

May 10, 2017



## Intellipharmaceuticals Announces FDA Final Approval of Generic Seroquel XR®

TORONTO, May 10, 2017 (GLOBE NEWSWIRE) -- Intellipharmaceuticals International Inc. (Nasdaq:IPCI) (TSX:IPCI) ("Intellipharmaceuticals" 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 it has today received final approval from the U.S. Food and Drug Administration ("FDA") for the Company's abbreviated new drug application ("ANDA") for quetiapine fumarate extended-release tablets in the 50, 150, 200, 300 and 400 mg strengths. This approval follows the expiry of 180-day exclusivity periods granted to the first filers of generic equivalents to the branded product, as previously disclosed by the Company. The approved product is a generic equivalent of the branded product Seroquel XR® sold in the U.S. by Astra Zeneca Pharmaceuticals LP.

The Company previously announced that it had entered into a license and commercial supply agreement with Mallinckrodt LLC ("Mallinckrodt"), granting Mallinckrodt a license to market, sell and distribute in the U.S. the Company's quetiapine fumarate extended-release tablets (generic Seroquel XR®). Under that agreement, the Company manufactures and supplies the licensed product for Mallinckrodt. The Company has manufactured commercial quantities of all strengths of generic Seroquel XR®, and expects to ship product to Mallinckrodt imminently under its commercialization agreement. That agreement also includes two other product candidates, our generic Pristiq® and generic Lamictal® XR™, for which the Company has ANDAs under FDA review.

Dr. Isa Odidi, CEO and co-founder of Intellipharmaceuticals, stated, *"We are thrilled that the FDA has granted final approval for our generic Seroquel XR®, and that we have successfully manufactured commercial quantities of all strengths. We have now demonstrated that our core drug development competency in controlled-release delivery technologies is complemented by our commercial drug manufacturing capability. We are pleased to have Mallinckrodt as our U.S. commercial partner and believe that generic Seroquel XR® represents a substantial commercial opportunity for Intellipharmaceuticals."*

Seroquel XR®, and the drug active quetiapine fumarate, are indicated for use in the treatment of schizophrenia and bipolar disorder. According to Symphony Health Solutions, sales in the United States for the 12 months ended March 2017 of the 50, 150, 200, 300 and 400 mg strengths of Seroquel XR® (branded and generic) were approximately U.S. \$908 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). There can be no assurance that the Company's generic Seroquel XR® in any of the 50, 150, 200, 300 and 400 mg strengths will be successfully commercialized.

## **About Intellipharma**

Intellipharma 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, Intellipharma 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 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.

Intellipharma also has New Drug Application ("NDA") 505(b)(2) specialty drug product candidates in its development pipeline. These include Rexista™, an abuse deterrent oxycodone 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," "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, 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, the timing and amount of profit-share payments from our commercial partners, 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 product 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® (dexamethylphenidate hydrochloride extended-release) capsules which may produce substantial fluctuations in revenues, the timing and amount of insurance reimbursement regarding our products, changes in laws and regulations affecting the conditions required by the FDA for approval, testing and labeling of drugs including abuse or overdose deterrent properties, and changes affecting how opioids are regulated and prescribed by physicians, changes in laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products, changes in U.S. federal income tax laws currently being considered, including, but not limited to, the U.S. changing the method by which foreign income is taxed and resulting changes to the passive foreign investment company laws and regulations which may impact our shareholders, 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 products or product candidates, the manufacturing capacity of third-party manufacturers that we may use for our products, potential product liability risks, the recoverability of the cost of any pre-launch inventory should a planned product launch encounter a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential issues, the successful compliance with FDA, Health Canada and other governmental regulations applicable to us and our third party manufacturers' facilities, products and/or businesses, 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 Rexista™ in particular, if a patent infringement suit is filed against us with respect to any particular product candidates (such as in the case of Rexista™), which could delay the FDA's final approval of such product candidates, healthcare reform measures that could hinder or prevent the commercial success of our products and product candidates, 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), risks associated with cyber-security and the potential for vulnerability of our digital information or the digital information of a current and/or future drug development or commercialization partner of ours, 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 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](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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Source: Intellipharmaceutics International Inc.