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Intellipharmaceutics Reports Update on Rexista™ XR: FDA Grants Waiver of NDA Filing Fee, and Topline Pharmacokinetics Results Indicate No Food Effect

TORONTO, July 05, 2016 (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 provided an update on its Rexista™ XR (oxycodone hydrochloride extended release tablets) new drug application ("NDA") candidate.

NDA Filing Fee Waiver

In February 2016, Intellipharmaceutics requested a waiver of the application user fee under the small business waiver provision, section 736(d)(1)(D) of the Federal Food, Drug, and Cosmetics Act (the "Act"), related to our Rexista™ XR (oxycodone hydrochloride extended release tablets) NDA product candidate. The United States Food and Drug Administration ("FDA") has completed its review of our request and has granted a waiver of the $1,187,100 application fee for Rexista™ XR.

Pharmacokinetics Results Show No Food Effect

Following an FDA request that we assess the food effect of the final to be marketed (upon FDA approval) product of Rexista™ XR, Intellipharmaceutics recently conducted and analyzed the results of a food effect study for Rexista™ XR. The study design was a randomized, one-treatment two periods, two sequences, crossover, open label, laboratory-blind bioavailability study for Rexista™ XR following a single 80 mg oral dose to healthy adults under fasting and fed conditions.

The food effect study showed that Rexista™ XR can be administered with or without a meal (i.e., no food effect). Rexista™ XR met the bioequivalence criteria (90 percent confidence interval of 80 to 125 percent) for all matrices, i.e., on the measure of maximum plasma concentration or C_{max}, the ratio of Rexista™ XR taken under fasted condition to Rexista™ XR taken under fed condition was 112.79 percent (90 percent confidence interval of 102.75 to 123.8 percent) and on the measure of area under the curve from time zero to time t (AUC_t) the ratio of Rexista™ XR taken under fasted condition to Rexista™ XR taken under fed condition was 99.99 percent (90 percent confidence interval of 95.24 to 104.99 percent) and on the measure of area under the curve from time zero to time infinity (AUC_{inf}) the ratio of Rexista™ XR taken under fasted condition to Rexista™ XR taken under fed condition

was 100.70 percent (90 percent confidence interval of 94.64 to 107.15 percent).

> Dr. Isa Odidi, Chairman and CEO, stated, *"The FDA waiver of the NDA application fee is a welcome decision in our development of Rexista™ XR. In addition, we believe the food effect studies demonstrate that Rexista™ XR taken under fasted and fed conditions is bioequivalent for all pharmacokinetic matrices studied and has no food effect, and that Rexista™ XR is well differentiated from currently marketed oral oxycodone extended release products, one of which is labelled to be taken with food due to food effects and the other whose C_{max} matrix has been reported not to be bioequivalent under fasting and fed conditions. The Company plans to file the NDA for Rexista™ XR in August of 2016."*

There can be no assurance that we will not be required to conduct further studies for Rexista™ XR, that we will continue to satisfy the criteria for the waiver of the application fee, that we will file an NDA for Rexista™ XR in August 2016, that the FDA will ultimately approve the NDA for the sale of Rexista™ XR in the U.S. market, or that it will ever be successfully commercialized.

Rexista™ XR (oxycodone hydrochloride extended release tablets)

The Company's Rexista™ XR (oxycodone hydrochloride extended release tablets) product candidate is intended as an abuse and alcohol-deterrent controlled-release oral formulation of oxycodone hydrochloride for the relief of pain. Rexista™ XR is an investigational drug, with a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time. The formulation 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™ XR formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. The blue dye will stain mucous membranes and skin if the product is manipulated and comes in contact with moisture. This stigmatizing blue dye is intended to act as a visible deterrent against inappropriate use if abused 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 (which have received final FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA (and one ANDS 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™ XR, an abuse deterrent oxycodone based on its proprietary nPODDDS™ novel Point Of Divergence Drug Delivery System and PODRAS™ Paradoxical OverDose Resistance Activating System, 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™ XR and Regabatin™ XR. 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 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, difficulties or delays in manufacturing, 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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