Intellipharmaceutics Announces FDA Acceptance for Filing of NDA for Rexista™ (oxycodone hydrochloride extended release), an Abuse Deterrent Opioid Analgesic for the Treatment of Moderate to Severe Pain

TORONTO, February 2, 2017 (GLOBE NEWSWIRE) -- Intellipharmaceutics International Inc. (Nasdaq:IPCI) (TSX:I) ("Intellipharmaceutics" 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, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing the Company's previously-announced New Drug Application ("NDA") seeking authorization to market its Rexista™ abuse-deterrent oxycodone hydrochloride extended release tablets in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg strengths. The FDA has determined that the Company's application is sufficiently complete to permit a substantive review, and has set a target action date under the Prescription Drug User Fee Act ("PDUFA") of September 25, 2017.

Rexista™ is indicated 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 submission is supported by pivotal pharmacokinetic studies that demonstrated that Rexista™ is bioequivalent to OxyContin® (oxycodone hydrochloride extended release). The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids — Evaluation and Labelling" guidance published in April 2015.

The abuse-deterrent properties incorporated into Rexista™ are designed to make the product unlikable and discourage or make it more difficult to manipulate for the purpose of abuse or misuse via common routes of administration including: ingestion following chewing, licking or crushing; insufflation; inhalation; or injection. If approved, Rexista™ may be the only abuse-deterrent oxycodone product with properties that may provide early warning of drug abuse if the product is manipulated or abused. The Company previously announced the results of a food effect study which showed that Rexista™ can be administered with or without a meal (i.e., no food effect), providing another point of differentiation from currently marketed oral oxycodone extended release products.

The CEO of Intellipharmaceutics, Dr. Isa Odidi, said, *"The acceptance of filing of our NDA for Rexista™ represents an important step towards the commercialization of a potentially best–in-class abuse-deterrent oxycodone hydrochloride extended release product. We look forward to working with the FDA during their review of our NDA submission."*

There can be no assurance that we will not be required to conduct further studies for Rexista™, that the FDA will ultimately approve the NDA for the sale of Rexista™ in the U.S. market, or that it will ever be successfully commercialized.

More About Rexista™

Our Rexista™ (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 Rexista™ 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 hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista™ formulation is difficult to abuse through the application of heat or an open flame, making it difficult to inhale the active ingredient from burning. Our Rexista™ formulation contains a blue dye that is emitted once the tablet is tampered with or crushed, and may act as a deterrent to a user who attempts to abuse it orally or via the intra-nasal route.

About Intellipharmaceutics

Intellipharmaceutics 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 the efficient development of a wide range of existing and new pharmaceuticals. Based on this technology platform, Intellipharmaceutics has developed several drug delivery systems and a pipeline of products (some of which have received FDA approval) and product candidates in various stages of development, including Abbreviated New Drug Application ("ANDAs") filed with the FDA (and one Abbreviated New Drug Submission filed with Health Canada) in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract, diabetes and pain.

Intellipharmaceutics also has NDA 505(b)(2) specialty drug product candidates in its development pipeline. These include Rexista® (abuse deterrent oxycodone hydrochloride extended release tablets), 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). Our current development effort is increasingly directed towards improved difficult-to-develop controlled-release drugs which follow an NDA 505(b)(2) regulatory pathway. The Company has increased its research and development emphasis towards new product development, facilitated by the 505(b)(2) regulatory pathway, by advancing the product development program for both Rexista® and Regabatin™. The 505(b)(2) pathway (which relies in part upon the approving agency's findings for a previously approved drug) both accelerates development timelines and reduces costs in comparison to NDAs for new chemical entities. An advantage of our strategy for development of NDA 505(b)(2) drugs is that our product candidates can, if approved for sale by the FDA, potentially enjoy an exclusivity period which may provide for greater commercial opportunity relative to the generic ANDA route.

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, 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 "may," "will," "should," "expects," "plans," "plans to," "anticipates," "believes," "estimates," "predicts," "potential," "continue," "intends," "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, the effects of general economic conditions, 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 potential dilutive effects of any future financing and the expected use of any proceeds from any offering of our securities, 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, and the timing and amount of any available investment tax credits, the actual or perceived benefits to users of our drug delivery technologies, products and product candidates as compared to others, 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, our ability to attract distributors and collaborators with the ability to fund patent litigation and with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts, sources of revenues and anticipated revenues, including contributions from distributors and collaborators, product sales, license agreements and other collaborative efforts for the development and commercialization of product candidates, our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly, the rate and degree of market acceptance of our products, delays that may be caused by changing regulatory requirements, the difficulty in predicting the timing of regulatory approval and launch of competitive products, the difficulty in predicting the impact of competitive products on volume, pricing, rebates and other allowances, the inability to forecast wholesaler demand and/or wholesaler buying patterns, the seasonal fluctuation in the numbers of prescriptions written for our Focalin XR® (dexmethylphenidate hydrochloride extended-release) capsules which may produce substantial fluctuations in revenues, the timing and amount of insurance reimbursement for our products, changes in laws and regulations affecting the conditions required by the FDA for approval and labelling of drugs including abuse or overdose deterrent properties, and changes affecting how opioids are regulated and prescribed by physicians, changes in the laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products, the success and pricing of other competing therapies that may become available, our ability to retain and hire qualified employees, the availability and pricing of third party sourced products and materials, challenges related to the development, commercialization, technology transfer, scale-up, and/or process validation of manufacturing processes for our product candidates, the manufacturing capacity of third-party manufacturers that we may use for our products, the successful compliance with FDA, Health Canada and other governmental regulations applicable to the Company and its third party manufacturers' facilities, products and/or businesses, difficulties, delays or changes in the FDA approval process or test criteria for ANDAs and NDAs, risks associated with cyber-security and the potential for vulnerability of the digital information of the Company or a current and/or future drug development or commercialization partner of the Company and risks arising from the ability and willingness of our third-party commercialization partners to provide documentation that may be required to support information on revenues earned by us from those

commercialization partners. Additional risks and uncertainties relating to the Company 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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