Long-Term Care in Canada: Where are we now and where are we heading? A case for Change.

Michael Nicin
Executive Director

October 22, 2019

NIA Long-Term Care Report Goals

The NIA's 2019 Policy Series has been sponsored by and produced in collaboration with AdvantAge Ontario, the Canadian Medical Association, Essity, and Home Instead Senior Care.

The purpose of the inaugural report of this series is to:

1. Explore the current provision of long-term care across Canada and place it within the global context of comparable countries that are tackling similar demographic transitions as they redevelop their systems of care.

2. Highlight Canada's current challenges.

3. Present evidence-informed opportunities and enablers of innovation in the growing and important area of care.

AdvantAge Ontario Advancing Senior Care · Association Médicale Canadienne / Canadian Medical Association · essity · Home Instead Senior Care To us, it's personal. · NIA National Institute on Ageing

NIA Long-Term Care Report Goals

The NIA's 2019 Policy Series has been sponsored by and produced in collaboration with AdvantAge Ontario, the Canadian Institute of Actuaries, the Canadian Medical Association, Essity, and Home Instead Senior Care.

The purpose of the second report of this series was to:

1. Better understand the challenges Canada faces over the next three decades in providing long-term care – both public costs and private costs to older Canadians and their families.

2. Project the future long-term care costs from a public policy lens.

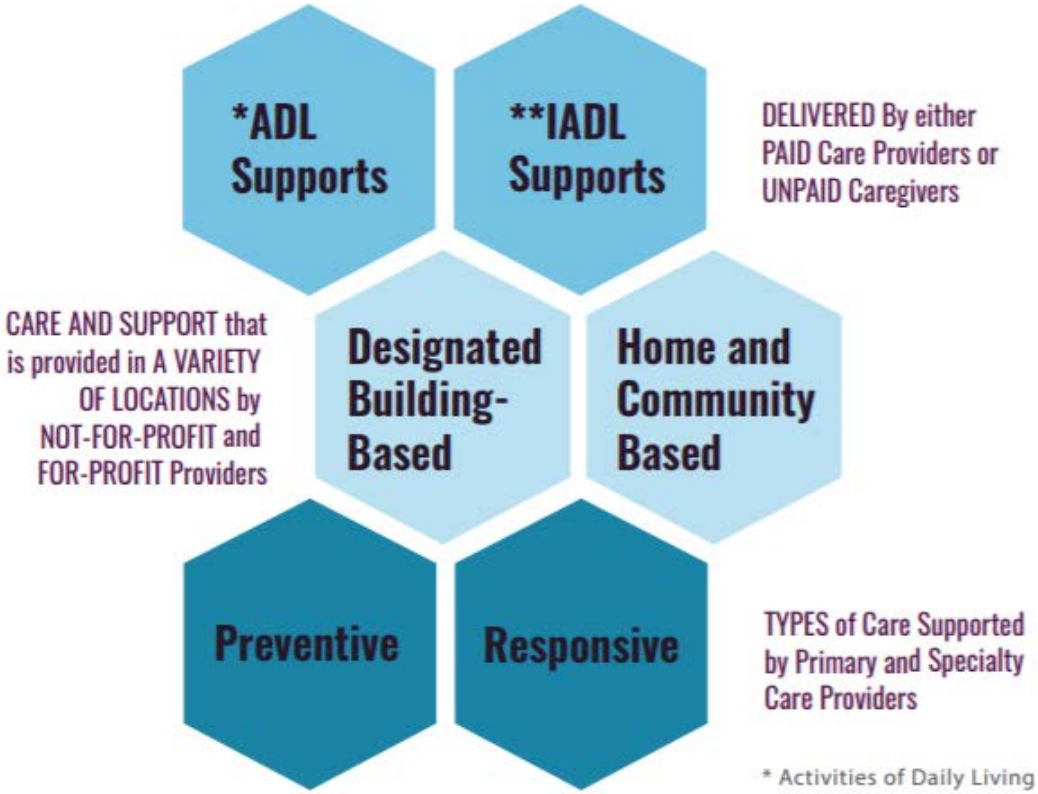
3. Examine the personal cost to seniors in terms of the unpaid care hours provided by personal support networks.

Why Long-Term Care Matters

- **It is the LARGEST form of hands-on care that is NOT covered under the Canada Health Act**
- Coverage levels and qualifying criteria vary significantly across provinces and territories
- So much of the healthcare Canadians receive occurs on the spectrum of long-term care
- The current demand for long-term care services is already unprecedented and is only expected to grow as the population ages

Defining Long-Term Care

Figure 1: NIA Visual of the Components Inherent to the International Provision of Long-Term Care (LTC)

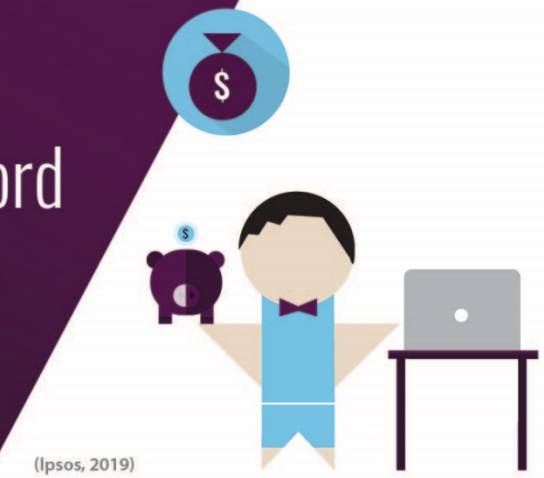


Why Long-Term Care Matters

- A 2015 national survey of 2,008 found that **63%** of respondents said their family was not in a good position (financially or otherwise) to care for older family members if they needed long-term health care, a significant source of concern (Ipsos Public Affairs, 2015).

Why Long-Term Care Matters

88% of Canadians are worried about the growing health care costs due to the ageing population, while **58%** believe many Canadians will delay their retirement to afford the health care they need to remain healthy and independent in their communities.



(Ipsos, 2019)

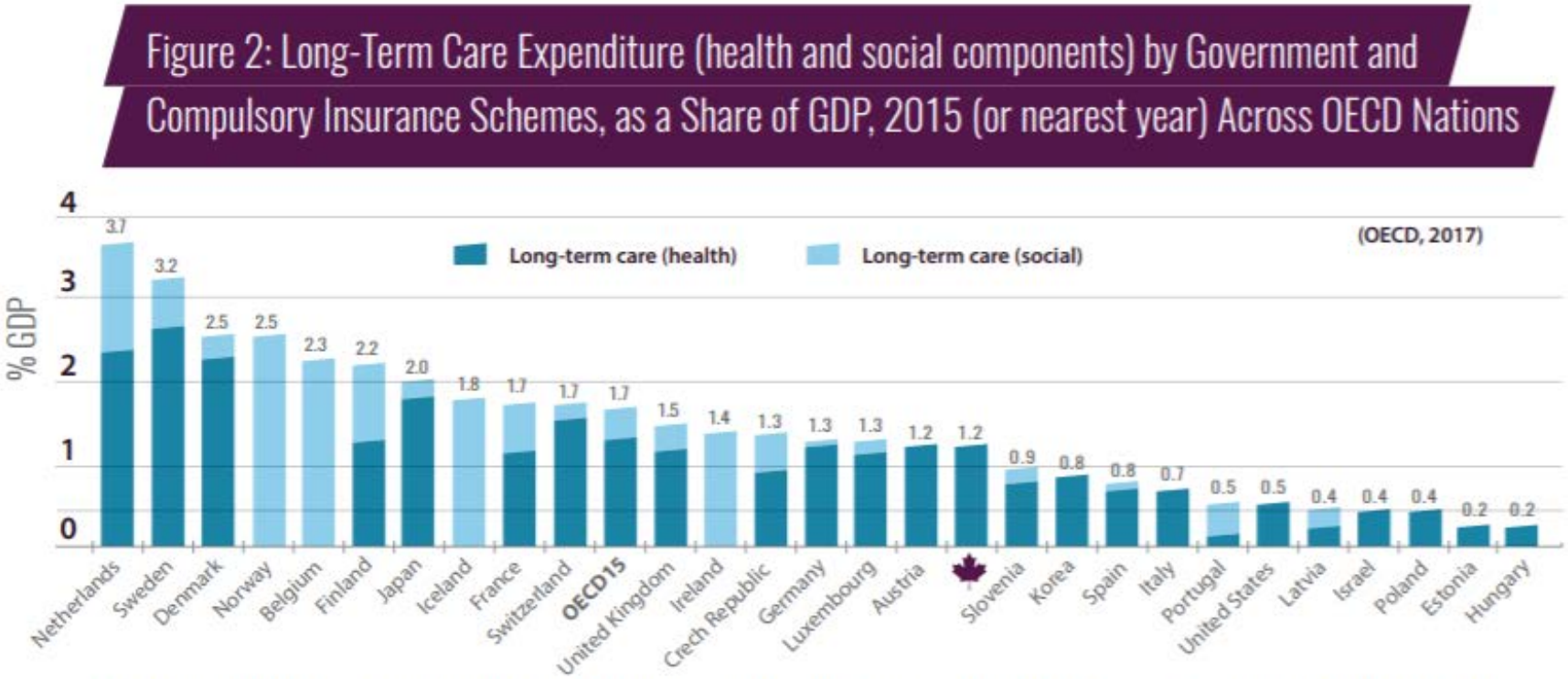
Where We Are Today

Over **430,000** Canadians currently have unmet home care needs, while **40,000** are on nursing home wait lists.

(Gilmour, 2018b)

NATIONAL INSTITUTE ON AGEING

Comparing Canada to Other OECD Nations, Canada Spends less on Average of its GDP on the Provision of Long-Term Care



Note: The OECD average only includes the 15 countries that report health and social LTC. Source: OECD Health Statistics 2017.

Comparing Canada to Other OECD Nations, Canada Spends far Less on Home and Community Care than on Nursing Home Care

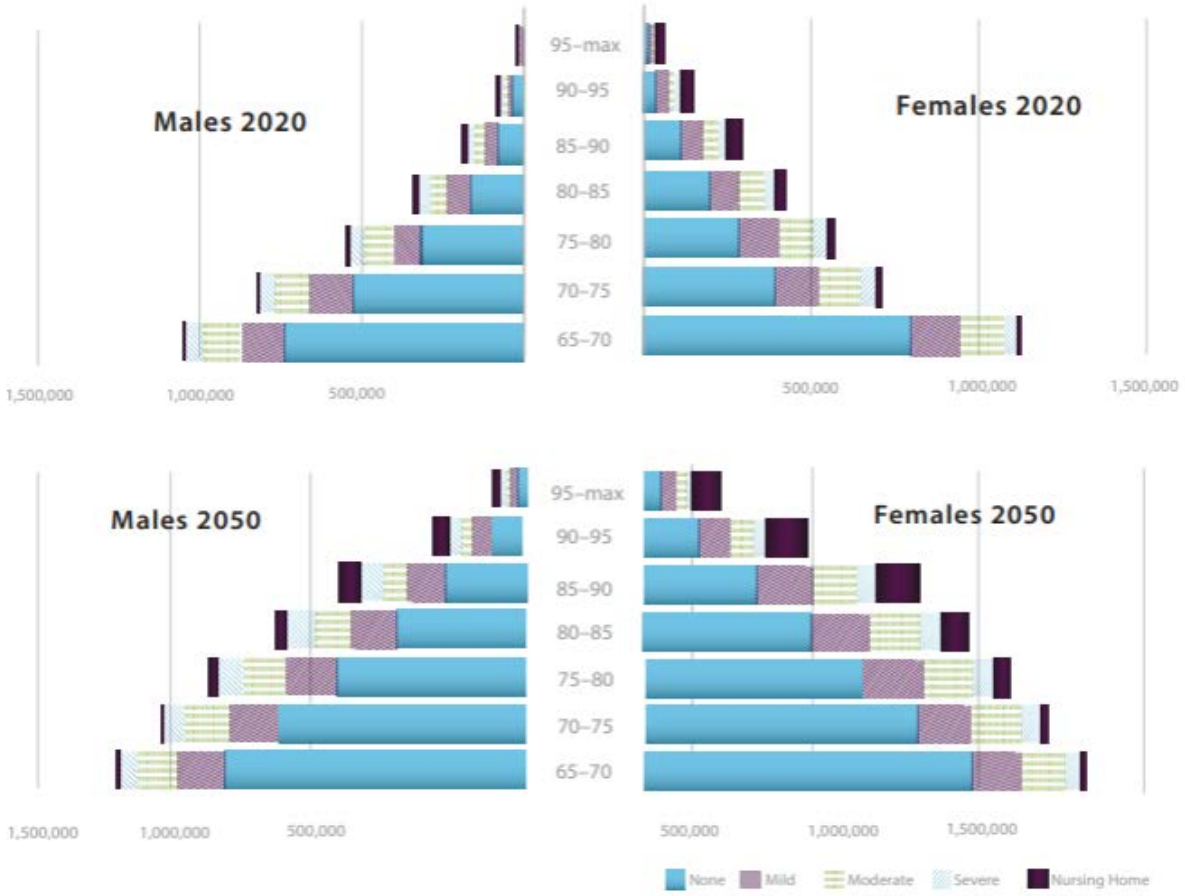
Figure 3: Government and Compulsory Insurance Spending on LTC (health) by Mode of Provision, 2015 (or nearest year) Across OECD Nations

Note: "Other" includes LTC day cases and outpatient LTC. Source: OECD Health Statistics 2017.

(Adapted from OECD, 2017)

Canada's Senior Population, 2020 and 2050

Figure 1 – Seniors' Population Pyramids by Disability Severity, 2020 and 2050



Source: Authors' *LifePaths* projections (see section "Analytical Methods" for details).

Between 2019 and 2050, the cost of public care in nursing homes and private homes will more than triple, growing from **$22 billion to $71 billion** annually (in constant 2019 dollars).

Between 2019 and 2050, there will be approximately **30%** fewer close family members available to provide unpaid care.

By 2050, the average unpaid family caregiver will need to increase their efforts by **40%** to keep up with care needs. More than twice the number of Canadian seniors will find themselves drawing on unpaid support.

If all unpaid hours of care provided by family inside the home were instead paid publicly, this would add **$27 billion** to public sector costs by 2050.

Cancer Care Ontario

Getting Real about RWE

Canadian Association of Population Therapeutics
October 22, 2019

Scott Gavura
Director Provincial Drug Reimbursement Programs

Ontario

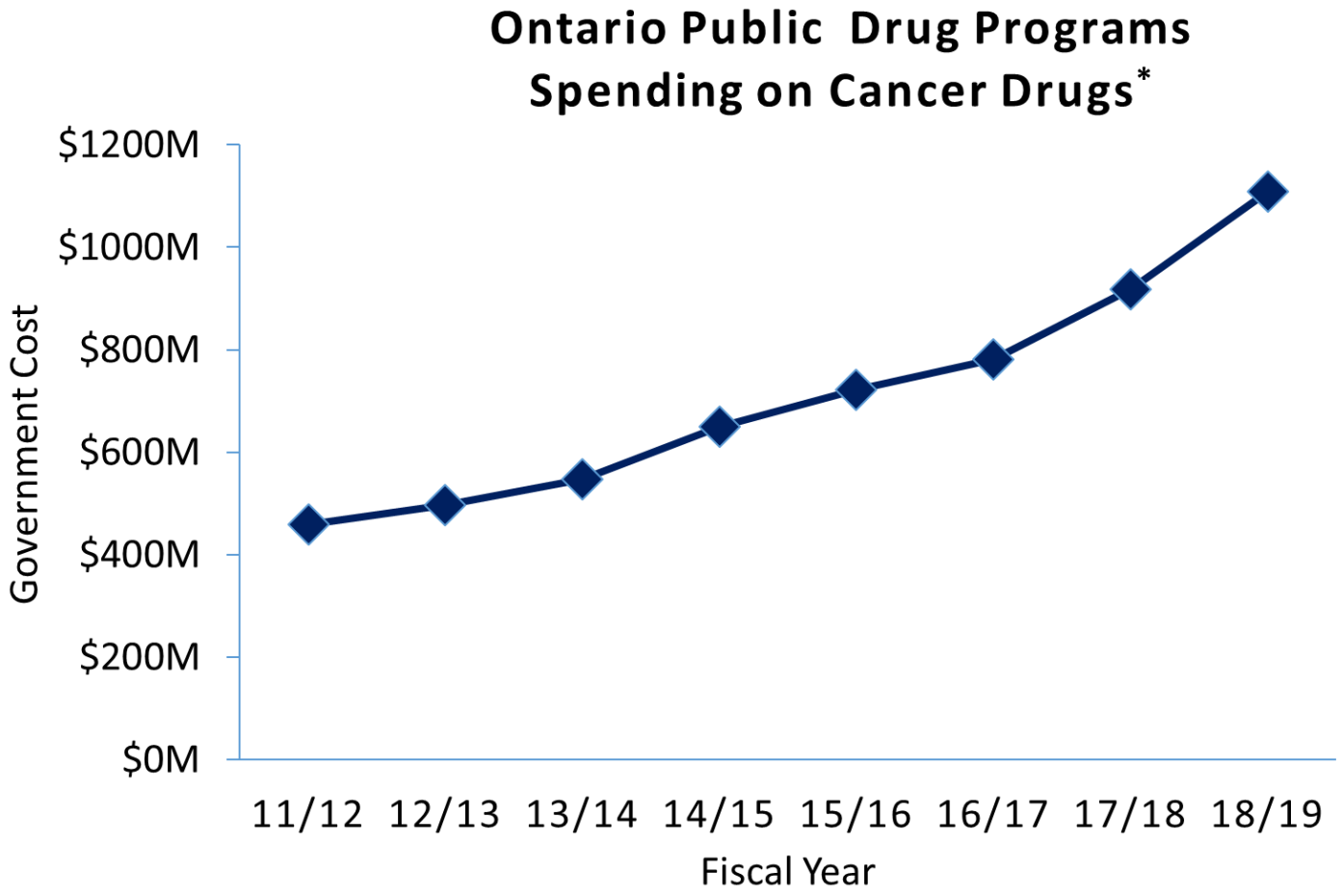
Disclosure

The speaker has no financial or other conflicts of interest to report.

Outline

- Current context in cancer drug funding
- When might RWE be useful?
- What work is Ontario doing in RWE for oncology services?
- What is the potential role of RWE in cancer?

Cancer drug costs now exceed $1 billion/year



*Annual expenditures are reported for IV cancer drugs (n=52) reimbursed by the New Drug Funding Program (NDFP) and take-home cancer drugs (n=91) reimbursed by the Ontario Drug Benefit Program (ODB).

†Government costs include drug costs and any associated pharmacy fees (for drugs reimbursed by ODB). Costs reported do not reflect manufacturer rebates (if applicable).

Source: ODB costs – ICES data (June 2019) ; NDFP costs – CCO data (June 2019)

What are the goals in cancer drug funding?

Select

- New treatments must offer a **meaningful clinical benefit (OS or QOL) vs. current treatments** (drug or non-drug)

Fund

- Pay more, get more: Prices should **align with the magnitude of the benefit**

Monitor

- **Manage overall spending** growth
- **Verify** drugs are delivering value and benefit expected

RWE?

OS: Overall Survival
QOL: Quality of Life

When to use RWE?[1,2]

- ✘ Determine the efficacy/safety of new drugs
- ✓ Confirm findings of an RCT in a broader population encountered in clinical practice *(e.g., elderly, multiple comorbidities, multiple prior treatments)*
- ✓ Supplement findings from small RCTs that show evidence of efficacy
- ✓ Identify rare and long-term treatment-related toxicities

"….potential for patient harm if therapies are adopted solely on the basis of analyses of RWD."[1]

RWE can test generalizability and augment the results of a clinical trial

[1]Karim S, Booth CM. J Clin Oncol. 2019 May 1;37(13):1047-1050.
[2]Booth CM, Tannock IF. Br J Cancer. 2014 Feb 4;110(3):551-5.

When to use RWE?[1,2]

- ✘ Determine effectiveness when prior RCTs have shown a lack of efficacy

- ✓ Address questions that will not (or can not) be evaluated in an RCT:

  e.g.,

  - Sequencing of oncology therapies
  - Costs of cancer care *(e.g., budget impact, treatment utilization)*
  - Rare outcomes in specific cancer patients
  - Establish PROs *(e.g., studies on symptom burden)*
  - *Confirm* cost-effectiveness

[1]Karim S, Booth CM. J Clin Oncol. 2019 May 1;37(13):1047-1050.
[2]Booth CM, Tannock IF. Br J Cancer. 2014 Feb 4;110(3):551-5.

But what about rare cancers?

- pCODR has issued positive recommendations for rare cancers with RCTs.
- For rare cancers, pCODR has issued negative recommendations where an RCT was deemed feasible.

Finding 2: Drugs for rare indications appear to have fewer submissions with RCTs conducted. For negative recommendations without an RCT, pERC deemed it feasible to conduct an RCT for all rare and non-rare indications.

	No RCT Conducted (n = 16)	RCT Conducted (n = 80)
Rare (<1/100,000)	8 (50%)	8 (50%)
Non Rare (>1/100,000)	8 (10%)	72 (90%)

Relative Risk = 5 (95% CI: 2.2, 11.35); Odds Ratio = 9 (95% CI: 2.7, 30.6); P-value <0.01

OR = the odds of having an RCT submitted with the funding submission.
RR = the relative risk of no RCT with a submission for rare indications vs. non rare indications.

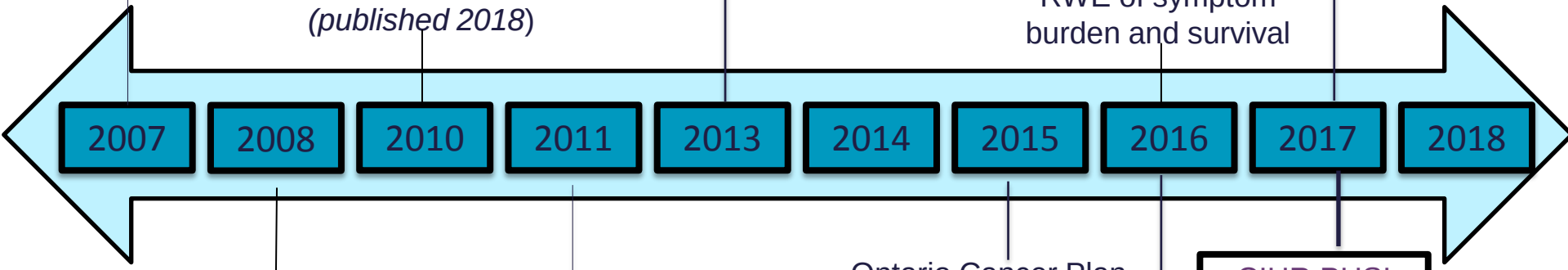
Source: Keech J, Dai WF, Beca J, Chan K. Poster Presentation. Impact of Rarity on Oncology Health Technology Assessment (HTA) and Funding ARCC Symposium 2019.

Cancer Care Ontario

Building Ontario expertise in RWE

Ontario

Significant Ontario oncology RWE initiatives & related events



Interactive Symptom Assessment and Collection tool launched to collect PROs

Azacitidine/MDS, AML: Funded by NDFP; prospective RWE *(published 2018)*

Oxaliplatin/CRC with extrahepatic mets: Funded via EBP; prospective RWE of survival

Ipilimumab/melanoma: RWE of efficacy/safety/cost-effectiveness

Pancreatic cancer: RWE of symptom burden and survival

Rituximab/DLBCL: retrospective, RWE of costs & cost-effectiveness *(published 2014)*[1]

Trastuzumab/ adjuvant breast ca: Funded via EBP; prospective RWE on safety

Ontario Cancer Plan IV (CCO)

CQCO Programmatic Review on Drug Funding Sustainability

CIHR PHSI Grant

CanREValue
Value-based decisions from Real World Evidence

Avastin (bevacizumab)/CRC multi-provincial RWE (ON/BC/SK) *(completed 2018)*

EBP: CCO's Evidence-Building Program
NDFP: CCO's New Drug Funding Program

[1]Khor S, Beca J et al. BMC Cancer 2014,14:586.
[2] Mozessohn L et al. Br J Haematol. 2018 Jun;181(6):803-815.

What are circumstances where RWE may be desirable?

- New/innovative technologies with broader (and potentially unclear) system impact.
- Where the real-world population is expected to differ from the patients studied in the clinical trials.
- Limited comparative data against current treatment approaches.
- Substantial budget impact and/or considerable uncertainty about budget impact.
- To address payer/clinician/stakeholder concerns systematically and transparently.

Oncology Biosimilars in Canada

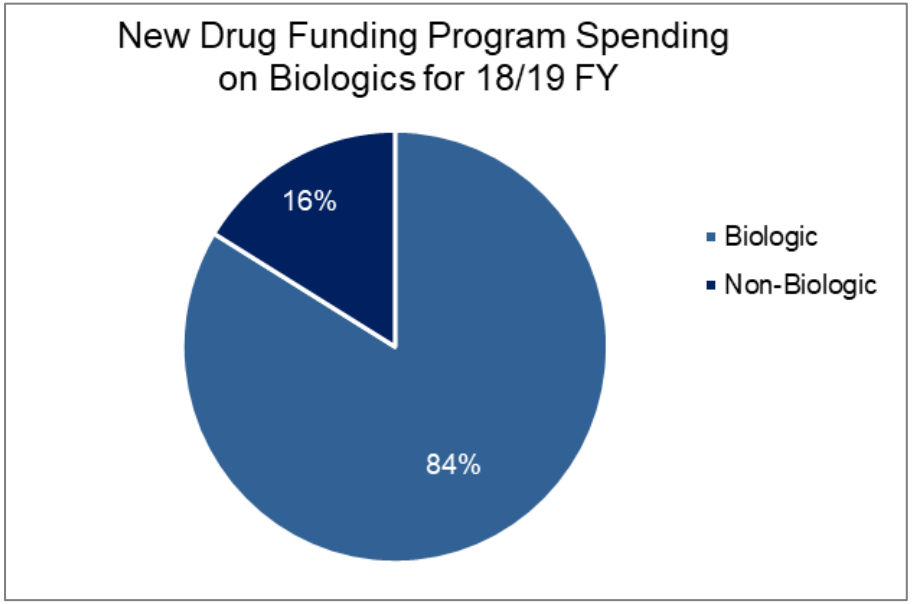
Biosimilar	Reference Biologic	Funded Indications*	Listing Status in Ontario
Mvasi (bevacizumab)	Avastin	• Colorectal cancer • Ovarian cancer (platinum-sensitive) • Cervical Cancer	**Funded – Sep 2019**
Zirabev (bevacizumab)	Avastin	• Colorectal cancer • Ovarian cancer – platinum-sensitive • Ovarian-cancer – platinum-resistant • Cervical cancer	**Funded – Oct 2019**
Herzuma, Ogivri, Trazimera (trastuzumab IV)	Herceptin	• Breast cancer (early; metastatic) • Gastric cancer	*Under pan-Canadian pricing negotiations*†
Truxima (rituximab IV)	Rituxan	• Rheumatoid arthritis • CLL, Non-Hodgkin's Lymphoma	*Under pan-Canadian pricing negotiations*†

*Publicly funded indications may vary by provincial formulary

†Source: Pan-Canadian Pharmaceutical Alliance: Active Negotiations. 30 Sep 2019

Why consider RWE for Oncology Biosimilars?

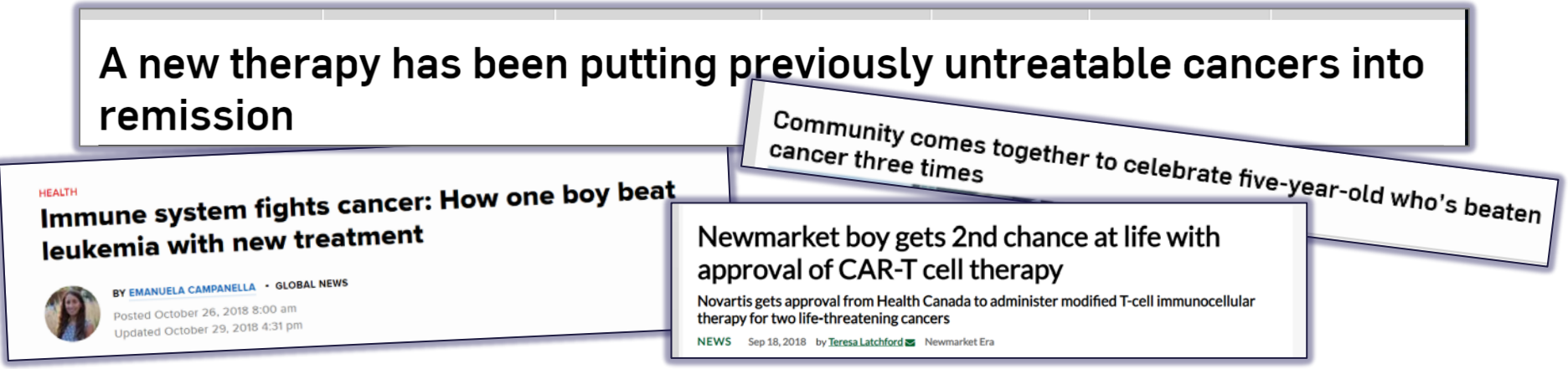
- Biosimilars have the potential to bring large savings to provincial cancer drug budgets.
- Desire to confirm that the use of biosimilars will have no negative patient or system outcomes.
- Address clinician and patient concerns that the implementation of these products should be assessed.
    - Build confidence in their continued use



Based on government costs for IV cancer drugs reimbursed the NDFP. Manufacturer rebates (if applicable) are not factored in.

Source: CCO data (extracted Oct 2019)

The Promise of Chimeric Antigen Receptor T-cell Therapy (CAR-T)



Kymriah (tisagenlecleucel)

- First studied in relapsed/refractory ALL in pediatrics and young adults
- In the pivotal trial, overall remission rate within 3 months was 81.3% after a single infusion.[1]
- Approved by Health Canada in September 2018

[1]Maude et al. N Engl J Med. 2018 February 01; 378(5): 439–448

Why RWE for CAR-T?

- CAR T pipeline for oncology is robust
- CAR T is a high cost and resource-intensive therapy **with significant capacity constraints.**
- Limited clinical trial data and limited long-term data exists.
- **Real-world data on system-level resource constraints and wait times** not currently available: e.g.,
    - % of patients who get CAR-T after bridging therapy
    - Wait time to manufacturer CAR-T
    - Wait time to receive CAR-T at in Ontario facility
- Public payers could use RWE on clinical and economics outcomes to inform future evaluations of CAR T-cell funding as well as new indications for use.

Cancer Care Ontario

Assessing the Real-World Clinical and Economic Outcomes of Emerging Innovative Technologies in Oncology: The Cases of Biosimilars and CAR T-cells*

Principal Investigators:

- Dr. Kelvin Chan, Sunnybrook HSC, CCO, ARCC
- Scott Gavura, Director, Provincial Drug Reimbursement Programs, CCO
- Dr. Wanrudee Isaranuwatchai, St. Michael's Hospital, ARCC

*Funded by the Ontario Institute for Cancer Research

Project Goals

Aim 1

- To examine the real-world uptake, safety, effectiveness and economic impact of the implementation of bevacizumab biosimilars in advanced colorectal cancer

Aim 2

- To evaluate the real-world health outcomes and economic impact of CAR T-cell therapy

***Results expected in 2021**

Envisioning the future state for cancer RWE

Plan

- Early planning of RWE is built into the decision-making process
- RWE proposals must include treatment outcomes and value measures
- RWE evaluations are routinely used to reassess initial funding decisions (all initial funding decisions are “conditional”)

Resources

- Established pan-Canadian governance structure for RWE, managing infrastructure and resources
- Pan-Canadian data linkages in place

Cost

- More sophisticated risk-sharing in LOIs

Summary

- Public payers want to pay for therapies with compelling evidence of meaningful clinical benefits (e.g., OS or QOL for cancer medicines).
- RWE should not be a replacement for well-designed RCTs for new medicine approvals by the regulator or the payor.
- Ontario continues to build experience in collecting and using RWE to inform drug funding decision-making.
- RWE has the potential to be a powerful tool for post-marketing studies to confirm clinical benefits and reassess reimbursement decisions.

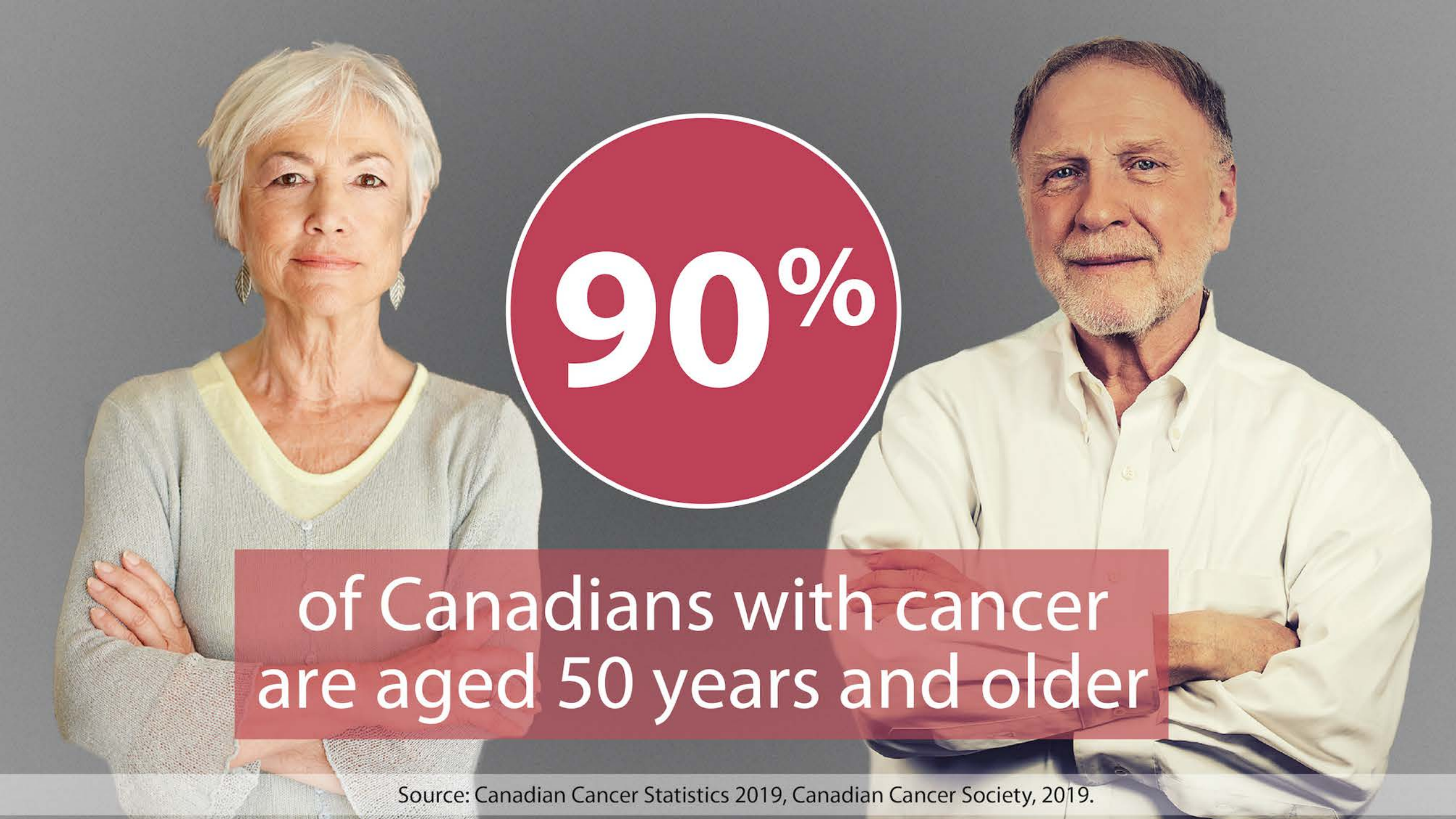
LEVERAGING REAL-WORLD DATA AND STRATEGIC PARTNERSHIPS IN CANCER CARE

MERCK

INVENTING FOR LIFE

Jennifer Chan, Vice President, Policy & External Affairs

October 22, 2019



Source: Canadian Cancer Statistics 2019, Canadian Cancer Society, 2019.

Source: Canadian Cancer Society, Media Release, May 27, 2015.

of CARP respondents believe that Canada's public health systems need to make new investments so they can be better prepared to treat cancer

Source: Canadian Association for Retired Persons (CARP) cancer survey, 2019.

3.0%

Current annual increase in Canada Health Transfer

5.2%

Annual healthcare inflation rate

Source (5.2%): Conference Board of Canada, 2016; https://www.canadaspremiers.ca/premiers-committed-to-healthcare-sustainability-call-on-federal-government-to-be-full-partner/

HEALTHCARE / COMBATING CANCER 2019

Immunotherapy: using the body's own defences to heal

Using the body's immune system to fight cancer is a fast-evolving treatment, which is giving patients a new lease on life

BY LINDA WHITNEY – OCTOBER 18, 2019

RCNT.EU/FY8TK

New immunotherapy shows promise against brain tumors in mice

By Catharine Paddock, Ph.D. | Published Monday 2 September 2019

Fact checked by Isabel Godfrey

For the first time, scientists have shown that a new type of immunotherapy can reach and treat brain cancer from the bloodstream in mice. The nano-immunotherapy stopped brain tumor cells multiplying and increased survival.

The researchers believe that the new treatment could be the key to improving survival in people with glioblastoma, the most common and aggressive type of brain cancer.

16 Oct 2019

Scientists harness the power of immune system to test novel cancer treatment

The field of immunotherapy has revolutionized the way people with incurable cancers are treated, saving the lives of many people whose disease would have otherwise been seen as a death sentence. Despite its success in treating people with deadly forms of leukemia and lymphoma, there are still many people who do not benefit from the treatment or eventually experience a relapse of their cancer.

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HEALTH / FOR BETTER

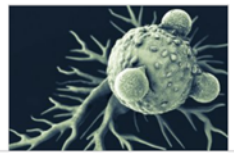
Immunotherapy: the Future of Cancer Treatment

Immunotherapy treatments tend to be much gentler on the body, and have fewer harsh side effects, than chemotherapy.

By **Leon Hwang, M.D.**, Contributor Sept. 5, 2019, at 6:00 a.m.

AS AN ONCOLOGIST, nothing makes me happier than to find a therapy that works for one of my patients – something that halts that patient's cancer in its tracks. So I am particularly excited by recent advances in immunotherapy, a medical strategy that enlists the patient's own body to recognize and fight off deadly types of cancer. Advances in immunotherapy are proceeding at an amazing pace, and today I have patients who are living three and four times longer than we ever could have hoped, and with minimal side effects, thanks to this type of treatment.

Immunotherapy treatments work in different ways. Some can stimulate your immune system to recognize cancer cells and work harder to vanquish them. Others use antibodies – similar to what your body makes to fight infections – to get the immune system to target the cancer. Both approaches have one thing in common: They tend to be much gentler on the



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New cancer research could help boost immunotherapy treatments

27th August 2019

EurekAlert! | AAAS

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NEWS RELEASE 27-AUG-2019

Researchers discover a new form of immunotherapy

Experiments on mice suggest that cancer patients in the future may benefit from a new type of cancer immunotherapy; behind the study is a number of international researchers with Anders Etzerodt from Aarhus University, Denmark, as the lead author

AARHUS UNIVERSITY

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A new form of immunotherapy that has so far been tested on mice makes it probable, that oncologists in the future may be able to treat some of the patients who are not responding to existing types of immunotherapy. Instead of attacking the cancer cells directly, the new technique target and remove a subtype of immune cells known as macrophages, after which the immune system itself begins to attack the cancer.

This is shown by a new study published in the *Journal of Experimental Medicine* in which researchers from Aarhus University, Denmark, have collaborated with colleagues in France,

“For the first time in human history, our ability to collect data on our biology has outpaced our ability to interpret and act on it.”

– Brendan Frey, Founder and CEO, Deep Genomics, Toronto

deep genomics

Merck’s Centre for Observational & Real World Evidence (CORE)