



Court of Appeals for the Federal Circuit Denies Motion for Rehearing or Rehearing En Banc

Slough, UK and Richmond, VA – February 5, 2019 – Indivior PLC (LON: INDV) (“Indivior” or the “Company”) today announced that the U.S. Court of Appeals for the Federal Circuit (“CAFC”) has denied Indivior’s motion for rehearing and rehearing *en banc* 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. The CAFC also stated its mandate is currently set to issue on February 11, 2019.

Indivior intends to file an emergency motion with the CAFC to stay issuance of the mandate pending resolution of Indivior’s appeal of the District of Delaware’s decision finding DRL does not infringe U.S. Patent No. 8,603,514 (“the ‘514 patent”), and pending Indivior’s forthcoming petition for a writ of *certiorari* to the Supreme Court of the United States in the PI matter. The mandate is a formal order by the CAFC that returns the case to the District Court for actions consistent with the CAFC’s ruling. After the mandate issues, DRL will no longer be prevented from selling, offering to sell, or importing its generic buprenorphine/naloxone sublingual film product in the U.S.

Indivior assumes that DRL will resume the launch of its generic buprenorphine/naloxone sublingual film product in the U.S. once the CAFC issues the mandate. Indivior also assumes that Alvogen Pine Brook LLC (“Alvogen”) will also launch its generic in the U.S. once the CAFC issues the mandate, pursuant to a January 31, 2019 agreement between Alvogen and Indivior. Industry analogs¹ suggest that a launch in the U.S. of a generic product that can be directly substituted by a pharmacist for the branded product without consultation with the patient would result in the branded incumbent (in this case, SUBOXONE® Film) losing up to 80% of its market share within a matter of months.

Any generic product sales in the U.S. by DRL and/or Alvogen would be on an “at-risk” basis, subject to the outcome of the appeal of the non-infringement judgments related to the ‘514 patent (as well as U.S. Patent No. 8,017,150 in the case of DRL), and ongoing litigation against DRL and Alvogen in the District of New Jersey asserting other Orange Book-listed patents (including U.S. Patent No. 9,931,305).

Shaun Thaxter, CEO of Indivior, Commented:

“We are disappointed that the CAFC has denied Indivior’s motion for rehearing,” said Shaun Thaxter, CEO of Indivior. “While we ultimately believe in the strength of our patent portfolio, we acknowledge that the Company faces major disruption in the immediate future from a potential material and rapid loss of market share by our SUBOXONE® film product to generic buprenorphine/naloxone sublingual film competition. We have been taking prudent steps toward this eventuality with our contingency plan, including reducing debt and certain operating expenses, while preserving a strong cash balance. We will continue to vigorously pursue our infringement cases against DRL to protect our SUBOXONE® (buprenorphine and naloxone) Sublingual Film patent portfolio, including continuing to pursue the appeals of the District of Delaware’s non-infringement decisions related to the ‘514 and ‘150 Patents, as well as litigating our more recently listed Orange Book patents for SUBOXONE® Film.”

¹ IMS Institute Report, January 2016: “Price Declines after Branded Medicines Lose Exclusivity in the U.S.”

Contingency Plan Implementation:

Indivior has implemented initial elements of the contingency plan shared on December 18, 2018. As outlined, these plans were developed with the objective of providing for the commercial success of SUBLOCADE™ and PERSERIS™ and ensuring a minimum cash balance of \$250m to remain in compliance with the Company's debt covenants. Specifically, the initial actions taken to date are:

- Reducing outstanding principal on the Term Loan by \$235m during FY 2018 to \$243m;
- Cash conservation through FY 2018 leading to cash and equivalents of approximately \$920m at the end of FY 2018; and,
- Headcount reductions as of this release and other previously committed savings.

In the event of a generic buprenorphine/naloxone sublingual film product launch in the U.S. by DRL and/or Alvogen, further parts of Indivior's contingency plan would be triggered, including:

- Launching an Authorized Generic of SUBOXONE® Film to capture some share of the generic segment and to generate a modest amount of net revenue in the range of tens of \$ millions; and,
- Further initiatives reducing structural costs, including delaying and/or cancelling R&D projects.

As a result of these cost initiatives, the FY 2019 operating expense base (SG&A and R&D) is expected to be reduced to \$440m to \$460m.

Indivior will announce its FY 2018 results on February 14 at 7:00 a.m. GMT (2:00 a.m. Eastern U.S.) on the RNS.

For Further Information

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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 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.

SUBOXONE® (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (CIII)

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](http://www.suboxoneREMS.com) 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](http://www.suboxoneREMS.com) and [Medication Guide](http://www.suboxoneREMS.com) at www.suboxoneREMS.com.

SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

INDICATION

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 dose adjustment for a minimum of 7 days.

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

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 body 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.**

HIGHLIGHTED SAFETY INFORMATION

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.

For more information about SUBLOCADE, the full Prescribing Information including **BOXED WARNING**, and Medication Guide visit www.sublocade.com.

PERSERIS™ (risperidone) for extended-release injectable suspension

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

PERSERIS™ (risperidone) is indicated for the treatment of schizophrenia in adults.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

See full prescribing information for complete boxed warning.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- PERSERIS is not approved for use in patients with dementia-related psychosis.

CONTRAINDICATIONS

PERSERIS should not be administered to patients with known hypersensitivity to risperidone, paliperidone, or other components of PERSERIS.

WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis: Increased risk of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities. PERSERIS is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

Metabolic Changes: Monitor for hyperglycemia, dyslipidemia and weight gain.

Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

Orthostatic Hypotension: Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing PERSERIS if a clinically significant decline in WBC occurs in absence of other causative factors.

Potential for Cognitive and Motor Impairment: Use caution when operating machinery.

Seizures: Use caution in patients with a history of seizures or with conditions that lower the seizure threshold.

ADVERSE REACTIONS

The most common adverse reactions in clinical trials ($\geq 5\%$ and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions ($\geq 5\%$) were injection site pain and erythema (reddening of the skin).

For more information about PERSERIS, the full Prescribing Information including BOXED WARNING, and Medication Guide visit www.perseris.com.