Intellipharmaceutics Corporation
www.intellipharmaceutics.com

Leveraging R&D expertise to target niche opportunities in pain management

By overcoming formulation challenges and applying its controlled-release delivery systems, Intellipharmaceutics is creating new options for pain therapies.

Intellipharmaceutics is at an important point in its nearly 20-year history. Having previously used its founders' decades of R&D experience and portfolio of controlled-release drug delivery technologies to advance other companies' pipelines, Intellipharmaceutics is now developing its own novel and proprietary drugs for filing for regulatory approval.

The internal pipeline is underpinned by the same capabilities that have enabled Intellipharmaceutics to successfully operate the ongoing licensing and collaboration side of the business for years. Isa Odidi and Amina Odidi, the co-founders, joint CSOs and, respectively, CEO and COO of Intellipharmaceutics, are the source of much of the expertise that has taken the company to where it is today.

With a stint at Biovail, a large number of approved patents, an extensive scientific publication bibliography, and the years at Intellipharmaceutics on their résumés, the co-founders have a track record of developing novel proprietary controlled-delivery platforms and applying technologies to drug development challenges. Increasingly, Intellipharmaceutics is looking to leverage that experience and capability to target new drug opportunities that improve patient compliance and health outcomes.

Tackling the opioid epidemic

Intellipharmaceutics is particularly interested in using its delivery technologies to develop solid oral-dosage forms of medication in the pain sector. In exploring this space, Intellipharmaceutics saw an opportunity to create a novel, improved formulation of the widely used—and often abused—opioid analgesic oxycodone. The formulation, branded as Rexista, is targeted to go through the regulatory process in the United States under what is known as the 505(b)(2) new drug application (NDA) pathway, possibly providing Intellipharmaceutics with a relatively shorter and more affordable path to market. The US Food and Drug Administration (FDA) filing for Rexista is imminent as of the writing of this profile.

Because a controlled-release formulation of oxycodone is already commercially available in the United States, Intellipharmaceutics will be able to apply for approval for Rexista without conducting many of the clinical trials typically needed to support regulatory filings for new drug molecules. Instead, Intellipharmaceutics performed bioequivalence tests intended to show that Rexista is comparable to the previously approved formulation of controlled-release oxycodone.

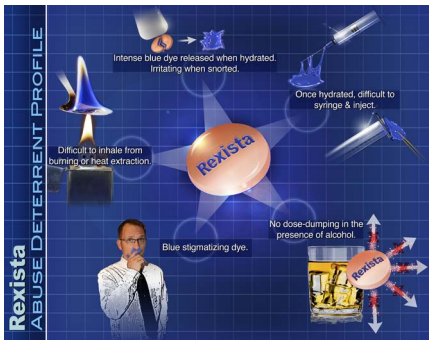

Figure 1: Abuse deterrent profile of Rexista. Deterring abusers, Rexista is difficult to inject, snort or inhale. The formulation design also prevents 'dose dumping' whereby active ingredients are rapidly released in the presence of alcohol.

This has provided Intellipharmaceutics with a possibly abbreviated development pathway, while enabling it to differentiate its oxycodone formulation through the use of abuse-resistant features. Rexista is designed to be difficult to inject, snort or inhale, all of which are routes of administration used by abusers of oxycodone. Intellipharmaceutics has also formulated Rexista so as to prevent 'dose dumping', a phenomenon in which the active ingredient is released rapidly in the presence of alcohol (**Fig. 1**).

The incorporation of these features makes Rexista a timely product. As recognition of the scale of the opioid epidemic has increased, politicians and the FDA have come under pressure to take action. This has intensified interest in abuse-resistant formulations of opioid pain killers, which have the potential to relieve patients' pain symptoms without opening the door to misuse.

Creating more convenient pain drugs

Intellipharmaceutics is also advancing a second drug, Regabatin XR, toward a 505(b)(2) NDA filing. This drug is another example of the company using its formulation technologies to develop controlled-release versions of approved immediate-release drugs. Regabatin XR is an extended-release formulation of pregabalin, the active ingredient in Pfizer's Lyrica. The drug, generic versions of which are available in some markets and for some indications, is used to treat the pain caused by conditions including fibromyalgia and spinal cord injury.

Depending on the indication, Lyrica is taken either two or three times a day. By applying its delivery capabilities to the drug's active ingredient, Intellipharmaceutics has created a formulation intended to be taken once a day. Such a controlled-release formulation of pregabalin has the potential to improve compliance to the treatment regimen, improving health outcomes for patients.

As the FDA has yet to approve an extended-release formulation of pregabalin, Regabatin XR will need to be tested in human clinical trials before it comes to market, although it will also enjoy the benefits of the 505(b)(2) pathway. To date, Intellipharmaceutics has run tests to assess whether once-daily doses of Regabatin XR provide a therapeutic range comparable to that seen with twice-daily doses of Lyrica. Intellipharmaceutics will need to run more clinical trials prior to filing an FDA application to bring the drug to market.

The potential payoff for performing this work is substantial. In the 2015 calendar year, US sales of Lyrica totaled $3.9 billion (£2.9 billion), according to Symphony Health Solutions. With those sales set to be captured by generic versions of the drug in the years to come, the opportunity for a product that improves on both Lyrica and its direct copycats is significant.

Building an R&D-focused business

Intellipharmaceutics is pursuing the opportunities available for Rexista and Regabatin XR in parallel to efforts to bring other drugs to market under the abbreviated new drug application (ANDA) pathway. ANDAs covering extended-release formulations of central nervous system drugs including quetiapine fumarate extended-release tablets and desvenlafaxine extended-release tablets, which are generics of the brand products Seroquel XR and Pristiq, respectively, are now under review by the FDA.

Whether Intellipharmaceutics is developing an in-house drug for an NDA or ANDA filing or working on a program with a collaborator, the project is underpinned by the same core strengths. The company and all of its programs are defined by an intense focus on R&D, proprietary controlled-release delivery systems, and knowledge of what it takes to overcome formulation challenges.

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