
CELL & GENE THERAPY REVOLUTION

Time to gown up!

in partnership
with



Commercializing
Living Therapies



Center for
Commercialisation of
Cancer
IMMUNOTHERAPY

CellCAN's Second pan-Canadian Strategic Forum on Cell & Gene Therapy

From Translation to Commercialization

March 13 to 15, 2019
Toronto

KNOWLEDGE – MOBILIZATION – ACTIONS
WWW.CELLCAN.COM/FORUM2019



NCE RCE

Supported by the Government of Canada through
the Networks of Centres of Excellence – KM programs.

SPECIAL ACKNOWLEDGEMENTS

SCIENTIFIC COMMITTEE:

Lambert Busque, Chief Medical Officer, C3i

David Courtman, Director, Biotherapeutics Manufacturing Centre,
The Ottawa Hospital Research Institute

Danielle Deverteuil, Business Development & Operations Manager, Biomarker Unit, C3i

Julie Fradette, Researcher, Centre de recherche en organogénèse
expérimentale de l'Université Laval/ LOEX, Director, ThéCell
CHU de Québec Research Center-Université Laval

Craig Hasilo, Chief Scientific Officer, CellCAN

Armand Keating, Director, Cell Therapy Program, University Health Network

Bernard Massie, Director General (acting), Human Health Therapeutics
Research Centre, National Research Council of Canada

Michael May, Chief Executive Officer, CCRM

Véronique Moulin, Researcher, Centre de Recherche en Organogénèse
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Denis Claude Roy, Chief Executive Officer, CellCAN

Duncan Stewart, Executive Vice-President of Research, The Ottawa Hospital,
CEO and Scientific Director, The Ottawa Hospital Research Institute

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Marie-Ève Desormeaux, Project Manager & Communications Coordinator, CellCAN

Véronique Arsenault, Founding President, Exponentiel Conseil

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EVENT COORDINATION TEAM:

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**THANK YOU FOR MAKING
THIS EVENT A SUCCESS!**

WELCOME WORD FROM CELLCAN



Dear attendees,

I am proud to welcome you to CellCAN's second pan-Canadian Strategic Forum on the Cell & Gene Therapy Revolution: Time to gown up! in the vibrant city of Toronto. Dedicated people like yourselves have turned this event into a tremendous success, as evidenced by the overwhelming positive feedback from the first edition. With more than 35 world renowned speakers and more than 150 delegates, the Forum is already shaping up to be a key meeting to network and learn about advancing regenerative medicine therapies in Canada and around the world.

The last Forum concluded with many great ideas and a vision: Canadian know-how, collaboration and knowledge dissemination will position Canada as a powerhouse for cell and gene therapy. Two years later, it's already time to gown up and take action. Things are moving fast and possibilities are blooming. It's with this new reality in mind that we tailored this year's Forum.

The program will cover some fascinating innovations (off-the-shelf therapies, FailSafe™ kill switch, and others), the evolution of cancer immunotherapy and regenerative medicine clinical trials, address various strategies such as cost of goods reduction techniques, and demystify the agile framework behind our evolving regulations. Nonetheless, things are shaking up in Canada and through collaboration, we have the ability to mold the future. It's time to showcase Canada and our ability to perform centre stage within the global regenerative medicine and cell therapy ecosystem.

On behalf of the CellCAN Board of directors, our incredible management team and the entire scientific organizing committee, I would like to thank our speakers, our invaluable partners and sponsors, and last but not least, you, for being part of this revolution. I wish you all insightful meetings, new partnerships and great discussions.

Sincerely,

Denis Claude Roy, M.D.
CEO

Chers délégués,

Je suis fier de vous accueillir au deuxième forum stratégique pancanadien de CellCAN sur la Révolution en thérapies cellulaires et géniques : C'est le temps d'agir! dans la vibrante ville de Toronto. Des personnes dévouées comme vous ont fait de cet événement un succès retentissant, comme en témoignent les retours extrêmement positifs de la première édition. Avec plus de 35 conférenciers de renommée mondiale et plus de 150 délégués, le Forum s'annonce déjà comme une réunion clé pour le réseautage et pour en savoir plus sur les avancées en matière de thérapies en médecine régénératrice au Canada et dans le monde.

Le dernier forum s'est conclu sur de nombreuses idées et une vision : le savoir-faire canadien, la collaboration et la diffusion des connaissances positionneront le Canada comme un centre puissant pour les thérapies cellulaires et géniques. Deux ans plus tard, il est déjà temps de se lever et d'agir. Les choses bougent vite et les possibilités s'épanouissent. C'est avec cette nouvelle réalité à l'esprit que nous avons développé le Forum de cette année.

Le programme couvrira des innovations fascinantes (thérapies universelles, FailSafe™ kill-switch et autres) et l'évolution de l'immunothérapie du cancer et des essais cliniques en médecine régénératrice. Il abordera également diverses stratégies telles que les techniques de réduction du coût de production et démystifiera le cadre réglementaire en pleine évolution. Les choses bougent au Canada et grâce à la collaboration, nous façonnons l'avenir. Il est temps de se positionner comme un leader capable de jouer un rôle central dans l'écosystème mondial.

Au nom du conseil d'administration de CellCAN, de notre incroyable équipe de direction et de l'ensemble du comité scientifique, je voudrais remercier nos conférenciers, nos partenaires et commanditaires, et enfin et surtout vous qui participez à cette révolution. Je vous souhaite à tous des rencontres utiles, de nouveaux partenariats et d'excellentes discussions.

Cordialement,

CellCAN AT A GLANCE

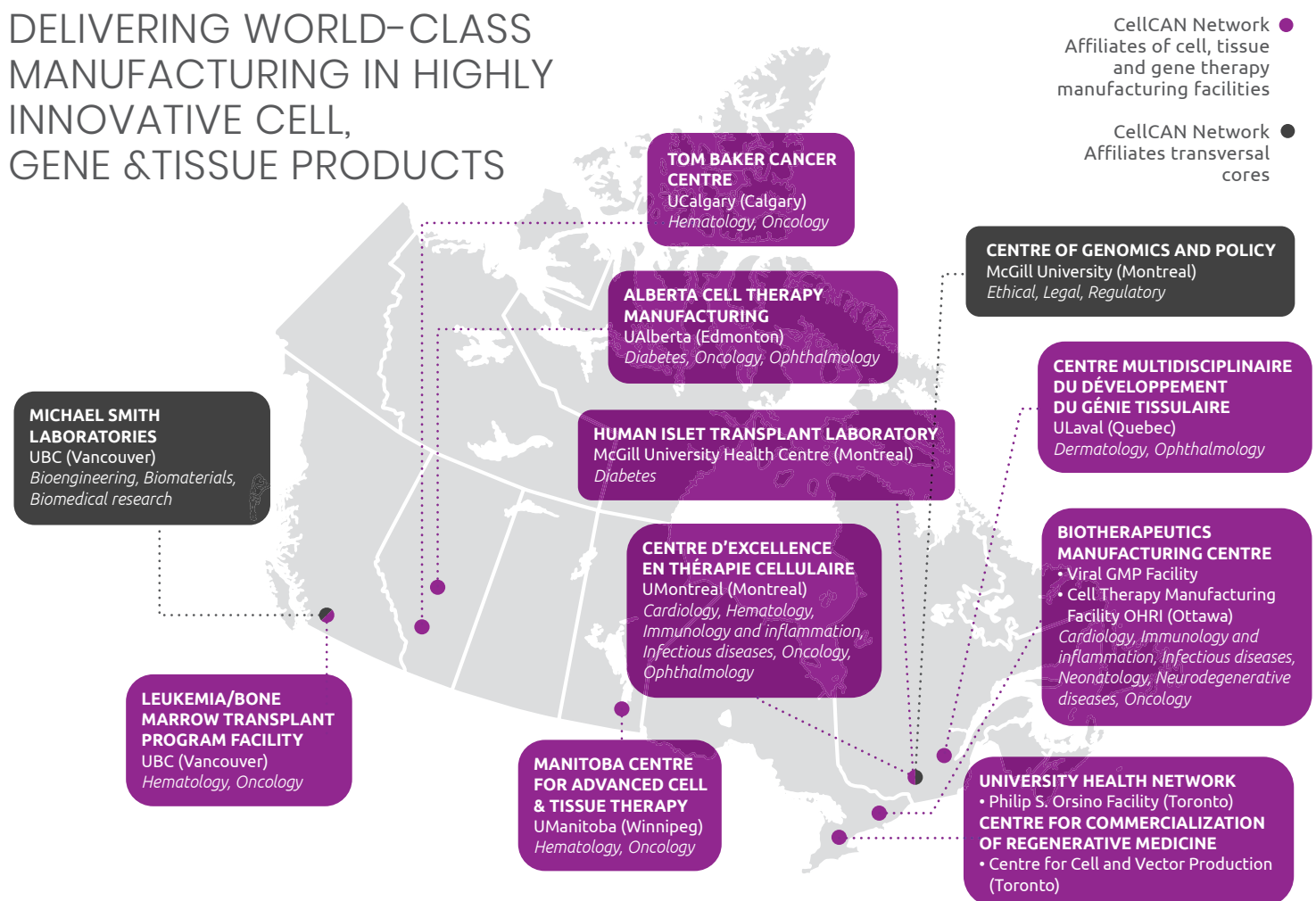
VISION

Our vision is that cell & gene therapy manufacturing in Canada must operate under a **common seal of quality** to increase capacity and rapidly and effectively migrate innovative treatment concepts into standard clinical practice.

MISSION

Our mission is to mobilize knowledge to improve the quality, safety and feasibility of cell & gene therapy in Canada through **optimal manufacturing practices**.

DELIVERING WORLD-CLASS MANUFACTURING IN HIGHLY INNOVATIVE CELL, GENE & TISSUE PRODUCTS



BUILD A STRONG CANADIAN NETWORK

We are translating and mobilizing knowledge to build a strong cell & gene manufacturing sector.



ADVANCE REGULATORY STANDARDS

We are channelling information from all Canadian CMF and providing input to Health Canada to advance regulatory standards and help establish adequate regulatory oversight. We take into account new technologies and deliver knowledge back to our stakeholders.



GENERATE EFFECTIVE OUTREACH

We are empowering information multipliers and Canadians to make informed decisions about their safety regarding cell & gene therapies.



POSITION CANADA AS A WORLD LEADER

We are helping to drive Canada's economy by creating business and networking opportunities with the cell & gene manufacturing community.

WELCOME WORD FROM C3I AND CCRM



The Centre for Commercialization of Cancer Immunotherapy (C3i) would like to welcome all participants to CellCAN's second pan-Canadian Strategic Forum on the *Cell & Gene Therapy Revolution: Time to gown up!* We are on the cusp of a global revolution in medicine. Medical researchers and product developers are now poised to bring forward new gene, cell and tissue engineering therapies that hold great promise for profound and durable responses in patients exhibiting a diverse array of serious and costly conditions, many of which lack current treatments.

We, at C3i, are pleased to be a part of this partnership with CellCAN and CCRM as the objective of this innovative forum aligns with our mandate to accelerate discovery and commercialization, thereby providing access to lifesaving breakthroughs in cancer immunotherapy. Indeed, future continuous growth of cellular and gene therapies will require the collaboration amongst experts from various disciplines, including clinical medicine, manufacturing, commercialisation, regulatory and reimbursement, in an effort to maximize the success in bringing life-saving therapies to patients.

We believe that you will find the topics and the program of this forum interesting, informative and inspirational. Our wish is for you to leave the conference enriched with ideas and plans for the future, with professional contacts and new friendships to support Canada's leadership in this important medical revolution.

Sincerely,
François Bettez
CEO



CCRM, a leader in developing and commercializing regenerative medicine-based technologies and cell and gene therapies, is delighted to welcome you to Toronto and CellCAN's second pan-Canadian Strategic Forum on the *Cell & Gene Therapy Revolution: Time to gown up!*

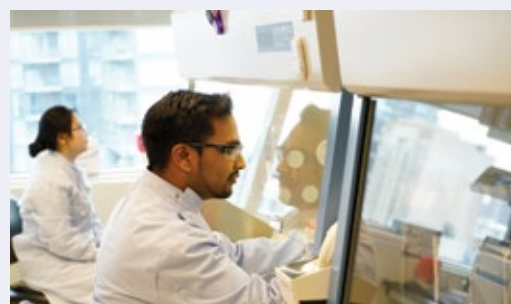
Canada has a strong legacy of scientific excellence in stem cell research, bioengineering and regenerative medicine. This conference brings together experts in the field to discuss the challenges we face in bringing these discoveries to the marketplace. CCRM believes that the pathway to Canadian leadership in the Life Sciences will build on our collaborative nature and our achievements in the science and industrialization of cell and gene therapies. We welcome opportunities, such as this event, to hear from industry, government, clinicians, researchers, and those knowledgeable in regulatory affairs and reimbursement, on how we can work together more productively to achieve this goal.

CCRM has invested heavily in personnel and infrastructure to boost Canada's capacity in advanced therapy manufacturing, but all the pieces of the puzzle have to be in place for Canada to be a preferred destination for therapy developers, and this will ideally translate into cell and gene therapy clinical trials happening here and more investment in our emerging companies.

CellCAN's Strategic Forum also allows us to hear from patients who will benefit directly from the research being commercialized and we'll learn what progress is being made on the research front. It will be an exciting conference!

CCRM appreciates the opportunity to partner with CellCAN and C3i in developing a program that will be informative, thought-provoking and even inspirational. We look forward to engaging with you over the next couple of days.

Sincerely,
Michael H. May, PhD
President and CEO



CCRM: Your Partner in Cell and Gene Therapy Manufacturing

Centre for Cell and Vector Production (CCVP)

CCVP is a world-class Good Manufacturing Practices (GMP) facility built in partnership with University Health Network. In a 20,000 ft² facility, CCVP produces clinical-grade cells and viral vectors for Phase I and II clinical trials to meet the growing global demand for a flexible and transparent approach to manufacturing.

CCVP has:

- 8 cell therapy & 2 viral vector suites
- ISO Class 7/Grade B clean rooms
- USFDA, Health Canada & EMA compliance
- On-site QC testing
- On-site QA/audit support

Centre for Advanced Therapeutic Cell Technologies (CATCT)

Built in collaboration with GE Healthcare and the Government of Canada, CATCT's 10,000 ft² state-of-the-art facility provides process development and optimization to address challenges in cell and gene therapy production. We welcome partners from pharma, biotech and cell therapy companies.

CATCT offers:

- Process closure, automation
- Cost analysis, risk reduction
- Work flow simplification
- Media & assay development
- Culture intensification

CONTACT US

cdmo@ccrm.ca | +1 416-978-3751
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processes

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www.centreC3i.com

PROGRAM PRE-CONFERENCE - MARCH 13, 2019

7:30 – 9:00	Registration Breakfast	<i>Hall – 2nd floor</i> <i>Pall Mall, Palm Court and</i> <i>Vanity Fair Ballroom B</i>
9:00 – 9:10	Welcome from C3i Lambert Busque, Chief Medical Officer, C3i	<i>Vanity Fair Ballroom A</i>
Theme 1	The role of biomarkers in supporting GMP manufacturing Moderator: Michel Rochon, Health and Science Journalist Chair: Denis Claude Roy, CEO, CellCAN, Chief Scientific Officer, C3i	<i>Vanity Fair Ballroom A</i>
9:10 – 10:30	Characterizing products for GMP manufacturing: What, how and when? Donna Rill, Chief Technology Officer, Triumvira Immunologics Analytical testing: preparing for the jump from research lab to GMP manufacturing Martin Giroux, Director of operations, CETC Raman spectroscopy analysis of cellular therapeutics for transplantation James Piret, Professor, Department of Chemical & Biological Engineering and the Michael Smith Laboratories, University of British Columbia	
10:30 – 10:50	Health break and exhibitors visit	
10:50 – 11:45	Regulatory expectations for cell therapy release criteria in Canada Dino Petrin, Senior Biologist/Evaluation Officer, Health Canada Panelist discussion: Regulatory expectations for cell therapy release criteria Donna Rill, Chief Technology Officer, Triumvira Immunologics Martin Giroux, Director of operations, CETC Dino Petrin, Senior Biologist/Evaluation Officer, Health Canada	
11:45 – 13:00	Lunch, networking and exhibitors visit	<i>Pall Mall, Palm Court,</i> <i>Vanity Fair Ballroom B</i>

PROGRAM PRE-CONFERENCE - MARCH 13, 2019

Theme 2

Characterizing the response to CAR-Ts and other cellular therapies

Vanity Fair Ballroom A

Moderator: Michel Rochon, Health and Science Journalist

Chair: Jean-Sébastien Delisle, Hematologist and Principal Investigator, Hôpital Maisonneuve-Rosemont

13:00 – 15:00

Characterizing the response to cellular therapies with immunophenotyping

Jean-Sébastien Delisle, Hematologist and Principal Investigator, Hôpital Maisonneuve-Rosemont

TAC technology, its unique and novel MoA, preclinical data and considerations for biomarker analysis in our Phase I/II trial

Andreas Bader, Senior Vice President R&D, Triumvira Immunologics

Determinants of response and resistance in CAR-T cell therapy

Joerg Krueger, Hematologist, Oncologist, SickKids

Improving the anti-tumor efficacy of gene-engineered T cells for the treatment of cancers

Jan Joseph Melenhorst, Adjunct Associate Professor, Pathology & Laboratory Medicine, University of Pennsylvania

15:00 – 15:20

Health break and exhibitors visit

Theme 3

Companion tests and patient stratification in the era of personalized medicine

Vanity Fair Ballroom A

Moderator: Michel Rochon, Health and Science Journalist

Chair: David Courtman, Director, Cell Manufacturing, Biotherapeutics Manufacturing Centre, The Ottawa Hospital

15:20 – 16:20

Biomarker development for immuno-oncology applications

Raffi Tonikian, Associate Director, Immuno-oncology Biomarkers and Companion Diagnostics, Merck

Integration of companion tests in the health care system

Lambert Busque, Chief Medical Officer, C3i

16:20 – 16:30

Closing remarks of the pre-conference

Lambert Busque, Chief Medical Officer, C3i

18:30 – 21:00

Welcome Reception (sponsored by CCRM) Food & beverages will be provided

CC Lounge & Whisky Bar,
45 Front St E



To learn more about our speakers,
visit www.cellcan.com/forum2019/speakers.



We believe...

in the pursuit of transformational science

in pushing boundaries with cutting-edge clinical trials

in a relentless focus on patients

that collaboration is key to a better future





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Chaque jour, nous nous efforçons de transformer et de simplifier les soins aux personnes souffrant de maladies menaçant leur vie.



GILEAD

Advancing Therapeutics.
Improving Lives.

PROGRAM CONFERENCE - MARCH 14, 2019

7:30 – 8:50	Registration Breakfast	<i>Hall – 2nd floor</i> <i>Pall Mall, Palm Court and</i> <i>Vanity Fair Ballroom B</i>
8:50 – 9:00	Welcome from CellCAN – Regenerative Medicine and Cell Therapy Network Denis Claude Roy, CEO, CellCAN	<i>Vanity Fair Ballroom A</i>
9:00 – 9:20	The patient to patient interview: a life changing therapy Moderator: William Brock , Survivor of acute myelogenous leukemia (AML), CellCAN Chairman of the Board Patient: Mai Duong , Survivor of leukemia, Founder, Swab the World	<i>Vanity Fair Ballroom A</i>
Theme 1	Innovation in allogeneic cellular therapies: game changer in regenerative medicine Moderator: Michel Rochon , Health and Science Journalist Chair: Heidi Elmoazzen , Director, Stem Cells, Canadian Blood Services	<i>Vanity Fair Ballroom A</i>
9:20 – 10:20	Engineering stem cells for islet cell replacement Tim Kieffer , Professor, Cellular & Physiological Sciences and Surgery, University of British Columbia Generating a FailSafe™ kill switch for allogeneic cellular therapies Andras Nagy , Canada Research Chair in Stem Cells and Regeneration, Senior Scientific Investigator, Lunenfeld-Tanenbaum Research Institute, Sinai Health System	
10:20 – 10:40	Health break and exhibitors visit	
10:40 – 12:00	Preparing for first human trial of iPSC-derived cells for Parkinson's disease Daisuke Doi , Research Associate, Department of Clinical Application, Center for iPS Cell Research and Application, Kyoto University, Japan Panelist discussion - Allogeneic vs autologous sourced donor cells: the strategic advantages Duncan Stewart , President, OHRI, CEO, OIRM Lucie Germain , Professor, Université Laval, CHU de Québec-Université Laval Andras Nagy , Canada Research Chair in Stem Cells and Regeneration, Senior Scientific Investigator, Lunenfeld-Tanenbaum Research Institute, Sinai Health System Daisuke Doi , Research Associate, Department of Clinical Application, Center for iPS Cell Research and Application, Kyoto University, Japan	
12:00 – 14:00	Lunch, networking and exhibitors visit	<i>Pall Mall, Palm Court and</i> <i>Vanity Fair Ballroom B</i>
	Lunch workshop CellCAN Cell Manufacturing Working Group (by invitation only)	<i>Belgravia Room</i>

PROGRAM CONFERENCE - MARCH 14, 2019

14:00 – 14:15

The patient to patient interview: a life changing therapy

Vanity Fair Ballroom A

Moderator: **William Brock**, Survivor of AML, CellCAN
Chairman of the Board

Patient: **Kevin Bolusi**, Self-assembling skin substitute
recipient, survivor of 3rd degree burns

Special guests: **Lucie Germain**, Professor, Université
Laval, CHU de Québec-Université Laval
and **Véronique Moulin**, Researcher,
LOEX, CHU de Québec Research
Center-Université Laval

Theme 2

The next generation of clinical trials

Vanity Fair Ballroom A

Moderator: **Michel Rochon**, Health and Science Journalist

Chair: **Janet Dancey**, Director, Canadian Cancer Trials Group,
Scientific Director, Canadian Cancer Clinical Trials Network,
Professor, Department of Oncology, Queen's University

14:15 – 15:15

Gene therapy studies for thalassemia and sickle cell anemia

Donna Wall, Blood and Marrow Transplant/Cellular Therapy Program, SickKids

Canadian manufacturing and delivery of CAR-T therapy as health care implementation research

Rob Holt, Co-Director and Distinguished Scientist, BC Cancer Immunotherapy Program,
BC Cancer Genome Sciences Centre

15:15 – 15:45

Health break and exhibitors visit

15:45 – 16:45

Taking CAR-T from theory to reality - the Novartis experience

Marta Majdan, Medical Advisor, Oncology, Novartis Canada

Panelist Discussion: Vision of clinical trials for the next 5-10 years

Denis Claude Roy, CEO, CellCAN

Donna Wall, Blood and Marrow Transplant/Cellular Therapy Program, SickKids

Marta Majdan, Medical Advisor, Cell and Gene Therapy, Novartis Canada

16:45 – 17:00

Wrap-up of Day 1

Denis Claude Roy, CEO, CellCAN

Armand Keating, Director, Cell Therapy Program,
University Health Network

17:00 – 20:00

Industry Networking cocktail sponsored by

Vanity Fair Foyer, Pall Mall
and Palm Court



To learn more about our speakers,
visit www.cellcan.com/forum2019/speakers.

PROGRAM CONFERENCE - MARCH 15, 2019

7:30 – 9:00	Registration Breakfast	<i>Hall</i> <i>Pall Mall, Palm Court and</i> <i>Vanity Fair Ballroom B</i>
8:00 – 8:05	Introduction to day 2 activities Denis Claude Roy, CEO, CellCAN	<i>Vanity Fair Ballroom A</i>
8:05 – 8:35	NRC Health Challenge Program: Initiatives & collaboration models to improve affordability and accessibility of cell and gene therapies in Canada Bernard Massie, Director General (acting), Human Health Therapeutics Research Centre, National Research Council of Canada	
Theme 3	Regulatory Reform and Reimbursement Moderator: Michel Rochon, Health and Science Journalist Chair: Sowmya Viswanathan, Affiliate Scientist, Krembil Research Institute, University Health Network	<i>Vanity Fair Ballroom A</i>
8:35 – 9:35	Regulatory reform in Canada: modernizing novel cell & gene therapy regulations Pierre Sabourin, Assistant Deputy Minister, Health Products and Food Branch, Health Canada Drug review process alignment: Health Canada, CADTH & INESSS collaboration Alexandra Chambers, Director of the pan-Canadian Oncology Drug Review (pCODR) program, CADTH	
9:35 – 10:00	Health break and exhibitors visit	
10:00 – 12:00	Redefining outcome measures for efficacy and novel clinical trial design in gene therapy treatments – A value demonstration approach Kathy Reape, Chief Medical Officer, Spark Therapeutics Challenges of implementing new technologies in the healthcare system Lambert Busque, Hematologist, Hôpital Maisonneuve-Rosemont, Chief Medical Officer, C3i Panel: Reimbursement for regenerative therapies: can we demonstrate value? Lesley Dunfield, Director of HTA and Program Development for Medical Devices and Clinical Interventions portfolio, CADTH Siofradh McMahon, Senior Manager, Clinical Translation and Regulatory Affairs, CCRM Michèle de Guise, Directrice des services de santé et de l'évaluation des technologies, INESSS Lambert Busque, Hematologist, Hôpital Maisonneuve-Rosemont, Chief Medical Officer, C3i	

PROGRAM CONFERENCE - MARCH 15, 2019

12:00 – 14:00	Lunch, networking and exhibitors visit	<i>Pall Mall, Palm Court and Vanity Fair Ballroom B</i>
	Lunch workshop Advancing regulatory standards CellCAN meeting (by invitation only)	<i>Belgravia Room</i>
14:00 – 14:15	The patient to patient interview: a life changing therapy Moderator: William Brock , Survivor of AML, CellCAN Chairman of the Board Patient: Marc Doucett , Survivor of multiple sclerosis	<i>Vanity Fair Ballroom A</i>
Theme 4	Optimizing cell and gene therapy manufacturing Moderator: Michel Rochon, Health and Science Journalist Chair: Michael May, CEO, CCRM	<i>Vanity Fair Ballroom A</i>
14:15 – 15:45	3D printing human tissue: where engineering meets biology Spiro Getsios, VP of Tissue Engineering, Aspect Biosystems Scale-up, cost reduction and data considerations for cell manufacturing Gary Pigeau, Director, Centre for Advanced Therapeutic Cell Technologies at CCRM, GE Healthcare Planning for success – The path to commercialization Donna Rill, Chief Technology Officer, Triumvira	
15:45 – 16:15	Health break and exhibitors visit	
16:15 – 17:15	Panelist Discussion – Opportunities & challenges in manufacturing: to centralize or decentralize? Behnam Baghbadernai, Global Head, Process Development & Emerging Technologies – Cell & Gene Therapy, Lonza Robert Preti, CEO and President of Hitachi Chemical Advanced Therapeutics Solutions Mayo Pujols, VP and Global Head of Cell & Gene Technical Development & Manufacturing, Novartis Nuala Trainor, Director of Biological Programs, Octane	
17:15 – 17:30	Closing remarks Denis Claude Roy, CEO, CellCAN	



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visit www.cellcan.com/forum2019/speakers.

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Chez Novartis, nous nous attaquons aux plus grands défis associés aux soins de santé grâce aux innovations scientifiques. Nous sommes passionnés par la découverte de nouvelles façons d'améliorer et de prolonger la vie des gens.

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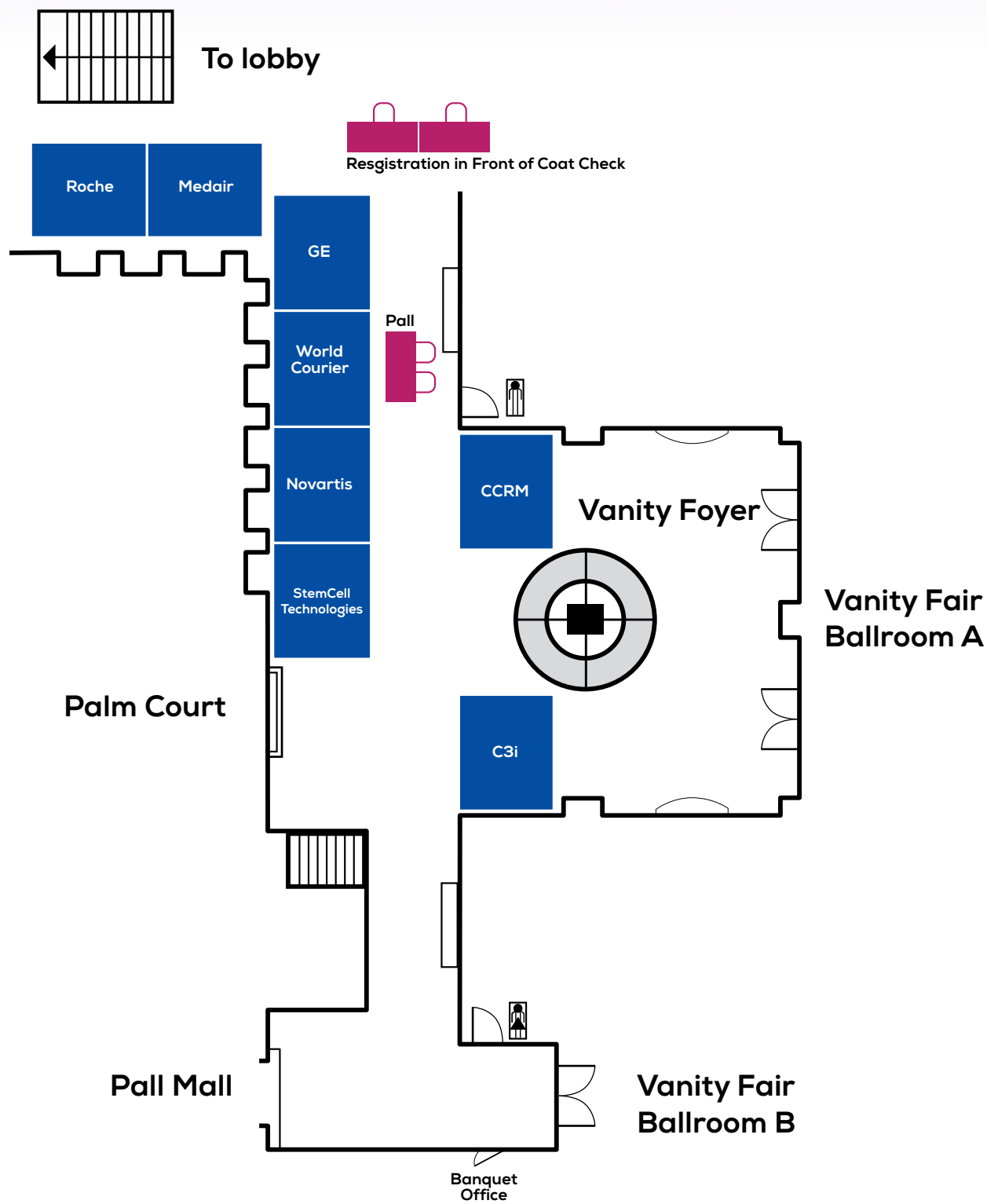


CELL & GENE THERAPY REVOLUTION

March 2021

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