

September 25, 2017



Intellipharma Receives Complete Response Letter from the FDA for Rexista™ NDA

FDA Response Provides Path toward Commercialization of Rexista™

TORONTO, Sept. 25, 2017 (GLOBE NEWSWIRE) -- Intellipharma International Inc. (Nasdaq:IPCI) (TSX:IPCI) ("Intellipharma" 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 provided an update on its Rexista™, henceforth referred to as Oxycodone Hydrochloride Extended-Release Tablets ("Oxycodone ER"), program.

The Company has received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") for its Oxycodone ER New Drug Application ("NDA"). In its CRL, the FDA provided certain recommendations and requests for information, including that Intellipharma complete the relevant Category 2 and Category 3 studies to assess the abuse-deterrent properties of Oxycodone ER by the oral and nasal routes of administration. The FDA also requested additional information related to the inclusion of the blue dye in the Oxycodone ER formulation, which is intended to deter abuse. The FDA has determined that it cannot approve the application in its present form.

"We are very encouraged by the FDA's response as it clarifies our path forward for Oxycodone ER," said, Dr. Isa Odidi, CEO of Intellipharma. "We had already planned the additional Category 2 and Category 3 studies the FDA has requested and we do not expect they will impact our anticipated commercialization timeline for Oxycodone ER."

Intellipharma has been given one year to respond to the CRL, and can request additional time if necessary. The FDA has also requested that Intellipharma submit an alternate proposed proprietary name for Oxycodone ER.

Dr. Odidi concluded, "We will continue to work closely with the FDA to provide them with the additional information they requested, including data supporting the label claims related to Oxycodone ER's abuse-deterrent properties. We believe our Oxycodone ER product can play an important preventative role in the midst of a serious opioid abuse crisis particularly impacting North America. The Company will be providing regular updates as we execute on our Oxycodone ER NDA resubmission plan."

There can be no assurance that Intellipharma 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 Intellipharma

Intellipharma 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. Intellipharma 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 our Oxycodone ER product, 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).

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 estimated proceeds (and the expected use of any proceeds) we may receive from any offering of our securities, the potential dilutive effects of any future financing, 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, 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/or commercial partners 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 commercial partners, 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 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 difficulty in predicting the impact of competitive products on volume, pricing, rebates and other allowances, the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow, the inability to forecast wholesaler demand and/or wholesaler buying patterns, 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, our reliance on commercial partners, and any future commercial partners, to market and commercialize our products and, if approved, our product candidates, 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 our Oxycodone ER product 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, 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 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.

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.