



# **Intellipharmaeutics Provides Update on FDA Advisory Committees Meeting for Aximris XR(TM) (Oxycodone Hydrochloride extended release) an Abuse Deterrent Opioid Analgesic for the Treatment of Moderate to Severe Pain**

**TORONTO, ON / ACCESSWIRE / January 16, 2020 / Intellipharmaeutics International Inc. (OTCQB:IPCIF and TSX:IPCI)** ("Intellipharmaeutics" or the "Company"), a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs, announced today that the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted to not support the approval of Aximris XR™ (oxycodone extended-release tablets) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

The Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration ("FDA") voted 24 to 2 against the voting question: "Do you recommend approval of AXIMRIS XR (oxycodone extended-release tablets) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?"

There can be no assurance that the FDA will ultimately approve the NDA for the sale of Aximris XR™ in the U.S. market, or that it will ever be successfully commercialized.

## **More About Aximris XR™**

Our Aximris XR™ (abuse deterrent oxycodone hydrochloride extended release tablets) NDA product candidate is intended as an abuse and alcohol-deterrent controlled-release oral formulation of oxycodone hydrochloride for the relief of pain. The Aximris XR™ long-acting formulation of oxycodone is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous material, which is intended to prevent syringing, injecting and snorting. Our Aximris XR™ formulation is difficult to abuse through the application of heat or an open flame, making it difficult to inhale the active ingredient from burning.

## **About Intellipharmaeutics**

Intellipharmaeutics International Inc. is a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. The Company's patented Hypermatrix™ technology is a multidimensional controlled-release drug delivery platform that can be applied to a wide range of existing and new pharmaceuticals. Intellipharmaeutics has developed several drug delivery systems based on this technology platform, with a pipeline of products (some of which have received FDA approval) in various stages of development. The Company has ANDA and NDA 505(b)(2) drug product candidates in its development pipeline. These include the Company's abuse-deterrent oxycodone hydrochloride extended release formulation ("Oxycodone ER") based on its proprietary nPODDDS™ novel Point Of Divergence Drug Delivery System (for which an NDA has been filed with the FDA), and Regabatin™ XR (pregabalin extended-release capsules).

## **Cautionary Statement Regarding Forward-Looking Information**

*Certain statements in this document constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or "forward-looking information" under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our expectations regarding our plans, goals and milestones, status of developments or expenditures relating to our business, plans to fund our current activities, and statements concerning our partnering activities, health regulatory submissions, strategy, future operations, future financial position, future sales, revenues and profitability, projected costs and market penetration and risks or uncertainties related to our ability to comply with OTCQB and TSX requirements. In some cases, you can identify forward-looking statements by terminology such as "appear", "unlikely", "target", "may", "will", "should", "expects", "plans", "plans to", "anticipates", "believes", "estimates", "predicts", "confident", "prospects", "potential", "continue", "intends", "look forward", "could", "would", "projected", "goals", "set to", "seeking" or the negative of such terms or other comparable terminology. We made a number of assumptions in the preparation of our forward-looking statements. You should not place undue reliance on our forward-looking statements, which are subject to a multitude of known and unknown risks and uncertainties that could cause actual results, future circumstances or events to differ materially from those stated in or implied by the forward-looking statements. Risks and uncertainties relating to us and our business can be found in the "Risk Factors" section of our latest annual information form, our latest Form 20-F, and our latest Form F-1 and Form F-3 registration statements (including any documents forming a part thereof or incorporated by reference therein), as amended, as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada and the U.S., which are available on [www.sedar.com](http://www.sedar.com) and [www.sec.gov](http://www.sec.gov). The forward-looking statements reflect our current views with respect to future events and are based on what we believe are reasonable assumptions as of the date of this document and we disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

*Trademarks used herein are the property of their respective holders.*

*Unless the context otherwise requires, all references to "we," "us," "our," "Intellipharmaceutics," and the "Company" refer to Intellipharmaceutics International Inc. and its subsidiaries.*

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