

Indivior Announces Ruling by the Court of Appeals for the Federal Circuit in ANDA Litigation

Slough, UK, July 15, 2019 – Indivior PLC (LON: INDV) (“Indivior” or the “Company”) today announced that the Court of Appeals for the Federal Circuit (CAFC) has affirmed the judgments of the U.S. District Court for the District of Delaware (the “District Court”) finding that Watson Laboratories Inc. (Watson); Dr. Reddy’s Laboratories (DRL); and Alvogen Pine Brook, LLC (“Alvogen”) failed to show that the asserted claims of U.S. Patent No. 8,603,514 (the “’514 Patent”) related to SUBOXONE® (buprenorphine and naloxone) Film are invalid, but that the asserted claims are not infringed by DRL and Alvogen. The CAFC also affirmed the judgments that DRL failed to provide that the asserted claims of U.S. Patent No. 8,017,150 (the “’150 Patent”) related to SUBOXONE® Film are invalid, but that those claims are not infringed by DRL. Alvogen and DRL have been marketing their generic buprenorphine/naloxone sublingual film products at-risk since February 2019. The CAFC also upheld the District Court’s decision that Watson (now known as Actavis Laboratories UT, Inc.) infringes the ’514 Patent. Therefore, Watson/Actavis remains enjoined from launching their generic buprenorphine/naloxone sublingual film product until the expiration of the ’514 Patent on April 3, 2024.

For Further Information

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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 800 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

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 (i.e., 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 (e.g., 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 labour.

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.