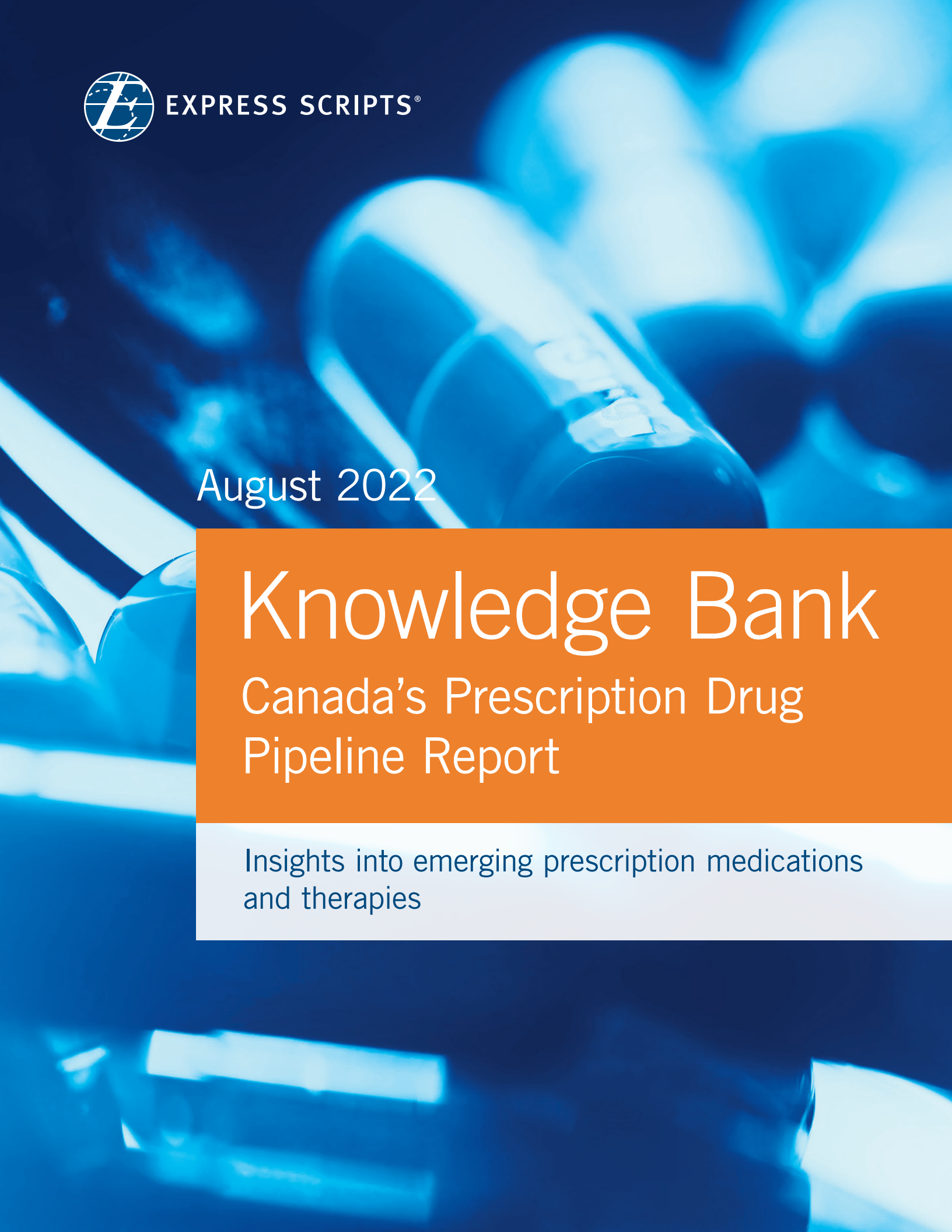

EXPRESS SCRIPTS®

August 2022

Knowledge Bank

Canada's Prescription Drug Pipeline Report

Insights into emerging prescription medications and therapies

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INTRODUCTION

Express Scripts Canada's Drug Pipeline Report continues to focus on developments in therapeutic areas that have a significant impact on the health of Canadians – cancer, heart conditions, and pain management.

The impact of biosimilars was a major focus in this year's Drug Trend Report. We continue to follow the status and approval of other biosimilars, particularly those used to treat ophthalmic conditions.

The opioid crisis was heightened during the COVID-19 pandemic. In the search for new therapeutic options for pain management with lower risk of addiction potential, one molecule has emerged which may relieve neuropathic type pain.

Rounding out updates this quarter, new immuno-oncology products and oral alternatives for breast cancer are being evaluated that may re-shape how and where patients receive their treatment.

UPDATE FROM OUR LAST REPORT

Biosimilars

Common Name	Biologic Reference Drug	Therapeutic Area	Submission dates to Health Canada	Estimated Impact on Private Plans[1]
Aflibercept	EYLEA®	Opthalmologicals	2022-05	High
Bevacizumab	AVASTIN®	Antineoplastic agents	2022-03	Low
Enoxaparin sodium	LOVENOX®	Antithrombotic agents	2021-12	Low
Etanercept	ENBREL®	Immunosuppressants	2020-02	Low-moderate
Human insulin (recombinant)	HUMULIN®	Drugs used in diabetes	2021-05	Low-moderate
Pegfilgrastim	NEULASTA®	Immunostimulants	2022-05	Low
Trastuzumab	HERCEPTIN®	Antineoplastic agents	2021-08	Low

[1] Impact estimated based on the number of marketed biosimilars, claims for the reference brand, and annual drug cost.

In an update from previous reports, Health Canada is currently reviewing 8 biosimilars. The ranibizumab biosimilar, BYOOVIZ®, has now been approved and is anticipated to help reduce spend on LUCENTIS® for the second half of 2022. Of note, a biosimilar for EYLEA® (aflibercept), a direct competitor of LUCENTIS®, has now been submitted for review to Health Canada. This would be the first biosimilar for EYLEA® and will help to further reduce spend on conditions related to vision impairment.

The U.S. FDA has approved another interchangeable biosimilar, this time for insulin aspart. Similar products are not yet approved in Canada.

Migraine

The oral gepants (ubrogepant and rimegepant) discussed in the last report are still awaiting full approval by Health Canada. These potential new entrants may dramatically shape the migraine treatment space once approved.

Diabetes

The injectable dual G1P and GLP-1 agonist, tirzepitide, has been approved by the FDA in the United States. This medication had promising results for both glycemic control and weight loss. This new potentially blockbuster therapeutic option may impact current treatment guidelines for diabetes.

COMING SOON

Cardiology

In January of this year, Bristol-Myers Squibb submitted mavacamten for review by Health Canada. If approved, it will become the first drug to specifically treat obstructive hypertrophic cardiomyopathy, an inherited form of heart failure prevalent in approximately 1 in 500 individuals. The condition is caused by the heart muscle thickening, which impairs the hearts ability to pump blood and leads to heart failure and shortness of breath. Mavacamten helps to relax the muscle fibers of the heart between beats so that more blood can enter the ventricles to be pumped out. In the EXPLORER trial of 251 patients, mavacamten was shown to improve exercise capacity and symptoms as it allowed for better left ventricular function.

Current therapies for obstructive hypertrophic cardiomyopathy include the widely genericized beta-blockers and calcium-channel blockers, which only act to mitigate symptoms, and most patients remain symptomatic and may require surgical intervention. The annual cost of mavacamten is anticipated to be significant in comparison. Its approval may lead to higher spend for cardiology drugs in 2023. Despite promising results, there is currently a black-box warning due to the risk of heart failure.

FURTHER DOWN THE LINE

Immuno-oncology

Immunotherapy has been a major breakthrough in the past decade in cancer research. While the products are costly, the approval of immuno-oncology (IO) agents has made a clinically significant impact on the oncology space. Checkpoint-inhibitors, such as KEYTRUDA®, YERVOY®, OPDIVO®, and TECENTRIQ® have been approved for various oncology conditions, including some which are highly-prevalent such as breast cancer, lung cancer, colon cancer, and melanoma. KEYTRUDA® is currently approved for 25 indications, with more on the way, for 12 types of cancer. OPDIVO® is not far behind as it is approved for 17 indications for 10 types of cancer. To a lesser degree are TECENTRIQ® and YERVOY®, which are approved for 7 and 8 indications respectively. This has led to an increase in the uptake of these molecules, and subsequently, an increase in spend for drug plans on oncology products.

One promising new agent is vidutolimod, a cancer vaccine developed by Checkmate Pharmaceuticals. It is being studied for its use in skin and blood cancers to be used in combination with treatments like KEYTRUDA® and OPDIVO®. If successful, approval of vidutolimod could lead to even greater spend in oncology.

Breast Cancer

Selective estrogen receptor degraders (SERDs) are used to treated hormone receptor positive metastatic breast cancer. Currently, fulvestrant is the only SERD available which is administered by injection. There are many trials underway investigating new SERDs which can be administered orally. This may shift treatment for this subtype of breast cancer from the hospital to home. These oral alternatives may also overcome the resistance that is common with existing options. Many clinical trials are investigating new SERDs, including giredestrant, amcenestrant, and elacestrant.

Pain Management

The opioid crisis has been at the forefront of health news cycles for many years due to the increase in opioid overdoses in the past decades. As such, much research has gone into looking for effective medications that provide opioid-level of relief, without the risk of addiction. With many potential agents still in the pipeline, excitingly a new pain management option was developed by Daiichi Sankyo and approved in Japan at the beginning of 2019. Mirogabalin was approved in Japan for the treatment of peripheral neuropathic pain, diabetic peripheral neuropathic pain and postherpetic neuralgia, as well as central neuropathic pain in 2021. Unfortunately, after mirogabalin failed to meet its primary endpoint as a treatment for fibromyalgia pain in Phase III trials, its development was halted in the United States and European Union. Nevertheless, a 2021 systematic review and meta-analysis of three trials for patient with diabetic peripheral neuropathic pain showed that mirogabalin significantly reduced pain scores relative to placebo and outperformed pregabalin after 3 weeks. Mirogabalin and other drugs in development lead to hope for better pain management with fewer risks.

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