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Intellipharmaceutics Announces FDA Approval for 500 mg and 750 mg Generic Keppra XR®

TORONTO, Feb. 24, 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 announced that the Company today received final approval from the U.S. Food and Drug Administration ("FDA") of the Company's abbreviated new drug application ("ANDA") for levetiracetam extended-release tablets for the 500 mg and 750 mg strengths. The Company's newly approved product is a generic equivalent for the corresponding strengths of the branded product Keppra XR® sold in the United States by UCB, Inc.

Dr. Isa Odidi, the CEO and a co-founder of Intellipharmaceutics, stated,*"FDA approval of our application for a generic version of Keppra XR® is an important milestone for the Company. It is our first approved product developed in house at Intellipharmaceutics without the support or regulatory input of a development partner. We believe that this approval of our generic Keppra XR® product represents a strong validation of our core drug development and regulatory competence and our controlled-release delivery technologies. The approval, under the Generic Drug Fee User Amendments of 2012, or GDUFA, fee regime at the FDA, is perhaps also an indication that the FDA is making progress to clear its backlog of ANDA drug candidates under review. We regard it as hopeful that some of the Company's other 8 ANDA candidates will be accorded further attention soon. We are actively exploring the best approach to maximize our commercial returns from this new approval."*

Keppra XR®, and the drug active levetiracetam, are indicated for use in the treatment of partial onset seizures associated with epilepsy. According to Symphony Health Solutions, sales in the United States for the 12 months ended December 2015 of the 500 mg and 750 mg strengths of *Keppra XR®* and all generic equivalents, were approximately $168 million (TRx MBS Dollars, which represents projected new and refilled prescriptions representing a standardized dollar metric based on manufacturer's published catalog or list prices to wholesalers, and does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price). The Company is aware that other generic versions of this product are currently available in the market. There can be no assurance that the Company's levetiracetam extended-release tablets for the 500 mg and 750 mg strengths will be successfully commercialized.

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 Abbreviated New Drug Submission ("ANDS") filed with Health Canada) in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract, diabetes and pain.

Intellipharmaceutics also has New Drug Application ("NDA") 505(b)(2) specialty drug product candidates in its development pipeline. These include Rexista™ Oxycodone 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™ 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.

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

of 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 the timing of launch of competitive products, the difficulty of predicting the impact of competitive products on volume and pricing, the inability to forecast wholesaler demand and/or wholesaler buying patterns, the seasonal fluctuation in the numbers of prescriptions written for our 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 and risks associated with cyber-security and vulnerability of the Company's digital information and the digital information of the Company's commercialization partner(s). 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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