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Report on Roche Canada

About the company

- F.Hoffmann-La Roche AG is a Swiss multinational healthcare company that operates worldwide under 2 divisions: Pharmaceuticals and Diagnostics
- Founded in 1896 by Fritz Hoffmann-La Rich
- The headquarters are in Basel, Switzerland
- In 2020, the company held a revenue of 58.32 billion CHF
- They are one of the few companies increasing their dividend every year, for 2018 as the 32nd consecutive year
- Descendants of the founding Hoffmann and Oeri families own slightly over half of the bearer shares with voting rights
- Subsidiaries: Genentech (an American biotechnology company), Ventana
    - They also control the Japanese biotechnology company Chugai Pharmaceuticals
- They are the world's largest spender in pharmaceutical R&D
- They are leaders in the field of cancer treatment, treatment against virus diseases, and for treatment of metabolic diseases
- They have produced a plethora of drugs as well as diabetes management products
- Their pipeline
- Disease areas of focus:
    - Inflammatory bowl diseases - ulcerative colitis and Crohn's disease
    - Cardiovascular and metabolism
    - Haematology
    - Haemophilia
    - Immunology
    - Infectious disease
    - Neuroscience - has one of the strongest pipelines in the industry
        - This is a major focus of R&D at Roche
        - They are investigating more than a dozen medicines for various diseases of the CNS
    - Oncology
    - Ophthalmology
    - Rare diseases
    - Respiratory
    - Personalized Her
- In addition to internal research and development activities, F.Hoffmann-La Roche is also involved in publicly funded collaborative research projects
    - Ex in the area of non-clinical safety assessment is the InnoMed PredTox
    - The company is expanding its activities in joint research projects within the framework of the Innovative Medicines Initiative of EFPIA and the European Commission

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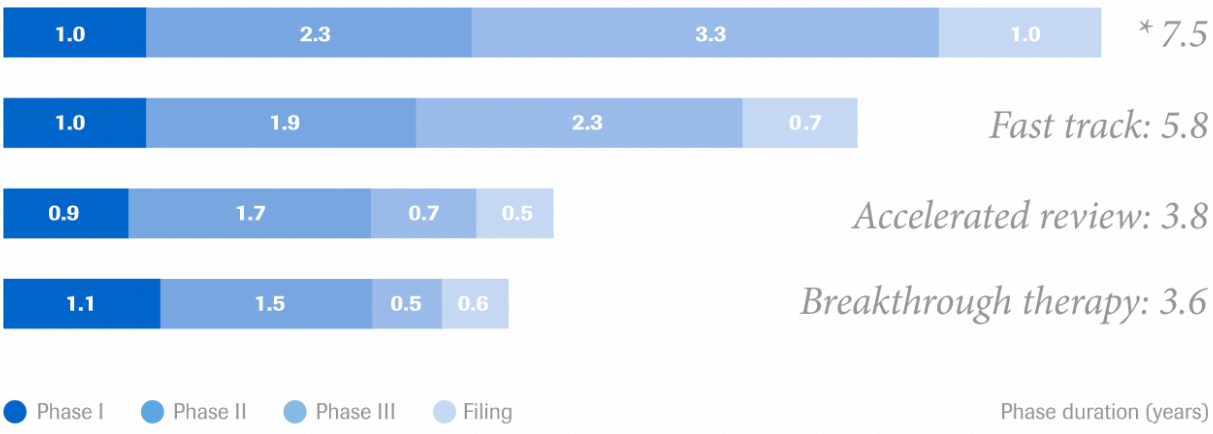
- The company has also demonstrated that they are committed to limiting their impact on the environment and climate change by proactively seeking new, more sustainable technologies to achieve this goal
    - The company's long-term goal is to reduce emissions from owned or controlled sources or from the generation of purchased energy to 0 by the middle of this century
    - They are also phasing out halogenated hydrocarbons which are very strong GHGs that significantly harm the ozone layer
    - Their headquarters in Switzerland have implemented thermal networks in the new buildings to use rejected, or otherwise wasted heat
    - They have reduce energy intensity by approximately 40% since 2004
    - At their site in Suzhou, China, the solar panel system produces enough electricity from sunlight to cover almost 80% of the energy needs of the administration building
    - The solar power programmes of Genentech, a member of the Roche Group, make the organization the largest corporate generator of solar energy in the San Francisco Bay Area.
- The number of drug candidates in pivotal/late stage clinical development has increase by 50% over the past 3years
- Breakthrough Therapy Designation is designed to accelerate the development and review of medicines intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate a substantial improvement over existing therapies



Strategy and Mission

- Purpose: Doing now what patients need next
- Focus: fitting treatment to patients - providing the right therapy for the right group of people at the right time

    - They are working to ensure personalized medicine becomes the norms across mainstream, everyday healthcare
    - They realize they can only achieve this goal through partnerships
- They are developing their internal capacities and building strategic partnerships to move to the next stage of personalized healthcare: to combine insights from multiple data sources with sophisticated analytics to drive more effective and efficient research and allow for better therapeutic decisions for patients
    - Access to their products are a critical part of their strategy
    - Their detailed access plans are embedded into the business at a local level
- They claim they will continue to concentrate their energies entirely on prescription medicines and in vitro diagnostics rather than diversity into other sectors
- Roche is committed to helping countries scale up HIV elimination programs and reach the WHO 2030 goals of 95% of people on treatment having suppressed viral loads
- Roche also strives to help reach the 2030 hepatitis elimination targets of 90% reduction in new chronic hepatitis B and C cases; 65% reduction in hepatitis-related deaths and 80% of eligible people with chronic hepatitis B and C infections receiving treatmen

Products/Services

Integrated Core Lab

- For nearly 50 years, Roche has provided hospitals and laboratories with the diagnostic tests and instruments they need to better understand disease and patient biology
- Worldwide, their instruments are used to conduct more than 20 billion tests every year
- In the increasingly complex healthcare environment, they offer a new vision: a resolution in simplicity
    - Their vision is to empower laboratories to manage the future by streamlining how they are designed and by simplifying their equipment and processes
    - The pioneered the 'Serum Work Area' - the integration of clinical chemistry and immunochemistry
    - Their technology enables a single automated system to conduct a vast array of testing that gives answers to challenges across the healthcare continuum
    - They believe that a fully connected laboratory is valuable in expanding the efficiency, scope, and quality of diagnostic capabilities
        - Less staff time is required to operate the system
        - Laboratory staff will be free to perform more skilled roles and higher value work
        - Will results in cost savings
        - Providers will be better equipped to meet the emerging needs of individuals
        - Will generate a wealth of diagnostic data, allowing doctors to provide patients with holistic, accurate, and precise diagnoses
        - Will provide faster answers to patients
- As a key milestone towards this, they have developed state-of-the-art technology that consolidates multiple systems in one easy-to-use and fully automated instrument and

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offers the broadest range of tests to date in areas as diverse as HIV, hepatitis, oncology, cardiology, and tests specific women's health in pregnancy and beyond
- In 2019, the company expanded their range of assays for the Integrated Core Lab with several launches and approvals
    - They also have important approvals for companion diagnostics in areas such as Brest and gastric cancer

Global Access Program
- The company created the Global Access Program to help developing countries gain access to diagnostic tools for prevention and treatment of HIV
    - They have had major positive impact on diagnosing HIV in low- and middle-income countries
    - Since 2104, over 14 million HIV diagnostic tests have reached 82 countries eligible for access
- In collaboration with the Clinton Health Access Initiative and other partners, they provide accessible and reduced pricing for diagnostic solutions
    - They offer support programmes that help build healthcare system capacity, including participation in public-private partnerships
    - They also invest in developing countries by helping them equip laboratories with the newest technologies
- The cobas Plasma Separation Card was launched in 2018 - it is a stable and easy-to-use sample collection device for HIV plasma and viral load testing that is the size of a credit card
    - With just a small amount of blood from the fingertip, the cobas Plasma Separation Card allows for reliable quantitative testing of patients with HIV living in renmote areas - even in places that experience temperatures of 45C and 85% humidity They aim to ensure that more people in Kenya have access to HIV/AIDS testing Gand viral load monitoring
- In 2018, they formally launched a partnership with the Kenya Medical Research Institute by installing a cobas 8800 for HIV assays
- Their public-private partnerships and initiatives like the Roche Scientific Campus in South Africa demonstrate their ongoing commitment to Africa through capacity building and skills development
- Their aim is that by 2020,90% of all those diagnosed with the HIV infection will receive sustained antiretroviral therapy and 90% of those receiving this will have viral suppression
- In 2019, the programme was expanded to include tests for HIV-1 viral load, HIV-1 and HIV-2 early infant diagnosis, tuberculosis, hepatitis B and C, and HPV
- They also expanded their range of tests with several launches and approvals
- 21 billion tests were conducted with Roche produce in 2019
- 100k Roche Diagnostics has a total of more than 100,000 instruments installed in laboratories, worldwide

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Phelophepa

- Roche and Transnet (the main freight logistics company in South Africa) established Phelophepa, which is the world's first comprehensive primary healthcare facility on rail
- The 19-coach trains each have 6 clinics on board and are equipped with pharmacies and diagnostic tools for diabetes and cancer screenings, such as breast examinations, cervical and prostate cancer checks
- They run extensive health education programmes for the local schools, HIV/AIDS and cancer awareness programmes for the surrounding communities, and primary healthcare training for student doctors, nurses, and pharmacists
- They also support the local economy by offering work on the trains in the communities which they visit
- Phelophepa has received the United National Public Service Award for its excellence in public service delivery
- Roche renewed its support of Phelophepa in 2019
    - They are the initiative's main external sponsor
- Roche Healthcare Consulting is a new service established by Roche Diagnostics
    - They consultant are experts in how to use VR and computer simulations to aid lab leader's decision making
    - With its Advanced, high-quality VR models, Roche Healthcare Consulting now leads the diagnostic laboratory consulting sector in its use of VR in healthcare
    - Roche Diagnostics is also pioneering the techniques required to design entire labs in real-time VR, down to the smallest architectural details and specifications of each instrument
    - The use of VR in hospitals is expected to rise exponentially, with the VR healthcare market projected to be worth $5.1 billion by 2025

Roche and Data Science

- In July 2020, Roche and its subsidiary Genetech signed a deal with PicnicHealth - a startup that helps patients access and share their medical records
    - This deal will allow the companies to have access to PicnicHealth's set of de-identified patient records in order to gain insights about certain diseases and treatments
    - The deal will focus specifically on multiple sclerosis
    - In later years, they are looking at teaming up to study Huntington's disease, paroxysmal nocturnal hemoglobinuria and hemophilia
    - This coincide with the news that PicnicHealth is launching a new scientific research platform that lets patients hare their medical records with researchers
- Roche has shown interest in using digital tools for real-world evidence - they stated this is an important step in their personalized healthcare strategy
    - In 2017, they acquired oncology EHR software firm Flatiron health for $1.9 billion

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- With the goal to shorten time to market for new medicines, Roche employs real world data, the re-use of clinical trial data along with advanced analytics to be on the cutting edge of delivering medical solutions and develop R&D innovations for the future

Roche Data Science Coalition

- Roche believes that one way the world can win the fight against COVID-19 is by sharing knowledge and healthcare data to better inform patient care and health system decision making
- To help achieve this, they assembled a group of public and private organizations who share this vision
- The coalition is dedicated to sharing knowledge and public data and break down the silos between the people who have access to useful information and the people who can use it to better understand the crisis
    - Alberta Machine Intelligence Institute (Amii)
    - doc.ai
    - NVIDIA
    - RGAX
    - Self Care Catalysts
    - COVID-19 Health Storylines
    - ThinkData Works Inc.
    - Vector Institute
- The Coalition has developed a centralized location with more than 200 curated publicly available population datasets gathered from sources across the globe to enhance COVID-19 research
- To get this data into the hands of researchers, data scientists, and the community at large, the Roche Data Science Coalition launched the United Network for COVID Data Exploration and Research (UNCOVER) Challenge
    - Administered by the Coalition through Kaggle
- They have developed over 100 digital solutions and insights including gAI models, advanced analytics, virtual dashboards, and market reports since its formation

History of the company

- The company was early on known for producing various vitamin preparations and derivatives
- 1934 - became the first company to mass produce synthetic vitamin C un de the brand name, Redoxon
- 1957 - introduced the class of tranquilizers known as benzodiazepines
- 1982- the United States arm of the company acquired Biomedical Reference Laboratories for US $163.5 million
    - That year, they merged it with all of its laboratories and incorporated the merged company as Roche Biomedical Laboratories Inc.
- Early 1990 - Roche Biomedical became one of the largest clinical laboratory networks in the U.S.

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    - 20 major laboratories and US$600 million in sales
- 1992- bought the patent for the polymerase chain reaction (PCR) technique
- 1994- Roche acquired Syntex
- 1995 - the era of highly active antiretroviral therapy (HAART) was initiated by the U.S FDA's approval of their HIV protease inhibitor sanquinavir
    - Within 2 years of its approval, annual deaths from AIDS in the U.S. fell from over 50,000 to approximately 18,000
- April 28 1995 - Hoffman-La Roche sold Roche Biomedical Laboratories Inc. to National Health Laboratories Holdings Inc. (which later changed its name to Laboratory Corporation of America Holdings)
- 1996 - Roche purchased the rights to Oseltamivir (primary antiviral drug used to combat bird flu)
    - Roche is then only drug company authorized to manufacture the drug, which was discovered by Gilead Sciences
    - Roche settled a royalty dispute in 2005 - agreeing to pay Gilead tiered royalties of 14-22% of annual net sales without adjusting the payment for manufacturing costs
    - Soon after, they decided to license other companies to manufacture Oseltamivir
- 2002- Roche acquired Chugai Pharmaceuticals
- 2005 - acquired the Swiss company GlycArt Biotechnology in order to acquire technology to afucosylate antibodies
    - One of its products in development at the time, obinutuzumab, gained FDA approval in November 2013 for treatment of chronic lymphocytic leukaemia
- January 22, 2008 - acquired Ventana Medical Systems for $3.4 billion
- January 2, 2009 - acquired Memory Pharmaceuticals For.
- March 12, 2009 - agreed to fully acquire Genentech, which it had held a majority stake since 1990
    - As a result of this, they moved its Palo Alto based research facilities to their campus in New Jersey
    - Roche's United States headquarters was moved to Genentech's facility in South San Francisco
    - Genentech became a wholly owned subsidiary group of Roche on March 25, 2009
- March 26, 2009 - acquired Genentech for $46.8 billion
- April 2010 - acquired Medingo Ltd. for $160 million
- August 2010 - acquired BioImagene Inc. for $100 million
- 2011- the company received the International Society for Pharmaceutical Engineering Facility of the Year Award for Process Innovation for Roche's "MyDose" Clinical Supply project
- March 2011 - acquired PVT Probenverteiltechnik GmbH for up to €85 million
- July 2010 - acquired mtm laboratories AG for up to 190 million EUR
- October 2010 - Racquired Anadys Pharmaceuticals, Inc. for $230 million
- December 2020 - announced it would acquire Munich-based Verum Diagnostica GmbH, gaining entry to the fastest-growing field in the coagulation diagnostics market

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- June 26, 2012, announced the closure of the Nutley/Clifton campus, which was completed in 2013
- July 2013 - Roche Diagnostics acquired blood diagnostics company Constitution Medical Inc. for $220 million
- April 7 2014 - announced its intention to acquire IQuum for up to $450 million, as well as the rights to an experimental drug (ORY-1001) from Spanish company Oryzon Genomics for $21 million and up to $500 million in milestone payments
- June 2, 2014 - announced its intention to acquire Genia Technologies Inc. for up to $350 million
- August 2014 - company agreed to purchase Californian-based pharmaceutical firm InterMune for $8.3 billion, as well as Santaris Pharma A/S for $450 million
- December 2014 - company acquired next-generation sequencing processing company Bina Technologies for an undisclosed sum
    - They also acquired Dutalys GmbH, a developer of next-generation anti-bodies
- January 16 2015 - announced they would acquire Trophos for 470 million euros in order to increase the company's neuromuscular disease presence
    - The deal entered around on the Phase II and III spinal muscular atrophy drug olesoxime
- April 2015 - acquired CAPP Medical and its chief development of technology for cancer screening and monitoring via the detection of circulating tutor DNA
- August 2015 - company announced its intention to acquire GeneWEAVE Inc. for up to $425 million in order to strengthen its microbial diagnostics business
    - Days later, the company acquired Kapa Biosystems Inc., which focuses on next generation sequencing and polymerase chain reaction applications, for $445M
- October 2015 - company acquired Adheron Therpeutics for $105 million
    - Plus up to $475 million in milestone payments
- January 2016 - company announced it would acquire Tensha Therapeutics for $115 million upfront, with $420 million in contingent payments
- January 2017- company acquired ForSight VISION4
- June 2017 - acquired the diabetes management platform, mySugr GmbG for an undisclosed price
- November 2017 - acquired Viewics, Inc.
- December 2017 - announced that would acquire Ignyta Inc. to expand its global oncology business
- February 2018 - announced they would acquire Flatiron Helath, a business specializing in US cancer data analytics for $1.9 billion
- June 2018 - announced it would acquire the outstanding shares of Foundation Medicine for $2.4 billion
- September 2018 - announced its intention to acquire Tusk Therapeutics for up to 655 million euros to expand their oncology pipeline
    - Tusk announced that the anti-CD38 antibody it is developing will be spun off to form a new company, Black Belt Therapeutics

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- November 2018 - announced that Genetech would acquire Jecure Therapeutics which would allow them to gain access to Jecure's portfolio of NLRP3 inhibitors developed to fight inflammatory disease like non-alcoholic steatohepatitis and liver fibrosis
- February 2019 - announced it would acquire gene therapy company, Spark Therapeutics for US$43 billion
    - Spark had an already approved treatment for Leber's congenital amaurosis, Luxtuma- price edit US$850,000 per patient
    - The offer to acquire Spark Therapeutics was extended to May 2019 after Roche was unable garner majority support from Spark shareholders
    - The company stated that they believe this acquisition will allows Orche to significantly improve the lives of patients through innovative genes therapies and that this acquisition supports their commitment to bringing transformational therapies and innovative approaches to people around the world
- November 2019 - acquired Promedior and its lead treatment, PRM-151, for the treatment of idiopathic pulmonary fibrosis for $390 million upfront and another $1 billion in milestone payments
- December 2019 - acquired non-U.S. rights to an investigational Duchenne muscular dystrophy gene therapy developed by Sarepta Therapeutics
- 2019 - launched new cancer medicines Polivy and Roxlytrek
- March 2020 - the Rich Diagnostics division reached a significant milestone with the FDA-approval of its high-volume SARS-CoV-2 diagnostics test that is capable of analyzing 1,400-8,800 samples within 24 hours on the proprietary cobas 6800/8800 molecular testing system
- May 2020 - announced it had acquired US-based Stratos Genomics for an undisclosed amount
- September 2020 - acquired Ireland-based Inflazome, for 380 million euros
    - This allowed them to gain control of its NLRP3 inflammasome inhibitors
- March 2021 - announced it would acquire GenMark Diagnostics for $1.8 billion

2019-2020 Achievements

- In 2019, the company invested about 1/5 of the company's sales to develop new tests and medicines for patients in need of new options
- In the area of oncology, they are now entering new disease areas with very low incidence rates such as multiple sclerosis, haemophilia and neuroscience diseases
- Of the last 20 medicines that have been approved over the last 20 years, 17 were first-in-class medicines
- Some of their latest innovations are first-in-class in small-cell lunch cancer and in triple-negative breast cancer
    - They also offer the first medicine that can cross the blood-brain barrier to treat a specific type of brain cancer
- They have launched 2 medicines in 2019 - a total of 15 since 2012
    - They are preparing for the launch of another 2 in 2020

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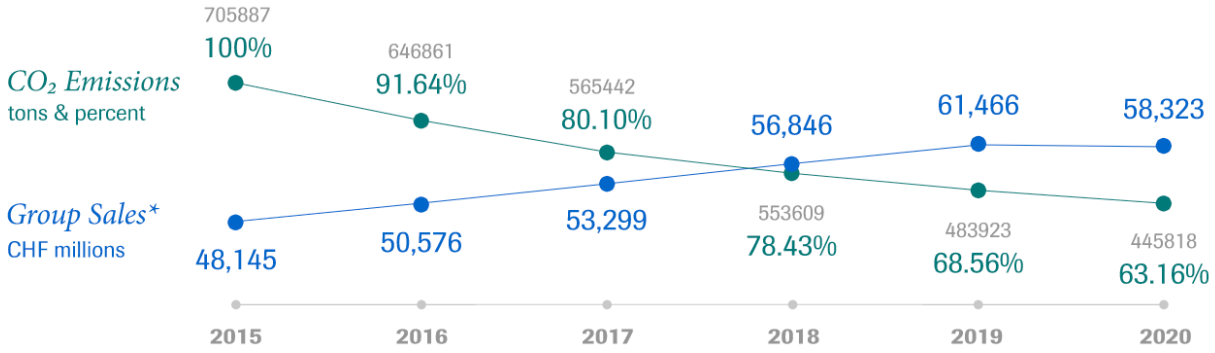
- In November 2020, Hoffmann-La Roche Limited (Roche Canada) launched the Roche AI Centre of Excellence (CoE) with Amii, Mila and Vector Institute
    - This is the first collaborative centre to combine the expertise of all 3 national AI institutes under the CIFAR Pan-Canadian AI Strategy
    - The CoE seeks to leverage collaboration and specialized expertise to work toward outcomes such as enhancing access to the right diagnostics and treatments at the right time, informing and de-risking healthcare decision making, elevating and scaling up Canadian AI startups, nurturing AI talent, and bringing science closer to citizens.
    - Roche recognizes the important role AI will play in delivering transformative solutions, and that only through meaningful partnerships and co-creation will we be able to deliver significantly more value to the health ecosystem

2020 Annual Report

- Roche has been monitoring and actively minimizing its environmental impact for many years while growing the business



- Roche started Flexcare transport in the Philippines to get patients in strict lockdown areas to get care
- Roche developed an open ecosystem for diabetes care that enables more meaningful interaction between people with diabetes and their physicians in response to the need of digital technologies due to the COVID-19 pandemic
- Developed 15 COVID-19 diagnostic solutions
- Roche launched 4 new medicines in 2020
    - Venclexta in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy
        - A first-in-class targeted medicine designed to selectively bind and inhibit the B-cell lymphoma-2 protein
        - Developed by AbbVie and Roche

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    - Ecrysdi for the treatment of spinal muscular atrophy in adults and children 2 months of age and older
    - Gavreto for the treatment of adults with metastatic RET fusion-positive non-small cell lung cancer
        - A once-daily, oral precision therapy that selectively inhibits RET-altered cancers
        - Genentech and Blueprint Medicines will co-commercialise Gavreto in the United States
        - FDA also granted Priority Review to Gavreto for the treatment of people with advanced or metastatic RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer
    - Xofluza for the prevention of influenza following contact with an infected person FDirst single-dose influenza medicine approved to prevent influenza for those who have had contact with an infected person
- 9 new molecules were moved to pivotal clinical studies
    - There are currently 92 new molecular entities in clinical development
- Partnering efforts provided access to 4 late-stage medicines
- The GDA approved FoundationONe Liquid Cdx - a pan-tumour liquid biopsy test for patients with solid tumours analyzing the tumour one more than 300 cancer-related genes and genomic signatures
- They also received FDA approvals for 2 addition companion diagnostic indications: advanced ovarian, breast, and non-small cell lunch cancer
- Following the explosion in Beirus on August 4, 2020, Roche contributed to relief efforts by supporting emergency response and rebuilding initiatives, donating a Roche antibiotic to healthcare centres, and replacing damaged diagnostic laboratory equipment

Roche's response to COVID-19

- Roche has developed a number of diagnostics solutions that help to detect and isganose the infection in patients
    - A high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, (FDA Emergency Use Authorisation (EUA) and available in countries accepting the CE Mark)
    - A SARS-CoV-2 laboratory-based antibody test, aimed at detecting the presence of antibodies in the blood targeting the nucleocapsid (FDA EUA and CE Mark)
    - An IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19 (FDA EUA and CE Mark)
    - Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemi
    - A SARS-CoV-2 rapid antibody test to help determine at the point of care whether a person has been exposed to the virus (CE Mark)
    - A rapid antigen test to support in the detection of SARS-CoV-2 at the point of care within 15 minutes (CE Mark)

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    - A high-volume molecular test to simultaneously detect and differentiate between SARS-CoV-2 and influenza A/B, as the symptoms are similar for both (FDA EUA and CE Mark)
    - A second SARS-CoV-2 antibody test, aimed at measuring the spike protein to support vaccination development and complement our existing portfoli
    - A point-of-care molecular PCR test that simultaneously detects and differentiates between SARS-CoV-2 and influenza A/B infections to support urgent triage and diagnosis (FDA EUA and CE Mark)
- In August 2020, they signed a collaboration agreement with Regeneron on developing and manufacturing and significantly increasing global supply of an investigational antibody combination for COVID-19 if it proves safe and effective in clinical trials and regulatory approvals are granted
- They are also partnering with Atea to jointly develop AT-527, an orally administered direct-acting antiviral currently in Phase 2 clinical trials
    - If approved, Roche will be responsible for global manufacturing and distribution outside the U.S
- On September 18, 2020, they announced that the phase III EMPACTA study showed Actemra/RoActemra plus standard of care reduced the likelihood of progression to mechanical ventilation or death in hospitalized patients with COVID-19 associated pneumonia compared to placebo plus standard of care
    - However, there was no statistical difference in mortality between patients who received Actemra/RoActemra or placebo
    - Actemra©/RoActemra© is not approved by any health authority for use in COVID-19 pneumonia
    - It will be the first and only single-agent cancer immunotherapy with three dosing options, allowing administration every two, three or four weeks, giving physicians and patients flexibility to manage their treatment.

Recent News

- March 26, 2021- Roce announced that the European Medicines Agency's Committee for Medicinal Products for Human Use has recommended the approval of Tecentriq® as a first-line treatment for adults with metastatic non-small cell lung cancer who tumours have high PD-L1 expression, with no epidermal growth factor receptor or anapaestic lymphoma kinase genomic tutor aberrations
    - A final decision regarding the approve low Tecentriq is expected in the near future
- March 23, 2021 - Roche announced that it obtained approval from the Ministry of Health, Labour, and Welfare for the anticancer agent/antimicrotubule binding anti-CD79b monoclonal antibody Polivy® intravenous infusion 30 mg and 140 mg [generic name: polatuzumab vedotin (genetical recombination)] in combination with bendamustine (freeze-dried formulation) and rituximab (BR therapy) for the treatment of relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL)
- March 23, 2021 - Roche hosted a virtual Diagnostics Investor Day event
    - They went over:

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    - Diagnostic market opportunities, strategy, and organization
    - Overview on R&D and new technologies
    - Late stage pipeline: Systems and diagnostics locations for selected disease areas such as infectious diseases, cardiology and oncology
- March 18, 2021 - Roche launched DISCOVERY Green HRP chromogen detection kit to expand immunohistochemistry multiplexing in cancer research
    - This is their newest addition to the comprehensive collection of modular-based detection kist to identify and profile biomarkers and cell populations in tissue-based research
    - Roche believes that advanced in the understanding of cancer biology can help pave the way for improved cancer testing
    - DISCOVERY Green HRP was designed and developed with researchers in mind and will enable them to see multiple biomarkers instantly
- March 16, 2021 - Roche launched SARS-CoV-2 vVariant 1 Test to detect and differentiate mutations found in variants that originated in the UK , South Africa, and Brazil
    - This is a research use only laboratory test which can be used to help scientists track mutation prevalence
    - It runs on the widely available, high-volume comas 6800/8800 Systems
- March 11, 2021 - Roche was awarded WHO pre-qualification for the HIV and HCV tests on the comas 6800/8800 Systems
    - WHO prequalification helps regulators and procurers in low and middle-income countries to identify products that meet high quality standards and are safe and suitable for their intended use.
    - For people who can not easily access healthcare facilities, the ability to simplify blood collection and sample transportation on a stable device improves access to reliable diagnostics.
        - The cobas HIV-1 Test can be used in conjunction with the first-of-its-kind cobas® Plasma Separation Card to process dried plasma spot samples collected in remote areas, where access to testing facilities can be difficult.
    - Roche is committed to helping countries scale up HIV elimination programs and reach the WHO 2030 goals of 95% of people on treatment having suppressed viral loads
    - Roche also strives to help reach the 2030 hepatitis elimination targets of 90% reduction in new chronic hepatitis B and C cases; 65% reduction in hepatitis-related deaths and 80% of eligible people with chronic hepatitis B and C infections receiving treatment.
- March 9, 2021 - Roche receives FDA approval for VENTANA ALK (D5F3) Cdx Assay
    - Approval was given to the VENTANA ALK (D5F3) CDx Assay as a companion diagnostic to identify ALK-positive non-small cell lung cancer (NSCLC) patients eligible for treatment with Pfizer's drug LORBRENA® (lorlatinib)
    - It is the only immunohistochemistry (IHIC) test approved by the FDA as a companion diagnostic for LORBRENA

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    - It is no approved as a companion diagnostic in four targeted treatments - XALKORI® (crizotinib), ZYKADIA® (ceritinib), ALECENSA® (alectinib) and LORBRENA® (lorlatinib)
    - The VENTANA ALK (D5F3) CDx Assay is available in the US for use on the BenchMark ULTRA and BenchMark XT immunohistochemistry/in situ hybridisation (IHC/ISH) slide staining instruments
- February 11, 2021 - Roche receives first FDA 510K clearance for urine sample type for BK virus quantitative test to aid in the improvement of care for transplant patients
    - A urine sample stabilized in cobas® PCR Media allows the integrity of urine results to be maintained
    - The cobas Test runs on the widely available, high-throughout comas 6800/8800 Systems
- January 11, 2021 - Roche announced the CE-IVD launch of its automated digital pathology algorithms, uPath HER2 (4B5) image analysis and uPath HER2 Dual ISH image analysis for breast cancer to help determine the best treatment strategy for each patient
    - The image analysis algorithms use AI to support pathologists in making fast, accurate patient diagnosis in breast cancer
    - uPath HER2 (4B5) image analysis for breast cancer helps pathologists to quickly determine whether tumours are positive for the HER2 biomarker, highlighting positively stained tumour cell membranes with a clear visual overlay for easy reference
    - th HER2 Dual ISH image analysis for breast cancer assists the pathologist in the determination of HER2 gene amplification
        - A heatmap is provided to guide pathologists to areas of interest where the algorithm can identify cells to inform the determination of a treatment strategy.
    - Validated for use with the VENTANA HER2 (4B5) assay and the VENTANA HER2 Dual ISH DNA Probe Cocktail, the algorithms are ready-to-use and integrated within the Roche uPath enterprise software.
- December 17, 2020 - Roch is the first manufacturer to receive an EU Quality Management System Certificate
    - This “EU Quality Management System Certificate (IVDR)” is mandatory for any manufacturer of in vitro diagnostic devices (IVDs) to issue declarations of conformity for their products and to get them (re-)certified in compliance with the new regulation
- December 16, 2020 - Roche recieved FDA approval for cobas® HIV-1/HIV-2 Qualitative Test for use on the fully automated cobas® 6800/8800 Systems in the U.S
    - The test provides healthcare professionals with a single result to confirm HIV diagnosis and differentiate HIV-1 and HIV-2
    - cobas HIV-1/HIV-2 Qualitative for use on the cobas 6800/8800 Systems is an in vitro nucleic acid amplification test for the qualitative detection and differentiation of human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) RNA in human serum and plasma

Eugene Consulting Inc.
1602- 111 St. Clair Ave W
Toronto, ON
M4V 1N5

- December 15, 2020 - Launched the cobas® PIK3CA Mutation Test for patients with advanced or metastatic beast cancer
    - This in vitro diagnostic test is now available in countries accepting the CE mark
    - The cobas PIK3CA Mutation Test is a PCR-based test that detects PIK3CA mutations in patients with metastatic breast cancer to help identify those most likely to benefit from approved therapy
        - This genetic test identifies mutations in the PIK3CA gene that can cause cells to grow uncontrollably, which may lead to cancer
- October 31, 2020 - Roche launched cobas prime Pre-analytical System to improve efficiency in molecular diagnostics laboratories
    - This system minimizes repetitive manual tasks, streamlines, and simplifies workflow in molecule labs
        - This reduces manual errors and increases confidence in results
    - Roche is first company to offer molecular labs complete end-to-end automation solution for testing consolidation
- October 29, 2020 - Roche received FDA approval of expanded claims for the cobas® EGFR Mutation Test v2 as a companion diagnostic (CDx) for a broader group of therapies in the treatment of non-small cell lung cancer (NSCLC)
    - This claim expansion allows the test to be used as a CDx for all five currently FDA-approved epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapies targeting EGFR mutations L858R and Exon 19 Deletions in accordance with the approved therapeutic product labellinG
    - This will also enable the test to be used as a CDx for any future approved EGFR TKI therapies targeting the same mutations, without the need to conduct individual clinical studies with the test for each new therapy
- September 30, 2020 - Roche launched Elecsys® HIV Duo immunoassay in the U.S. following FDA approval in April 2020
    - Through separate measurement of the HIV p24 antigen (the virus) and anti-HIV antibodies (caused by immune reaction), this test can detect an acute HIV infection earlier than current methods
    - The Elecsys® HIV Duo immunoassay detects both the HIV p24 antigen and anti-HIV antibody
- September 16, 2020 - Roche received FDA approval for the expanded use of CINtec® PLUS Cytology - the firs triage test based on biomarker technology for women whose cervical cancer screening results are positive for high-risk types of human papillomavirus (HPV)
    - Additional information from this test supports clinical decisions about which women will benefit most from immediate follow-up.