ed] that if there [was] a return to market dominance of buprenorphine/naloxone tablets without unit-of-use packaging, pediatric exposures are likely to rise.”
- Consistent with these concerns, the FDA convened an April 2013 meeting with a group of generic buprenorphine manufacturers and informed them that “unit-dose packaging is a measure to reduce pediatric exposures.” At that meeting, the FDA further stated that it viewed “the packaging of buprenorphine-containing products as a significant safety issue in regards to pediatric exposure,” and recommended that each of the industry group’s members voluntarily move to unit-dose packaging for their buprenorphine-containing products.

On Misuse and Diversion:

- Suboxone’s FDA-approved Package Insert states that the maintenance dose is usually in the range of 4 mg to 24 mg of buprenorphine per day. The recommended target dose is 16 mg taken once daily. [Research](#) has shown that for some patients, doses of less than 16 mg per day may not stop the opioid craving, and doses at 24 mg per day may be needed. The Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the U.S. Department for Health and Human Services, [advises](#) prescribers that some patients may require up to 32 mg per day and has recommended dosing at that level for some patients.
- Though it is under no legal obligation to do so, Indivior’s sales representatives regularly educate doctors about the patient limits contained in federal law. The company also instructs doctors about the appropriate dosing levels for Suboxone. It has instructed its sales representatives to note “red flags” of potential diversion when seeing prescribers, and it educates doctors about recommended Suboxone prescribing limits when it develops concerns.
- Indivior’s compensation structure for sales representatives does not encourage excessive dosing. As far back as 2006, Indivior has excluded doses higher than 16 mg per day from its quarterly compensation algorithm for sales representatives and their managers.
- Indivior took many steps during the relevant period to reach out to risky prescribers and attempt to curtail problematic prescribing patterns, and it continually buttresses those efforts to this day. Put simply, Indivior is not a contributor to the opioid epidemic. Rather, as acknowledged by government experts at the FDA and CDC, its medicines are a key part of combatting it.

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 to learn more.

Forward-Looking Statements

This announcement 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 2018 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 announcement 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.

About SUBOXONE® Film

Indication

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) 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.

Treatment should be initiated under the direction of healthcare providers qualified under the Drug Addiction Treatment Act.

Important Safety Information

Do not take SUBOXONE® Film if you are allergic to buprenorphine or naloxone as serious negative effects, including anaphylactic shock, have been reported.

SUBOXONE® Film can be abused in a manner similar to other opioids, legal or illicit.

SUBOXONE® Film contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your healthcare provider can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE® Film suddenly without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

SUBOXONE® Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE® Film.

You should not drink alcohol while taking SUBOXONE® Film, as this can lead to loss of consciousness or even death.

Death has been reported in those who are not opioid dependent.

Your healthcare provider may monitor liver function before and during treatment.

SUBOXONE® Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE® Film may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

Keep SUBOXONE® Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE® Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE® Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting the SUBOXONE® Film product may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE® Film, tell your healthcare provider if you are pregnant or plan to become pregnant. If you are pregnant, tell your healthcare provider as withdrawal signs and symptoms should be monitored closely and the dose adjusted as necessary. If you are pregnant or become pregnant while taking SUBOXONE® Film, alert your healthcare provider immediately and you should report it using the contact information provided below.

Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy, whether that use is medically-authorized or illicit. Unlike opioid withdrawal syndrome in adults, NOWS may be life-threatening if not recognized and treated in the neonate. Healthcare professionals should observe newborns for signs of NOWS and manage accordingly.

Before taking SUBOXONE® Film, talk to your healthcare provider if you are breastfeeding or plan to breastfeed your baby. The active ingredients of SUBOXONE® Film can pass into your breast milk. You and your healthcare provider should consider the development and health benefits of breastfeeding along with your clinical need for SUBOXONE® Film and should also consider any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE® Film affects you. Buprenorphine in SUBOXONE® Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE® Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

This is not a complete list of potential adverse events associated with SUBOXONE® Film. Please see [full Prescribing Information](#) www.suboxoneREMS.com for a complete list.

*To report pregnancy or side effects associated with taking SUBOXONE® Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about SUBOXONE® Film, SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), or SUBUTEX® (buprenorphine) Sublingual Tablets (CIII), please see the respective [full Prescribing Information](#) and [Medication Guide](#) at www.suboxoneREMS.com.

About SUBLOCADE™ (buprenorphine extended-release) Injection

For further product information, see full [Prescribing Information](#) including BOXED WARNING and [Medication Guide](#) at www.SUBLOCADE.com.

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by a dose adjustment period for a minimum of seven days.

SUBLOCADE should be used as part of a complete treatment program that includes counseling and psychosocial support.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with bodily fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

Prescription use of this product is limited under the Drug Addiction Treatment Act.

CONTRAINDICATIONS

SUBLOCADE should not be administered to patients who have been shown to be hypersensitive to buprenorphine or any component of the ATRIGEL® delivery system.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Respiratory Depression: Life threatening respiratory depression and death have occurred in association with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBLOCADE.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome is an expected and treatable outcome of prolonged use of opioids during pregnancy.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Risk of Opioid Withdrawal With Abrupt Discontinuation: If treatment with SUBLOCADE is discontinued, monitor patients for several months for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to and during treatment.

Risk of Withdrawal in Patients Dependent on Full Agonist Opioids: Verify that patient is clinically stable on transmucosal buprenorphine before injecting SUBLOCADE.

Treatment of Emergent Acute Pain: Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.

Media Contacts

US

IndiviorMediaContacts@indivior.com

+1 804-594-0836

Matthew Miller

+1 202-783-0277

UK

Tulchan Communications

+44 207-353-4200

Investor Contact

Jason Thompson, Indivior

Vice President, Investor Relations

+1 804-379-1033

Jason.Thompson@indivior.com

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