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Intellipharmaceutics Meets with FDA Regarding Oxycodone ER NDA Development Program

TORONTO, ON / ACCESSWIRE / February 9, 2018 /Intellipharmaceutics International Inc. (NASDAQ: IPCI) (TSX: IPCI) ("Intellipharmaceutics" or the "Company"), a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled- and targeted-release oral solid dosage drugs, today announced that it held a meeting with the United States Food and Drug Administration ("FDA") regarding the Company's abuse-deterrent oxycodone hydrochloride extended release tablets ("Oxycodone ER") product candidate.

The Company and the FDA discussed the previously announced Complete Response Letter for Oxycodone ER, including issues related to the blue dye in the product candidate. Based on the meeting, the product candidate will no longer include the blue dye. The blue dye was intended to act as an additional deterrent if Oxycodone ER is abused and serve as an early warning mechanism to flag potential misuse or abuse. The FDA confirmed that the removal of the blue dye is unlikely to have any impact on formulation quality and performance. As a result, the Company will not be required to repeat in vivo bioequivalence studies and pharmacokinetic studies submitted in the Oxycodone ER New Drug Application ("NDA"). The FDA also indicated that, from an abuse liability perspective, Category 1 studies will not have to be repeated on Oxycodone ER with the blue dye removed.

"Oxycodone ER was designed to have what we consider best in class abuse deterrence properties. As an additional feature, we introduced the innovative blue dye which is released when the product candidate is manipulated, to act as an early-warning system that may indicate when people need help," said Dr. Isa Odidi, CEO of Intellipharmaceutics. *"The work to show the potential social benefits of Oxycodone ER with blue dye may be lengthy. Since there is no impact on the abuse deterrent properties with the removal of the blue dye, we intend to conduct our previously announced Category 2 and 3 studies to support abuse-deterrent label claims using Oxycodone ER that does not contain the blue dye."*

The Company has already begun screening potential study participants for the previously announced Category 2 and 3 studies, which we intend to conduct over the coming months with an NDA resubmission targeted for later this year.

Dr. Isa Odidi concluded that, *"We appreciate the additional direction given to us by the FDA, which allows us to further refine our path for Oxycodone ER. We believe its superior abuse-deterrent features are what really set our product candidate apart. Removing the blue dye at this time will facilitate making our important Oxycodone ER product candidate available to patients as quickly as possible."*

There can be no assurance that Intellipharmaceutics will not be required to conduct further

studies for Oxycodone ER, that the FDA will approve any of the Company's requested abuse-deterrent label claims or that the FDA will ultimately approve the NDA for the sale of Oxycodone ER in the U.S. market, or that it will ever be successfully commercialized.

About Intellipharmaceutics

Intellipharmaceutics International Inc. is a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled- 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. Intellipharmaceutics 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 Abbreviated New Drug Application ("ANDA") and NDA 505(b)(2) drug product candidates in its development pipeline. These include Oxycodone ER abuse deterrent oxycodone formulation 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 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. 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," 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, uncertainties and other factors that could affect our actual results include, but are not limited to, securing and maintaining corporate alliances, our estimates regarding our capital requirements and the effect of capital market conditions and other factors, including the current status of our product development programs, on capital availability, the estimated proceeds (and the expected use of any proceeds) we may receive from any offering or our securities, potential liability from and costs of defending pending or future litigation, our ability to maintain compliance with the continued listing requirements of the principal markets on which our securities are traded, our programs regarding research, development and commercialization of our product candidates, the timing of such programs, the timing, costs and uncertainties regarding obtaining regulatory approvals to market our product candidates and the difficulty in predicting the timing and results of any product launches, our ability to establish and maintain valid and enforceable intellectual property rights in our drug delivery

technologies, products and product candidates, the scope of protection provided by intellectual property for our drug delivery technologies, products and product candidates, the actual size of the potential markets for any of our products and product candidates compared to our market estimates, our selection and licensing of products and product candidates, sources of revenues and anticipated revenues, including contributions from distributors and commercial partners, product sales, license agreements and other collaborative efforts for the development and commercialization of product candidates, delays in product approvals that may be caused by changing regulatory requirements, the difficulty in predicting the timing of regulatory approval and launch of competitive products, the availability and pricing of third-party sourced products and materials, difficulties, delays, or changes in the FDA approval process or test criteria for ANDAs and NDAs challenges in securing final FDA approval for our product candidates, including Oxycodone ER in particular, if a patent infringement suit is filed against us, with respect to any particular product candidates (such as in the case of Oxycodone ER), which could delay the FDA's final approval of such product candidates, and the FDA may not approve requested product labeling for our product candidate(s) having abuse-deterrent properties targeting common forms of abuse (oral, intra-nasal and intravenous). Additional 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-3 (including any documents forming a part thereof or incorporated by reference therein), 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 and 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.

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

Company Contact:

Intellipharmaceutics International Inc.
Andrew Patient
Chief Financial Officer
416-798-3001 ext. 106
investors@intellipharmaceutics.com

Investor Contact:

ProActive Capital
Kirin Smith
646-863-6519
ksmith@pcgadvisors.com

SOURCE: Intellipharmaceutics International Inc.