



FILMS

INTELGENX > PRODUCT > FILMS

PRODUCT

- Overview
- Films
- Tablets

RIZAPORT™ – INDICATED FOR MIGRAINE

Rizaport™ is the first rizatriptan oral disintegrating film for the treatment of migraine to achieve EU marketing approval. Rizaport™ is a new product opportunity co-developed in partnership with RedHill Biopharma and formulated using VersaFilm™, IntelGenx's proprietary thin film technology. Rizatriptan is a selective 5-HT_{1B/1D} receptor agonist indicated for the treatment of migraine. Compared to other triptan-based medications, rizatriptan demonstrates the highest efficacy and exhibits the shortest T_{max} providing a quick onset of action for migraine sufferers. Rizatriptan is also indicated for the treatment of migraine attacks in children and elderly who could both benefit from the ease of administration of the film formulation. Rizaport™ demonstrated bioequivalence in a successful pivotal clinical trial compared to the reference listed drug Maxalt MLT®. IntelGenx submitted a 505(b)(2) New Drug Application for regulatory approval to the U.S. Food and Drug Administration in Q1 2013. In addition, in November 2015, the German Federal Institute for Drugs and Medical Devices (BfArM) has granted national marketing approval for Rizaport™ for the treatment of acute migraines under the European Decentralized Procedure (DCP). According to Merck's annual report, sales of Maxalt® were \$638 million in 2012. IntelGenx and RedHill are currently looking for a partnership or alliance opportunity to commercialize Rizaport™.

INDICATED FOR OPIOID DEPENDENCE

An ANDA for an oral film product indicated for the treatment of opioid dependence was submitted in July 2013. The ANDA was filed by IntelGenx's U.S. based co-development and commercialization partner for this product, Par Pharmaceutical. According to IMS data, the oral film market for opioid dependence was worth more than \$1.4B US in 2014.

TADALAFIL FILM - INDICATED FOR ERECTILE DYSFUNCTION

INT0007 is a tadalafil film is a new product opportunity formulated using VersaFilm™, IntelGenx's proprietary thin film technology. Tadalafil is one of the three major PDE5 inhibitors in the erectile dysfunction market. Compared with the competitors, tadalafil shows longer duration of action and less food effect. IntelGenx's tadalafil film offers an improved discrete dosage form that does not require water intake. IntelGenx tadalafil film formulations have been tested in various clinical trials to improve the pharmacokinetics and optimize the formulation. The latest formulation successfully demonstrated bioequivalence to Cialis® tablet in a pilot study. Tadalafil film's development program targets launch readiness ahead of Cialis® patent expiry, which could lead to tadalafil VersaFilm™ being the first competitor to Cialis® tablets. IntelGenx is currently looking for a partnership or alliance opportunity to complete development and commercialize tadalafil VersaFilm™.

LOXAPINE FILM - INDICATED FOR SCHIZOPHRENIA

Loxapine is for the treatment of anxiety and aggression in patients suffering from schizophrenia or bipolar 1 disorder.

Loxapine oral film will utilize the company's proprietary VersaFilm™ technology, allowing for an improved product to offer patients significant therapeutic benefits compared to existing medications. A fast acting loxapine oral film dosage form that can be used to effectively treat acute agitation associated with schizophrenia or bipolar 1 disorder in non-institutionalized patients while reducing the risk of pulmonary problems is needed as it could substantially reduce the potential risks of violence and injury to patients and others by preventing or reducing the duration and severity of an episode of acute agitation.

IntelGenx has demonstrated in a successful pilot study that buccal absorption of the drug from the loxapine oral film results in a significantly higher bioavailability of the drug compared to oral tablets. IntelGenx is currently optimizing the film to further improve time to reach peak plasma concentrations. According to Datamonitor, sales of schizophrenia drugs across the seven major markets (the US, Japan, France, Germany, Italy, Spain, and the UK) were estimated at \$5.2 billion in 2012 and by 2021, the market is forecast to grow to \$6.9 billion at a compound annual growth rate (CAGR) of 3.3%.

Agitation associated with schizophrenia or bipolar mania is not uncommon, and

agitation associated with schizophrenia and bipolar mania are often effectively managed with behavioral and psychological techniques, with unexpected acute agitation typically being treated with parenterally administered sedatives such as benzodiazepines and/or antipsychotic drugs such as olanzapine and ziprasidone.

On December 21, 2012, the U.S. Food and Drug Administration approved a loxapine product formulated into an inhaled powder for direct administration to the lungs and is indicated for the treatment of acute agitation associated with schizophrenia or bipolar 1 disorder in adults. A statistically significant reduction in agitation occurs at 2 hours, and an improvement is achieved at 10 minutes after administration. The onset of a statistically significant reduction in agitation occurs at 5 minutes. However, to mitigate the risk of bronchospasm, inhaled loxapine powder must be administered only in an enrolled healthcare facility, and only to patients that have been pre-screened to ensure they are not susceptible to pulmonary issues.

Loxapine oral capsules have been available for the treatment of schizophrenia since about 1988, with the typical dosage being 30-50 mg twice daily. The loxapine capsules are unsuitable for treating acute agitation associated with schizophrenia or bipolar 1 disorder because onset of therapeutic relief occurs approximately 20-30 minutes after administration. Such delayed onset of relief would significantly increase the risk of injury to a person being treated and those administering treatment.

INT0036 is indicated for the treatment of schizophrenia and utilizes the company's proprietary VersaFilm™ technology, allowing for an improved product to offer patients significant therapeutic benefits compared to existing medications. IntelGenx has demonstrated in a successful pilot study that buccal absorption of the drug from the INT0036 film product results in a significantly higher bioavailability of the drug compared to oral tablets. According to Datamonitor, sales of schizophrenia drugs across the seven major markets (the US, Japan, France, Germany, Italy, Spain, and the UK) were estimated at \$5.2 billion in 2012 and by 2021, the market is forecast to grow to \$6.9 billion at a compound annual growth rate (CAGR) of 3.3%. IntelGenx is currently looking for a partnership or alliance opportunity to complete development and commercialize INT0036.

GENERIC FORMULATION INDICATED FOR PAIN MANAGEMENT

INT0039 is a film product to the management of pain based on IntelGenx's proprietary thin film technology. IntelGenx is currently looking for a partnership or alliance opportunity to complete development and commercialize INT0039.

CNS APPLICATION

INT0040 is a CNS application indicated for the management of degenerative diseases. IntelGenx proposes the development of a fast onset of action film product for use in degenerative diseases using VersaFilm™, IntelGenx's proprietary thin film technology. IntelGenx is currently looking for a partnership or alliance opportunity to complete development and commercialize INT0040.

ALZHEIMER'S DISEASE

INT0043 is a unique repurposing opportunity for the treatment of Alzheimer 's disease. IntelGenx is developing a film product based on the VersaFilm™ proprietary thin film technology and using an already FDA approved drug that has demonstrated potential for the treatment of Alzheimer 's disease. IntelGenx is currently looking for a partnership or alliance opportunity to complete development and commercialize INT0043.

ABOUT US

- [Overview](#)
- [Management](#)
- [Board of Directors](#)
- [Careers](#)

PRODUCT

- [Overview](#)
- [Films](#)
- [Tablets](#)

R&D SERVICES

- [Overview](#)
- [VersaFilm](#)
- [VersaTab](#)

MANUFACTURING SERVICES

- [Overview](#)
- [Film Manufacturing Services](#)

PARTNERING

[Overview](#)

INVESTORS

[Overview](#)
[Financial Reports](#)
[Corporate Governance](#)
[Press Releases](#)
[Stock Price](#)
[Presentations](#)
[Regulatory Filings](#)
[Analyst Coverage](#)
[IR Contact](#)

MORE LINKS

[Facebook](#)
[Twitter](#)
[Linkedin](#)
[Contact us](#)
[Careers](#)
[Email Signup](#)
[RSS Feeds](#)

© COPYRIGHT 2016. INTELGENX CORP. ALL RIGHTS RESERVED.

[TERMS OF SERVICE](#)

[PRIVACY](#)

[CONTACT US](#)

POWERED BY Q4 WEB SYSTEMS 4.1.3.41