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Report on Debiopharm Group

About the Company

- https://www.debiopharm.com
- A Swiss-headquartered global biopharmaceutical group which includes 5 companies that are active in the life science areas of drug development, GMP manufacturing of proprietary drugs, diagnostic tools and investment management
    - Family-owned business
    - Sole Proprietorship
- Besides drug development, Debiopharm has recently developed in-house skills in the field of companion diagnostics
- Debiopharm Group independently funds the worldwide development of all of its products while providing expertise in all areas
- The company was founded in 1979 by Dr Rolland-Yves Mauvernay
- Total revenue: about $25 billion USD
- Subsidiaries:
    - ***Debiopharm International SA*** - searches, evaluates and in-licenses candidates or technologies, develops them, and then licenses them to 3rd parties for for world-wide marketing and sales
    - ***Debiopharm Research and Manufacturing SA*** **-** pharmaceutical research, development and production facility, inspected and registered with the main regulatory authorities.
        - Provides contract manufacturing and contract research services to Debiopharm
    - ***Debiopharm Investment SA*** - manages group's money and invests in real estate and in other companies
        - Their main objectives is the preservation of capital of Debiopharm Group, and the generation of regular financial incomes for Debiopharm Group's companies
    - ***Debiopharm Innovation Fund SA*** *(formerly knowns as Debiopharm Diagnostics* - the strategic investment fund of the Debiopharm Group
- Company size: About 400 employees
- They have 2 completed the development and licensed out 2 compounds:
    1. *Oxalipatin* - for the treatment of cancer
    2. Depot formulations of *triptorelin* - a gonadotropin-releasing hormone agonist that is approved to treat advanced prostate cancer
- In 2017, Debiopharm acquired a phase 2 drug candidate from ImmunoGen that intends to target Non-Hodgkin lymphoma

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Awards and Grants

- The JCA-Mauvernay Award
  - Launched in 2005, the Japanese Cancer Association (JCA) and Debiopharm Group have co-organized the JCA-Mauvernay Award
  - The award has a total value of CHF 25000 and it aims at recognizing outstanding achievements in the field of oncology amongst Japanese researchers, in both the fundamental and clinical aspects
- The Debiopharm-Inartis Challenge
  - Co-created by the Inartis Foundation and Debiopharm Group
  - This aims to encourage innovation in the health sector by rewarding projects intended to improve patient comfort and quality of life
  - Goal = speed up the implementation and/or commercialization of successful entries
  - The Challenge has a total lvalue of CHF75,000, of which 25,000 will go to the chosen project
- Innovation Debiopharm Academica Leman (IDEAL)
  - Partnering with lemanic institutions
    - The Lemanic region has a rich ecosystem of scientific, academic and pharmaceutical organizations that focus on new breakthrough therapies for cancer patients
  - Through IDEAL, Debiopharm is aiming to accelerate the translation of scientific discoveries of the Lemanic region into new anti-cancer and anti-infective treatments with global reach
  - The initiative allows Debiopharm to establish pre-agreed collaborations with academic and medical institutions to enable researchers to mature and tailor early-stage innovations in the field of oncology and antibiotics, with the financial support of Debiopharm, up to a stage where promising programs could be in-licensed for further development
    - Those who have an early-stage oncology of anti-infective compound can send their project proposals for reviews by their Steering Committee
    - If the project is selected for IDEAL funding, a research and development plan is defined
    - At the end of the project, partners are asked to send a final report of their research and results for evaluation and if they are to advance to become a Debiopaharm development program, they enter into negotiation for a partnership through license or research collaboration
  - Current partners:
    - Université de Genève - involved in most cutting-edge sectors and active in interdisciplinary research
    - Institut des Sciences pharmaceutiques de Suisse occidentale - conducts research to discover new therapeutic agents and develop novel formulation and delivery strategies

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The Company's Social Responsibilities

- Dialogue Générations - an association created by Debiopharm to foster knowledge and new ideas
- They are supporters of Lépac's project of 'Novel Atlas des Future du Monde 2038' - an analysis of humanity's future societies, lifestyles, needs and aspirations

Philanthropic project

1. Foundation Téléthon Action Suisse - Debiopharm has been a supported since 2014
    - https://telethon.ch/

2. Kantuta Association - Debiopharm has been involved with the Kantuta Association which is active with street children in Bolivia since its creation in 200
    - http://www.association-kantuta.org/?ln=en

3. Les Pinceaus Magiques - Debiopharm supports an organization which gives hope to hospitalized children
    - https://www.pinceauxmagiques.ch/

4. Prix George Mathé - They are supported of the Prix George Mathé, which promotes therapeutic advances and translational research in medical oncology and immunotherapy
    - This prize was established in 2010 and in organized each year by the Institut du Cancer et d'Immunogénétique (ICIG)

Chair

- Debiopharm supports the creation of the 'Debiopharm Chair for Family Philanthropy' at IMD business school in Lausanne with a donation of several million Swiss francs over the next 15 years

Entrepreneurship

- Debiopharm has a stake in Polutech Ventures - a seed fund that offers early stage investment to technology companies in Western Switzerland
    - https://polytechventures.ch/
- Debiopharm support the National Pre-Seed Fund venture kick, which contributes to the development of high potential business ideas at Switzerland's institutes of higher learning and universities
    - https://www.venturekick.ch/index.cfm?page=119286&cfid=189324746&cftoken=13287858
- Debiopharm supports FIT (Foundation pour l'Innovation Technologique), which assists innovative technological projects in link with one of the universities of the French speaking part of Switzerland
    - https://fondation-fit.ch/

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Clinical trials

- When screening, extensive medical examinations are conducted to confirm whether someone can participate in the clinical trial
- Participants are continuously monitored during and after the trail to measure effectiveness and ensure there are no long-term side-effects

Drug Development

- Debiopharm identifies high potential compounds for in-licensing
    - They look for promising oncology and antibacterial compounds to transform them into valuable treatments
- They also conduct clinical development and select large pharmaceutical commercialization partners to maximize patient access across the globe
- Debiopharm partners with universities, biotech, and big Pharma
- Their main areas are in oncology and bacterial infections

Commercialized Products

1) Oxaliplatin - a diaminocyclohexane (DACH) platin

- The active substance of the branded Eloxatin®/Elplat®/Dacotin®/Dacplat
- Oxaliplatin is a worldwide standard treatment in metastatic and adjuvant colorectal cancer as well as metastatic and adjuvant pancreatic cancer
    - It is also used to treat liver cancer in China
- Product Characteristics
    - 3 dosages: 50 mg - 100mg - 200mg
    - IV infusion
    - Freeze-dried and solution formulations
- Commercial partners:
    - Sanofi, Yakult, Dr. Reddy's Laboratories, Pfizer
- In March 2015, Yakult Honsha announced the approval of Elplat® (oxaliplatin) for patients with unresectable advanced or recurrent gastric cancer
- In March 2017, Debiopharm International appealed to the Supreme Court of Japan against the decision from the Grand Panel of the IP High Court, according to which the generic product of Elplat® commercialized by Towa Pharmaceuticals Co. Ltd have not infringed the Japanese patent JP 3547755, which is owned by Debiopharm and exclusively licensed to Yakult Honsha Co. Ltd in Japan
- A similar appeal was filed before the Supreme Court of Japan against the decision form the IP High Court, according to which the generic product of Elplat® commercialized by Nippon Kayaku Co., Ltf. have not infringed the Japanese patent JP 4430229, which is owned by Debiopharm and exclusively licensed to Yakult Honsha Co. Ltd in Japan

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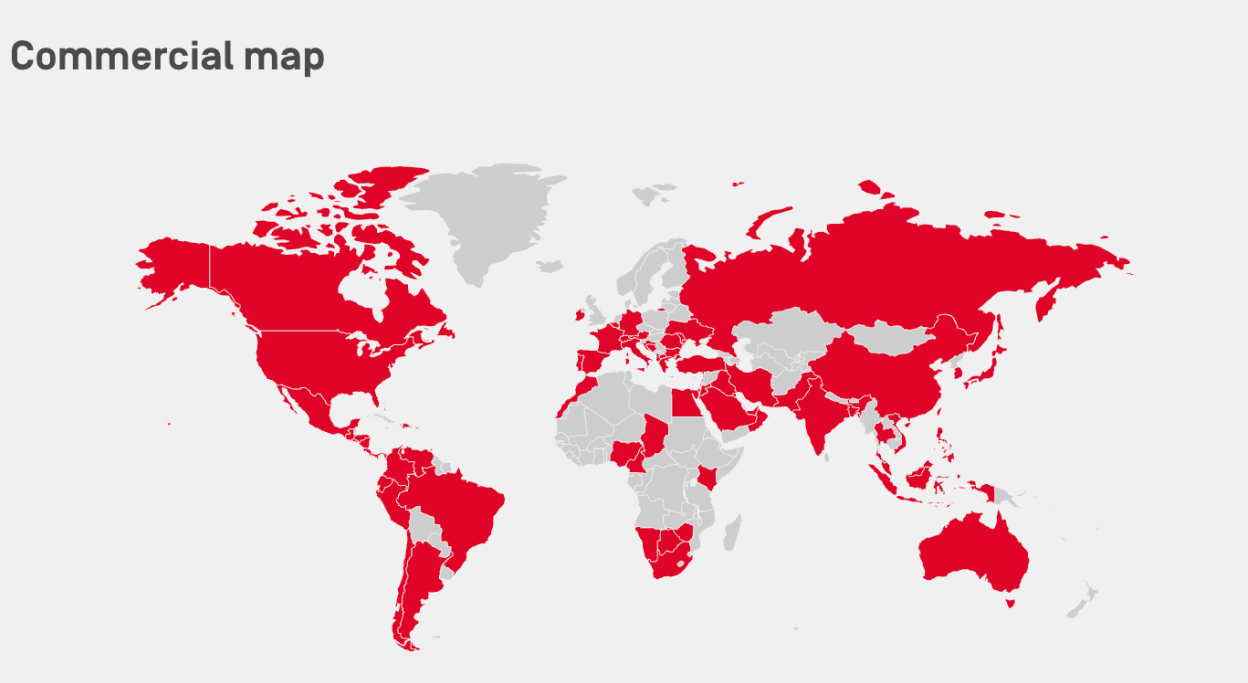

- Debiopharm stated that they will continue to take legal actions against any activity that infringes the intellectual property rights owned by Debiopharm and exclusively licensed to Yakult
- In August of 2018. Prof Thierry Control, medical oncologist and Director of the Institut de Cancerologie de Lorraine presented at ASCO 2018 the results of phase II study to compare adjuvant chemotherapy with gemcitabine versus mFolfirinox in patients with resected pancreatic adenocarcinomas
  - mFolfirinox is a modified regimen containing Debiopharm's Oxaliplatin, combined with irinotecan, fluorouracil and leucovorin
  - Results showed a significant improvement of the OS and disease-free survival

2) Triptorelin - a gonadotropin releasing hormone (GnRH) agonist

- The active substance of Decapeptyl®/Trelstar®/ Triptodur®1, 3 and 6-month formulation and Moapar®/ Salcacyl®
- Triptorelin decreases the serum testosterone to castrate levels (estradiol in females)
- Andorgen deprivation stops the growth of the androgen dependent prostate cancer, alleviating pain and improving the quality of life of patients
- GnRH agonist treatment achieves similar overall survival rates in advanced prostate cancer as surgical castration
- Indications:

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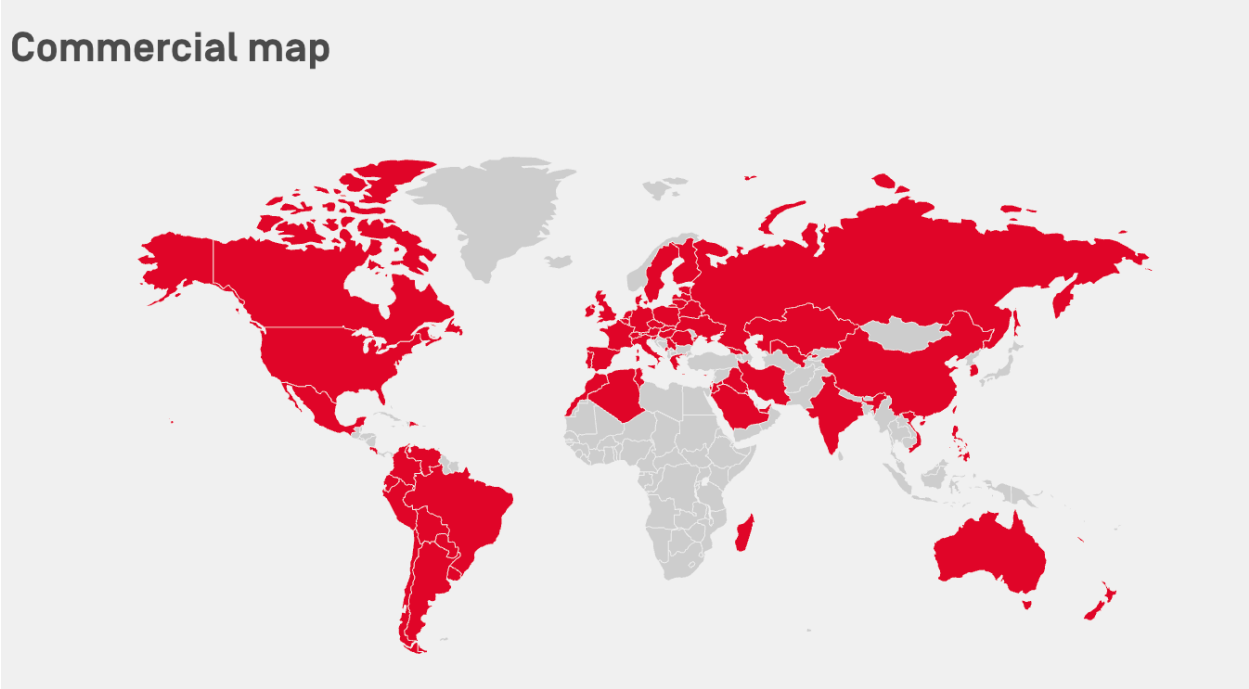

    - Advanced prostate cancer
    - Endometriosis
    - In-vitro fertilization programs
    - Uterine fibroids
    - Precocious puberty
- Product characteristics:
    - 3 dosages, 1 month (3.75mg), 3 month (11.2 mg), and 6 months (22.5mg)
- Commercialization partners:
    - Aché Laboratórios Farmacêuticos SA
    - Verity Pharmaceuticals Inc.
    - Arbor Pharmaceuticals
    - Dr. Reddy's Laboratories
    - Ferring International Center
    - Ipsen Pharma
    - Orient Europharma
    - Tecnofarma International
    - Unilab
    - Debiopharm
    - Knight Therapeutics Inc.

- In May 2015, it was presented at PAS 2015 San Diego that Triptorelin 6-month formulations show good efficacy and safety in patients with central precocious puberty
    - https://www.debiopharm.com/wp-content/uploads/2018/08/2015-CPP.pdf

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- Following this, in January 2016, Debiopharm International SA and Arbor Pharmaceuticals, LLC announced their US commercialization partnership for Triptorelin in Central Precocious Puberty
    - This gave Arbor exclusive commercial rights for triptorelin 22.5mg in the U.S for the CPP indicator
    - The product will be exported from Debiopharm Research and Manufacturing SA to Arbor
- In January 2017, Debiopharm Group's Triptorelin 6-month formulation received approval for the treatment of central precocious puberty in 22 European countries
    - The 6 month formulation was already registered for the treatment of prostate cancer
    - Developed by Debiopharm, the product is manufactured in Switzerland by Debiopharm Research & Manufacturing SA and licensed for distribution under exclusive rights to Ipsen for Europe and other parts of the world.
- In June 2017, the FDA approved Triptodur for the treatment of paediatric patients 2 years and older with CPP
    - Triptodur™, a gonadotropin-releasing hormone (GnRH) agonist administered through intramuscular injection (IM), is the first GnRH agonist to offer once-every six-month dosing approved for the treatment of CPP in the U.S.
    - In a phase III clinical trial, Triptodur™ demonstrated a return to pre-pubertal luteinizing hormone (LH) levels in 93 percent of patients, with pre-pubertal LH suppression maintained at 12 months by 98 percent of patients
    - The most common adverse reactions in clinical studies were injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection
- In October 2019, Triptodur became commercially available in the U.S for the treatment of paediatric patients 2 years and older diagnosed with CPP
- In June 2019, Debiopharm and Ipsen Extended their strategic Decapeptyl® (Triptorelin) partnership for another 15 years through 2034
    - This extends and strengthens their strategic partnership for the development, manufacturing and distribution of Decapeptyl® across Europe and certain Asian and African markets
    - Their collaboration was established in the 1980s
    - Under the renewed agreement, both parties will co-develop novel formulations and explore additional indications for other patient populations with high unmet needs
- In January 2020, Debiopharm and Knight Therapeutics enter into an exclusive agreement that grants Knight the right to commercialize Trelstar® (Triptorelin) in Canda
    - Knight took over commercial activities from Allergan
- In June 2020, Debiopharm and Verity Pharmaceuticals enter into an exclusive agreement that grants Verity Pharmaceuticals the right to commercialize Trelstar® (Triptorelin) for the palliative treatment of prostate cancer in the U.S

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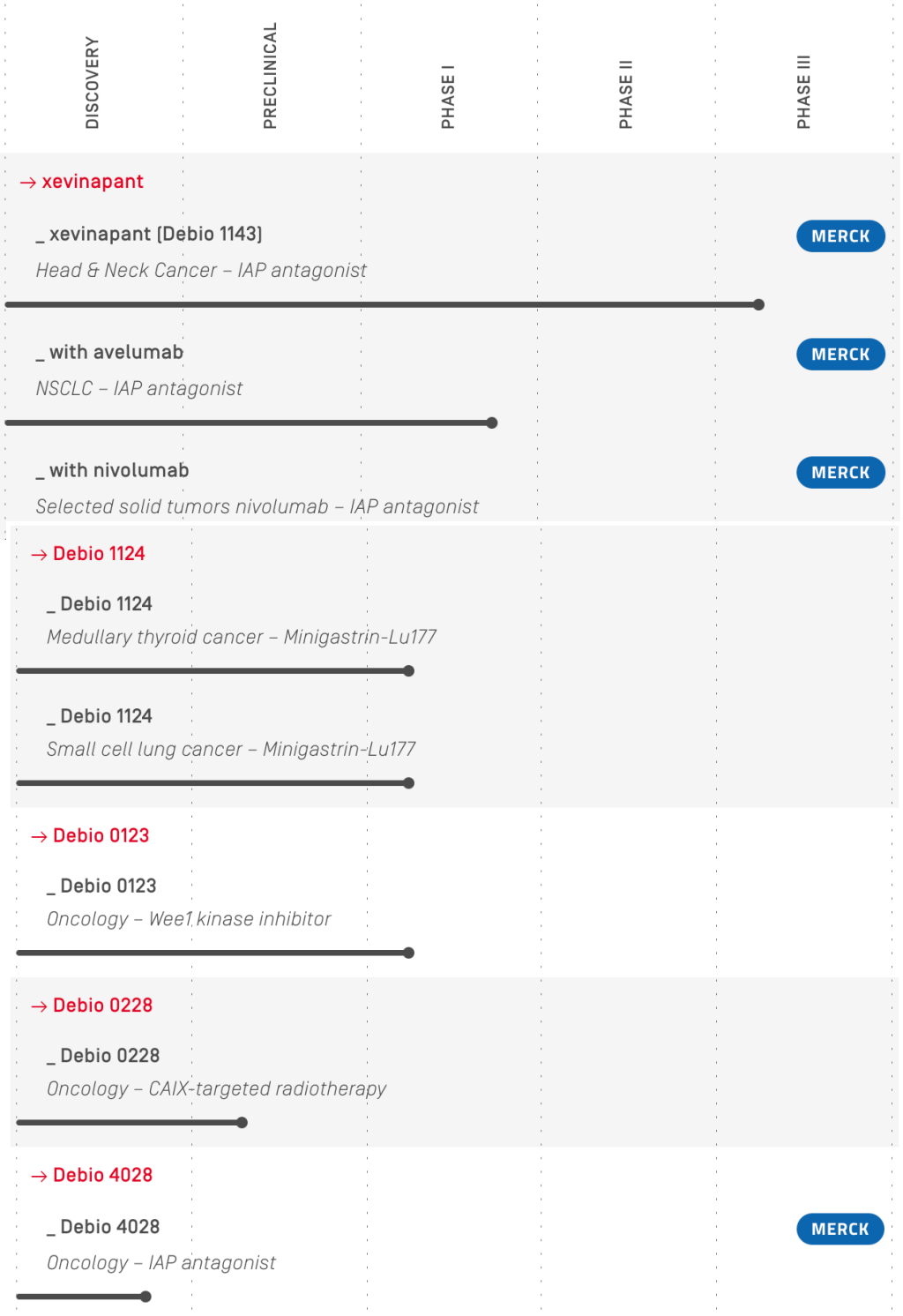
Pipeline

Oncology



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Xevinapan

- A potent, orally available, inhibitor of IAPs (Inhibitor of Apoptosis Proteins)
- This class of products is particularly suited to be combined with widely used but often sub-optimal chemo- and radiotherapy (CRT)
- Xevinapant established proof of efficacy in high-risk locally advanced squamous cell carcinoma of the head and neck (LASCCHN) patients for which the combination provided highly significant and sustainable clinical benefit as compared to CRT alone
- Xevinapant is currently being investigated in the pivotal Phase III TrilynX study for previously untreated high-risk locally advanced squamous cell carcinoma of the head and neck (LA SCCHN), in combination with platinum-based chemotherapy and standard fractionation intensity-modulated radiotherapy
- 3-year follow-up results from the Phase II trial in high-risk LA-SCCHN patients revealed significant improvement in overall survival, progression free survival and duration of response with Debio 1143 in combination with CRT vs. CRT alone
- In February 2020, the FDA granted Breakthrough Therapy Designation to xevinapant for front-line treatment of Head & Neck Cancer
- Xevinapant (Debio 1143) is being investigated in a phase I in combination with avelumab*, a human anti-PD-L1 IgG1 monoclonal antibody, in patients with advanced solid tumors including non-small cell lung cancer (NSCLC)
    - The trial is being conducted under a clinical collaboration agreement between Debiopharm International SA and the Merck-Pfizer Alliance
- SMARTPLUS-106 is an exploratory study investigating the safety and efficacy of xevinapant (Debio 1143) in combination with the Immune Checkpoint Inhibitor (ICI), nivolumab, in patients with advanced solid tumors, such as small cell lung cancer (SCLC) or squamous cell carcinoma of the head & neck (SCCHN), who have progressed during or immediately after anti-PD-1/PD-L1 treatment
- CATRIPCA is a Phase I study initiated by Dr. Phillippe Cassier, combining xevinapant (Debio 1143) with Merck Sharpe & Dohme's (MSD) anti-PD1 Keytruda® (pembrolizumab).
    - The study focuses on two cancer patient populations with conditions that are intrinsically resistant to Immune Checkpoint Inhibitors (ICI)
    - The trial will recruit patients without other available therapeutic options in Non-microsatellite instability (non-MSI)-high colorectal cancer (CRC) and pancreatic ductal adenocarcinoma cancer (PDAC)
    - The safety and preliminary efficacy of the combination will be assessed with the primary endpoint of the study extension being the Objective Response rate
- On March 21, 2021 Debiopharm announced an exclusive license agreement with Merck, for the development and commercialization of xevinapant (Debio1143) worldwide

Naratuximab emtansine (Debio 1562)

- An antibody-drug conjugate targeting CD37

    - The naratuximab emtansine ADC binds with high affinity and specificity to CD37, obstructing cell proliferation pathways while allowing internalization, processing, and intracellular release of the DM1 payload
    - As a result of its ability to disrupt microtubule assembly, DM1 subsequently induces cell cycle arrest and apoptosis.
- A potential new treatment for patients with B-cell malignancies, such as non-Hodgkin's lymphomas (NHL)
    - Demonstrated evidence of anti-cancer activity in NHL in a Phase 1 monotherapy trial and successfully completed a safety lead-in study in combination with rituximab
    - Phase II data has shown promise for the treatment of non-Hodgkin's lymphoma
        - The response rate was 31.6% in all patients with diffuse large B cell lymphoma and 32% in patients with more than 2 prior therapies
        - 8% of patients stopped treatment due to side effects
- The product is currently in phase IIb in relapsed/refractory diffuse large-cell B-cell lymphoma (R/R DLBCL) for which it benefits from Orphan Drug status
- Debiopharm is currently investigating naratuximab emtansine in a phase II, open-label study to establish the safety and efficacy profile of this CD37 ADC in combination with CD20 targeting rituximab in patients with R/R DLBCL and other forms of NHL
    - Naratuximab emtansine targets the CD37 antigen to release a toxic DM1 payload
    - On June 14, 2021, the company announced that naratuximab emtansine co-administered with rituximab revealed meaningful efficacy and high complete response rates (CRR), especially in heavily pre-treated patients with ≥2 prior lines of treatment
    - The safety profile was predictable and manageable, with a low rate of treatment discontinuation due to adverse events (8%) and low incidence of serious febrile neutropenia (4%).
    - Results were particularly impressive for heavily pre-treated DLBCL patients for whom options are remain limited
    - The high response rates and durability combined with the manageable safety profile offer a strong rationale for further research of naratuximab emtansine in B-cell malignancies.
- It has also shown promising signs of efficacy in Marginal Zone Lymphoma and Follicular Lymphoma and has potential in Acute Myeloid Leukemia.

Debio 1124 - Clinical stage Radio-conjugate

- Debio 1124 is a radioconjugated minigastrin analogue designed to target the CholeCystoKinin 2 Receptor (CCK2R) expressed in certain tumors
- Debio 1124 belongs to the emerging class of Peptide Receptor Radionuclide Therapies (PRRT) which selectively delivers radiotherapy to cells expressing CCK2R
    - With Debio 1124, the specific receptor-binding property of gastrin peptides is exploited by using them as carriers to guide the radioactivity to the tumors that express their specific receptors

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    - Debio 1124 has been formulated to transport radiotherapy specifically to cells harbouring CCK2R receptors, in order to reduce the toxicity burden observed with systemic radiation
    - When the compound binds to tumor cell surfaces expressing CCK2R, the radionuclide is released to destroy the cells' DNA and thereby inducing cell death.
- The product is being developed in Medullary Thyroid Cancer (MTC) and is also being studied in Small Cell Lung Cancer (SCLC)
- The compound can also be used as a sensitive diagnostic tool, therefore, an initial imaging step allows the selection of patients whose tumor expresses the target receptor and so are expected to benefit from this innovative treatment
- In August 2020, a multicenter, single-arm, open-label Phase 1 study was initiated to assess the safety, distribution, and dosing of Debio 1124 in patients with advanced, unresectable pulmonary and extrapulmonary small cell carcinoma.

Debio 0123

- Debio 0123 is a Wee1 kinase inhibitor currently in phase I research in refractory solid tumors
    - Inhibition of WEE1 prevents cells to arrest to repair DNA damages and force then to prematurely continue through the cell cycle, therefore accumulating unrepaired DNA damages ultimately leading to cell death
    - Asc
- Pre-clinical models have shown anti-tumor activity both as a single agent and in combination with carboplatin
- The primary objective of the Phase 1, first-in-human, study (NCT03968653) is to determine the recommended phase 2 dose of Debio 0123 in combination with carboplatin in participants with advanced solid tumors that have recurred or progressed following prior platinum based therapy

Debio 0228 - Currently in Lead Optimization stage

- The Debio 0228 program is set to identify a Development Candidate with best-in-class potential, designed to selectively destroy tumor cells that express the CAIX target
- The selected compound will be developed using a theranostic approach, a combination of diagnostic and therapeutic features with the same compound, allowing the pre-identification of patients who have the receptors necessary to respond to the targeted radiotherapy

Debio 4028

- This program leverages the immunomodulatory, pro-apoptotic of a new generation of potent, Inhibitor of Apoptosis Proteins (IAP) antagonists to treat various types of cancer.

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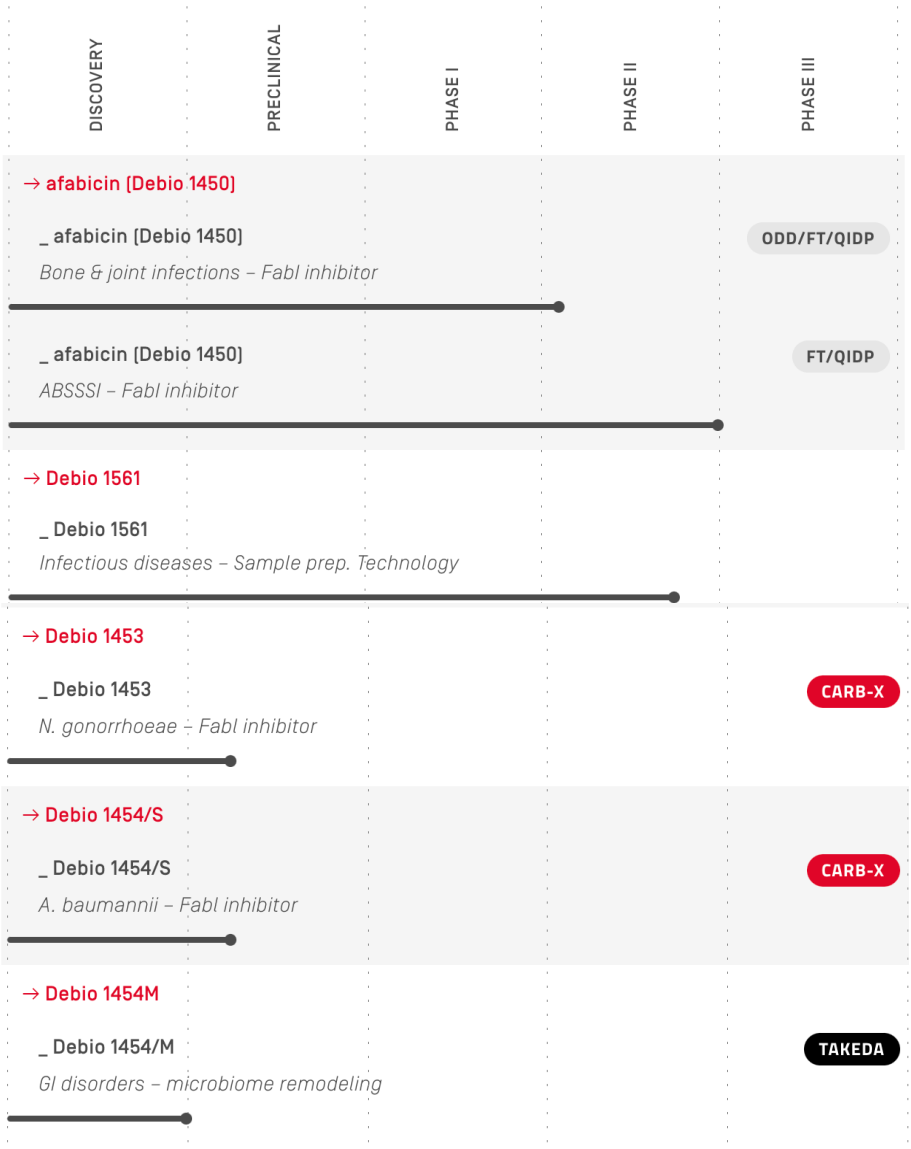
Infectious disease



ODD: Orphan Drug Designation **FT:** Fast-Track

QIDP: Qualified Infectious Disease Product **CARB-X:** CARB-X **Takeda:** Takeda

Afabicin (Debio1450

- A fabiotics, that inhibits fatty acid synthesis in staphylococci by targeting the FabI enzyme
  - The FabI enzyme is essential for bacterial growth and survival and it is highly conserved across all staphylococcal species

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    - By inhibiting FabI, Fabiotics represent a novel antibacterial class that has the potential to address challenges of bacterial resistance
    - Afabicin specifically targets staphylococci while preserving intestinal microbiota
- A phase II study was conducted in patients with staphylococcal Acute Bacterial Skin and Skin Structure Infections (ABSSSI) demonstrating the efficacy and safety with the two doses tested vs. active comparator vancomycin / oral linezolid
    - Treatment with Debio 1450 at both doses was safe and well tolerated.
- The compound in both oral and intravenous formulations currently is in phase II research for the treatment of Bone and Joint infections (BJI) due to staphylococci
- It is also being researched in staphylococcal acute bacterial skin and skin structure infections (ABSSSI)

Debio 1561

- Debio 1561 FibroTrap is a unique sample preparation technology for the concentration of bacteria and other microorganisms in blood samples of patients with bloodstream infections
- The technology will enable faster identification and diagnosis of pathogens directly from patient samples and will promote an accelerated selection of more appropriate antibiotics to improve treatment outcomes

Alisporivir - Debio 025

- A class of drugs called cyclophilin inhibitors
- Alisporivir was first thoroughly investigated for its antiviral properties in hepatitis C and HIV patients
- Pre-clinical in vitro research from the Mondor Institute of Biomedical Research (INSERM U955) has shown evidence for the effectiveness of alisporivir against the replication of SARS-COV-2 (COVID-19)
- Alisporivir is currently tested in a phase II study conducted in France by the AP-HP (Greater Paris University Hospitals) to assess the efficacy and safety of the compound

Debio 1453

- A FabI inhibitor specifically targeting N. gonorrhoeae developed in collaboration with Nobelex
- Belongs to a family of narrow-spectrum antiobiotics that combines a very potent activity on pathogens of interest while reducing the selective pressure on other bacterial strains and sparing the microbiome

Debio 1454/S

- A FabI inhibitor targeting a combination of enteric bacteria species - A. baumannii, Enterobacter Spp., Klebsiella pneumoniae and E.coli.
- Belongs to a family of narrow-spectrum antiobiotics that combines a very potent activity on pathogens of interest while reducing the selective pressure on other bacterial strains and sparing the microbiome

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Debio 1454M - Currently in drug candidate identification stage

- The Debio 1454M program includes novel microbiome therapeutics for the treatment of gastrointestinal (GI) disorders.
    - The program aims to identify effective treatment against inflammatory bowel disease (IBD) and other GI disorders
- In June 2020, Debiopharm announced an exclusive license agreement and research collaboration with Takeda Pharmaceutical Company Limited (Takeda) to develop novel microbiome therapeutics for the treatment of gastrointestinal disorders
    - Under the agreement, Takeda will screen and optimize compounds derived from Debiopharm's discovery Debio 145M program to identify candidates for further development for the treatment of inflammatory bowel disease (IBD) and other GI disorders

Recent Scientific Publications

- June 12, 2021 - A phase 2 study on the safety and efficacy of CD37- Targeting Naratuximab Emtansine plus Rituximab in diffuse large B-cell lymphoma and other non-hadgkin's B-cell lymphomas was presented at EHA 2021
    - https://www.debiopharm.com/wp-content/uploads/2021/06/2021-Debiopharm-naratuximab-emtansine-PhaseII-EHA-compresse.pdf
    - In March of 2021, Debiopharm published ani interview with 2 key opinion leaders regarding CD37-trageted therapy as a viable alternative in the treatment of diffuse b-cell lymphoma
    - Key points from the interview are as follows:
        - CD37 (tetraspanin TSPAN26) is a B-cell surface antigen widely expressed on mature B cells. CD37 is involved in immune regulation and tumour suppression.
        - CD37 forms complexes with other tetraspanins and major histocompatibility complex (MHC) Class II antigens on B cells.
        - CD37 is also important for T-cell–B-cell interaction, IgG/IgA production, and a balance between immune responses and tolerance.
        - The loss of CD37 results in increased IL-6 signalling and STAT3 activation, which are both known to be involved in the pathogenesis of haematological malignancies.
        - A study by Oostindie et al. demonstrated that the combinations of hexamerisation-enhanced CD20 and CD37 antibodies co-operated in C1q binding and induced superior and synergistic complement-dependent cytotoxicity in patient-derived cancer cells, compared with the single agents. Consistent with these data, a strategy of dual-ligand immunoliposomes of anti-CD20 combined with anti-CD37 demonstrated highly specific targeting to both leukaemia cell lines and B-cell chronic lymphocytic leukaemia patient cells.

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- Compared with the single-antibody immunoliposomes, the combination demonstrated superior delivery efficiency and apoptosis induction to B-cell chronic lymphocytic leukaemia patient cells.
- These findings provide novel insights into the mechanisms of synergy in antibody-mediated, complement-dependent cytotoxicity, provide a rationale to enhance the co-operativity and therapeutic efficacy of antibody combinations, and provide a preferred strategy of personalised nanomedicine for the treatment of B-cell malignancies
- Naratuximab emtansine (IMGN529 or Debio 1562 [Debiopharm, Lausanne, Switzerland]) is an investigational ADC comprising a CD37-targeting antibody conjugated to the maitansine-derived microtubule disruptor DM1 via a succinimidyl-4-(N-maleimidomethyl)cyclohexane-1-carboxylate (SMCC) linker, forming a nonreducible thioether bond
- Naratuximab emtansine binds with high affinity and specificity to CD37, obstructing cell proliferation pathways while allowing internalisation, processing, and intracellular release of the DM1 payload. As a result of its ability to disrupt microtubule assembly, DM1 subsequently induces cell cycle arrest and apoptosis
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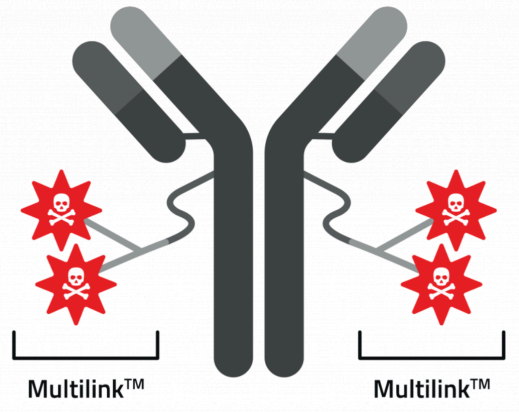
Manufacturing, Research & Development

- Debiopharm International SA focuses on the development of prescription drugs that target unmet medical needs
- The company in-licenses and develops promising drug candidates
    - The Company is a world leader in polylactic-co-glycolic acid (PLGA)-based injectable, sustained-release technology.
- The products are commercialized by pharmaceutical out-licensing partners to give access to the largest number of patients worldwide

Multilink

- Multilink is a new cleavable linker platform suited for multi drug attachment and compatible with any conjugation technology to produce ADCs with high DAR (drug-to-antibody ratio)
- Multilink™ is a unique and innovative technology in that it allows the loading of multiple payloads on an antibody
- Goal = To allow any biotech or pharma company with an antibody to generate a proprietary clinical-stage



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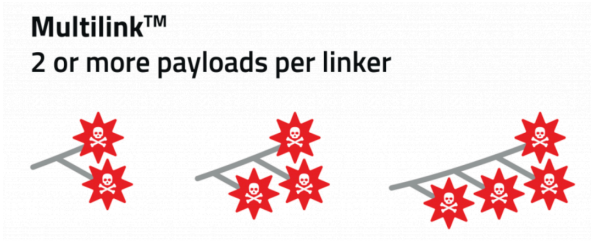
ADC (using our Linker Multilink™) that is significantly more effective and better tolerated



- They claim to be able to generate nonclinical proof-of-concept (POC) material in just a few weeks
- On June 16 2021, Debiopharm and a South Korea-based biotech company, UBIX Therapeutics announced their co-research agreement combining 2 novel proprietary technologies to specifically target cancer cells (https://www.pharmaceutical-technology.com/features/debiopharm-ubix-anti-cancer-modality/)
    - The two companies are aiming to develop a new drug modality known as Antibody Degraducer® Conjugates (ADC), by combining one of Ubix's Degraducer® molecule, with Debiopharm's antibody drug conjugate linker Multilink™
    - Degraducer® is a powerful, bifunctional, inhibitor technology that enables selective protein degradation and prolonged therapeutic effects.
        - ADCs combine monoclonal antibodies with the cancer-killing drugs, designed to attack cancer cells while avoiding healthy cells
    - Degraducer® linked to therapeutic antibodies via MultilinkTM will improve drug targeting and could have a synergistic effect on tumor cells, thereby resulting in improved efficacy and safety of cancer therapies
        - Linkers are crucial to the function of ADCs, helping to attach the cytotoxic payload to the antibody, stabilise the molecule during circulation and release the toxic payload specifically into the target tissue.
- In February 2021, Debiopharm and Genome & Company entered a research collaboration for the discovery of innovative cancer therapies in the expanding antibody-drug conjugates (ADC) class
- The collaboration between the two companies is built on the rapidly expanding Genome & Company's novel target-based oncology drug pipeline and Debiopharm's proven track record in oncology
- Genome & Company, having generated several antibodies against novel oncology targets discovered based on its own drug development platform , GNOCLE , which will now be armed with Debiopharm's Multilink technology to deliver cytotoxic payloads to tumor cells

Abylink

- AbYlink™ is an antibody conjugation technology ideally suited for therapeutic and diagnostic applications
    - Thanks to AbYlink™, cytotoxic or imaging cargos can be selectively attached to the Fc portion of any IgG without prior modification of the antibody
    - This technology preserves the original affinity of the antibody to its target
- Aby link is compatible with any human IgG as well as with bispecifc antibodies and protein-Fc fusions

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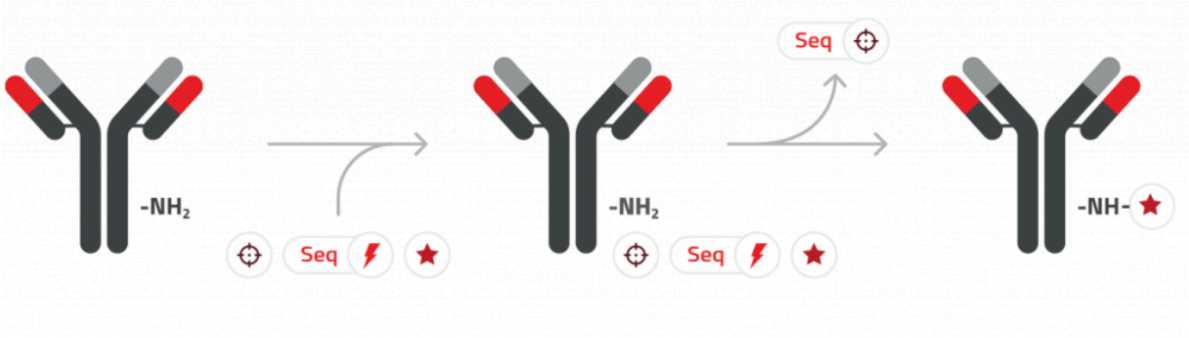

- Their Goal = to provide a solution to biotech or pharma partners to generate rapidly a proprietary antibody drug conjugates or imaging antibody.
- Key features:
    - Defined, reproducible and invariable conjugation with no impact on antigen-binding regions
    - Homogenous antibody conjugation
    - Conjugation process completed in less than 1 hour
    - Non enzymatic conjugation process
    - No prior antibody purification or modification necessary
    - Compatible with most linker technologies for Antibody Drug conjugations
    - Compatible with most imaging agents for use as PET, SPECT and fluorescent tracers
    - Compatible with all IgG formats
    - GMP-compatible technology

Digital Health Investments - Debiopharm Innovation Fund

- Founded in 2008
    - CEO: Tanja Dowe
    - President: Thierry Mauvernay
    - Director: Dr Tom Gibbs
- Debiopharm Innovation Fund twitter: https://twitter.com/debiopharmfund?lang=en
- Debiopharm Innovation Fund SA invests in Digital Health, Smart Data & innovative tech start-ups with a focus on oncology and infectious disease applications
    - Smart Data - companies that leverage medical data and AI to have an impact on either the patient journey or the development of pharmaceutical products
    - Digital Health - tools and technologies that add medical value to patient care
- Their mission is to support start ups that aim to improve the cancer patient journey and reimagine how clinical trials are conducted, as well as digital health companies that focus on bacterial infections by providing expertise in drug development, regulatory processes, reimbursement and market access, as well as management of health-tech companies
- They aim to increase the pace of these companies scale-up process, provide long-term funding, work alongside these companies' teams to achieve a positive return on

investment for all stakeholders, and to drive their portfolio investments towards successful exits
- Typically the fund invests in therapeutic startups at the preclinical stage, in diagnostics at the development stage, and in smart data at the early commercialization stage.
- Debiopharm has invested 120 million USD since 2008 and led 19 out of 25 last investment rounds
- Their portfolio companies have achieved 10 FDS clearance, 13 CE marks, 2 IPOS, and 4 trade exits
- Cumulative equity raised across companied amounts to over 500 million USD
- Criteria they look for in a company:
    - Investment round: A or B
        - Debiopharm Innovation Fund prefers to fund companies during the Series A and B financing round
        - Initial investment can be in the range of $3M – 5M
    - Pre-commercial to commercial stage
        - Large pilots and early clients to validate commercial interest
    - Strong management
        - Management team with entrepreneurial and industry experience
    - Innovative technology
        - Product answering a need with a clear USP
        - Market with tangible entry barriers.
    - Execution plan
        - Well defined operational plan and commercial strategy with a realistic budget
- What Debiopharm offer as investors:
    - Active participation in the board of directors
    - Pharma & healthcare development, regulatory and market expertise
    - Experience in growing small companies
    - Focus on long term value creation
- Past Investments:
    - ***Kaiku health*** - A digital health start-up that provides a personalized digital health intervention for every cancer patient
        - Treatment modality specific algorithms screen symptoms, alert care team and provide personalized support for patients in order to optimize the personal care journeys.
        - https://kaikuhealth.com/
        - Acquired by Elekta in May 2020
    - ***Biocartis*** - an innovative molecular diagnostics company committed to revolutionize molecular testing with its unique proprietary Idylla™ platform
        - Biocartis' proprietary molecular diagnostics (MDx) Idylla™ platform is a fully automated sample-to-result, real-time PCR system that offers accurate, highly reliable molecular information from virtually any biological sample, in virtually any setting, allowing fast and effective treatment selection and treatment progress monitoring

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    - They offer tests supporting melanoma, colorectal and lung cancer, as well as tests for SARS-CoV-2 and sepsis.
    - IPO in April 2015
    - https://www.biocartis.com/en
- ***OSE Immune Therapeutics*** - An integrated biotechnology company focused on developing and partnering therapies to control the immune system for immune-oncology and autoimmune diseases
    - They immunology research and development platform focuses on 3 areas: T-cell based vaccination, Immune-oncology, auto-immunity and inflammation
    - They utilize several scientific and technological approaches including neoepitopes and agonist/antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases
    - https://ose-immuno.com/en/about/
- ***ABAC Therapeutics - c***ommitted to finding therapeutic solutions for patients that are infected with highly antibiotic-resistant bacterial pathogens and that leave affected patients with few (or no) treatment options
    - Their goal is to create precision treatments of serious bacterial infections with pathogen-specific, novel-mechanism antibacterials that selectively eliminate the targeted pathogen while sparing the normal flora and minimizing the selective pressure on non-targeted strain
    - http://www.abactherapeutics.com/
- ***Spinmix*** - A Swiss technology platform company providing innovative sample processing solutions to the life sciences sector
    - In 2015, Debiopharm Group acquired Spinomix' FibroTrap sample processing technology
        - FibroTrap is a fibrinogen-based technology allowing the highly specific separation and efficient concentration of target molecules from liquid samples within a simple, routine sample-collection tube
        - This technology greatly simplifies the sample processing workflow, improves sensitivity and significantly shortens the time taken from sample collection to delivery of results
        - FibroTrap is applicable to a wide variety of matrices (blood, urine, swabs, food, etc.) to isolate a large spectrum of targets (bacteria, viruses, tumor cells, etc.) and hence could provide a breakthrough in sample processing applied to clinical diagnostics and the food industry
- ***Diagnoplex*** - A molecular diagnostic company that developed COLOX, a non-invasive peripheral blood-based test for the early detection of Colorectal Cancer
    - The company has performed a 140 patient prospective pilot study demonstrating technical and clinical feasibility of its colorectal cancer screening test COLOX as wellas its high sensitivity and specificity
    - They entered the Switzerland market in collaboration with Novigenix in 2014
- ***Neovacs -*** A French Biotechnology company that develops products and invests in innovative companies

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- 2 main activities: R&D and Investment
- At research and development, their activities revolve around the Kinoid technological platform in two main therapeutic indications, lupus disease and allergies
- They also invest in promising projects, both in the development of drug candidates and medical devices
- Current vaccine development efforts are in Crohn's disease, rheumatoid arthritis and lupus - Phase IIb/II
- https://www.neovacs.com/fr/

Companies they are currently invested in

- Voluntis is a leader in the field of digital therapeutics
- https://www.voluntis.com/
- They create digital therapeutics that empower cancer patients and people with chronic conditions to self-manage their treatment
- Their solutions combines mobile and web apps, use clinical algorithms to deliver personalized recommendations to patients and their care teams
    - On their Theraxium technology platform, they operate multiple digital therapeutics, especially in oncology and diabetes
- Reason for investing in Voluntis:
    - Belief that all oncology drugs will have a digital companion in the future
    - Due to side effects, it will be important for cancer patients to be empowered to manage their treatment, receive personalized support and guidance through digital therapeutic apps
- On June 7 2021, Voluntis received the FDA 510(k) clearance for a new version of Insulia supporting an additional basal insulin product, expanding the scope of insulins covered by the solution
    - Voluntis has integrated this new product version within the scope of its CE mark for Insulia
    - This enables the use of this solution in countries of the EU and European Free Trade Association
    - This is Voluntis' 14th regulatory clearance for a digital therapeutic
- On May 12 2021, Voluntis received the CE mark for a new version of Oleena (digital therapeutic for people with cancer) featuring expanded clinical intelligence
    - The new version of Oleena embeds new clinical algorithms that provide decision support recommendations to patients
    - It is designed to facilitate self-management of an increased number of symptoms that people with cancer may experience along their treatment journey

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    - This new CE-marked version of Oleena, a Class IIa medical device in Europe, is also authorized for marketing in the United States
- On April 27 2021, Voluntis announced a collaboration agreement with Eisai (headquarter: Tokyo) to design and develop innovative digital therapeutics (DTx) to support patients treated for cancer as well as a strategic investment from Eisai in Voluntis
    - By leveraging Voluntis' Theraxium technology platform, the two companies will collaborate on novel DTx specifically designed for patients and healthcare professionals to support cancer treatment
        - Ultimately, the companies would collaborate on the commercialization of the DTx, once authorized for marketing by regulatory authorities
        - The new assets will be designed with the intent to be commercialized in the US, Japan and European markets.
    - In addition to their partnership in oncology, the partners will explore other opportunities of collaboration to develop, evaluate and commercialize digital therapeutics based on the Theraxium platform in the field of neurology, another area of strategic focus for Eisai notably for Alzheimer's disease and dementia
- On February 15, 2021 Voluntis announced the issuance of a new patent by the European Patent Office for intelligent patient support in drug dosing applied in the field of diabetes for insulin titration support
    - This new patent covers the management of the sensitivity of the titration algorithms to changes in the patient's blood glucose levels to optimize the achievement and maintenance of the dose enabling glycemic control.

Oncomfort
Digital Sedation

- Oncomfort is a start-up in digital therapy for pain and anxiety management
- They are the inventor and leader in Digital Sedation - a completely new method for relieving patients' pain and anxiety before, during and after medical intervention
- They combine clinical hypnosis and evidence-based integrative therapy techniques through virtual reality
- Headquarter: Brussels, Belgium
- https://www.oncomfort.com/en
- Reason for investing in Oncomfort:
    - Clinical methods for diagnosing and treating cancer cause pain and anxiety to the patients and while Debiopharm develops drugs for cancer, they also want to see that patients are treated on a holistic level

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    - They are confident of the power of Digital Sedation with the strong clinical data supporting Oncomfort's approach
    - The management team at Debiopharm tested the Sedakit(TM) and believe that Oncomfort can actually help patients control pain and anxiety without medication
- On September 9 2020, Debiopharm co-lead a 10 million euro Series A funding round in Oncomfort to scale up its Virtual Reality Digital Solution with Credit Mutuel Innovation
    - Debiopharm will join Oncomfort's board of director

nucleai

- NucleAI is a leading provider of AI-powered precision oncology technology
- They use AI to develop precision oncology biomarkers to drive research and treatment decisions
    - NucleAI's core technology analyzes large and unique datasets of tissue images using computer vision and machine learning methods to model the spatial characteristics of tissues, such as both the tumor and the patient's immune system cells, creating unique signatures that are predictive of patients response
    - These biomarkers allow further stratification of responder/non-responder patient populations, improve the success rate of clinical trials, and shorten time-to-market for pharmaceutical treatments
- The company is at the early commercial stage
- Headquarter: Tel Aviv, Israel
- https://www.nucleaimd.com/
- Reason for investing in nucleAI:
    - Pathology slides, and paticularly tumor biopsies, contain a wealth of pertinent information that may be captured/measured easily with image analysis to generate new biomarkers
    - They believe NucleAI has the ultimate technical skills and will be a strong force in developing treatments that work better
- On March 16 2021, NucleAI entered a strategic data partnership with ARC Innovation Center at Sheba Medical Center to accelerate the use of AI pathology in drug development and clinical testing
    - This new partnership will sallow NucleAI to gain access to millions of patient records at Israel's largest hospital, which will include pathology images, clinical data, genomics and radiomics, along with other data modalities
    - The two have an existing collaboration to work on identifying the histological biomarkers that can predict the body's response to immunotherapy for non-small-cell lung cancer patients

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    - One success to come out of this partnership was a successful study that demonstrated the prediction efficiency of tumor microenvironment AI-based analysis for breast cancer
- On January 14 2021, NucleAI and Debiopharm entered into a long-term collaboration to leverage NucleAI's AI-powered biomarker research and discovery platform for one of Debiopharm's clinical stage oncology assets
    - Debiopharm has multiple therapeutic development programs in oncology that they believe may benefit from this digital pathology biomarker and imaging platform, enabling better patient selection and improved clinical performance
    - The agreement includes an initial installment to Nucleai followed by success-based milestone payments should Debiopharm integrate Nucleai's biomarkers in its clinical studies and further develop them as companion diagnostics
- In July 2002, Debiopharm led a $6.5 million series-A investment in Nucleai

- Carevive Systems is an oncology-focused health technology company dedicated to understanding and improving the cancer patient experience
- Founded in 2013
- Their platform enables providers to deliver better quality cancer care, and patients to be more engaged in their treatment, which will improve survival outcomes
- Use of Carevive unlocks critical data on the real-world cancer patient experience to continuously improve patient care
- https://www.carevive.com/
- Reason for investing in Carevive:
    - Based on belief that bringing the patient experience into the clinical pathway is critical for patient-centric medicine
    - The data collected using Carevive's system forms registries of real world evidence, that could be used to improve drug development and Debiopharm wants to be in the forefront of this
- On February 19, 2021, Carevive announced that it has completed its Series C fund-raising led by Philips Health Technology Ventures with Qure Ventures, Debiopharm Innovation Fund, OurCrowd's digital health fund, HLM Venture Partners, LRVHealth, Cerner, and founder Madelyn Trupkin Herzfeld
- In November 2020, Carevive won the first Pfizer Patient Reported Outcomes Challenge - designed to identify innovative PRO-based platforms and technologies that can provide novel patient-centric support & insight mechanisms for cancer patients
    - The award was presented Carevive based on demonstrated experience with oncology PROs, proven partnership capabilities, and success in supporting value-based contracting models

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- Initially, the collaboration with Pfizer will focus on developing PRO-based longitudinal datasets to uncover insights along the cancer patient journey to support value-based agreements
- To generate these data and insights, Carevive will work within its growing network of 26 health system customers, including sites that are participating in the Carevive Oncology Pragmatic Trial Investigator Network (Carevive OPT-IN®)

- Nova Discovery is a pioneer in silicon medicine
- They simulate clinical trails with virtual patients to de-risk research programs and optimize clinical development
- Jinkō is Nova's in silico clinical trials platform that uses AI and virtual populations at the heart of it
    - Nova builds mathematical models of disease and treatment to optimise trial design, to capture best responders, and to demonstrate value to payers
- Headquarter: Lyon, France
- https://www.novadiscovery.com/
- Reason for investing in Nova Discovery:
    - Nova introduces a new category, in silico clinical trials, that reduces the need for trial and error, helping pharma to focus on those treatments that more likely work for given patient groups
        - This can help to reduce research & development (R&D) costs and time-to-market of novel drugs
    - As model informed drug development has become a strategic priority also for reglators worldwide, Debiopharm wanted to partner with the best and build the future together
- On March 26 2021, NOA announced that they have entered into a new collaboration with Takeda Pharmaceutical Company Limited aimed at incorporating clinical simulation technology on virtual patients into Takeda France's access strategy
    - This agreement builds on an existing relationship they began in 2017
    - Takeda, through its association with NOVA, is leading the way in incorporating disease modelling and trial simulation in virtual populations in its pipeline development programs.
- On February 16 2021, NOVA announced they raised 2.5 million euros in a Series A2 financing round from Sanofi

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- On January 19 2021, Nova was awarded 2.4 million euros to leverage Jinko to conduct in silicon studies for graft0vs-host disease
    - The results will be used to support future regulatory approval applications by ElsaLys for inolimomab in Europe
- In January 2020, Debiopharm led a 5 million euro Series A round

- BC platforms is a world leader in genomic data management solutions
- They provide a powerful genomic and clinical data management and analysis platform for personalized medicine, accelerating the translation of insights into clinical practice
    - Their genomic data discovery platform enables flexible data integration, secure analysis and interpretation of molecular and clinical information
- BC Platforms aims to build the world's leading analytics platform for healthcare and industry and to revolutionize decision making in drug development bringing clinical benefits to patients
- Headquarter: Zurich, Switzerland
- https://www.bcplatforms.com/
- Reason for investing in BC Platforms:
    - BC Platforms has the technology and the means to federate clinical and genomic data
    - With BC Platforms, precision medicine becomes a reality for healthcare providers, and big data enabled drug development becomes a real tool for pharma industry
    - Both benefit Debiopharm's ultimate goal: better care for patients
- On February 23 2021, BC Platforms and Genomenon announced that they will partner to bring together Genomenon's Mastermind tools and BC Platforms' clinical genomics pipeline and research platform
    - With the vision to advance clinical genomics, Genomenon's Mastermind Genomic Search Engine will be integrated into BC Platforms' genomic analysis and interpretation platform BC|GENOME
    - On the research side, Mastermind will also be integrated into BC Platforms' research platform BC|INSIGHT to facilitate complex genomic research by simplifying genomic data annotations and thus enabling AI/ML applications
- On January 26 2021, the Finnish Institute for Health and Welfare (THL) and RIKEM joined forces in an international research effort to support development of a precision prediction model to identify those most at risk from COVID-19.
    - BC Platforms is providing its BC|INSIGHT platform to enable the curation, integration and analysis of THL's clinical data of 300 to 1,000 Finnish COVIDprog research subjects using RIKEN's algorithms

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    - This is to identify a 'COVID-19 prediction procedure' that can estimate symptoms and outcomes of COVID-19 based on health records of infected patients obtained before SARS-CoV-2 infection.
- In May 2017, BC platforms closed a USD$ 10 million series B financing round led by Debiopharm Innovation Fund

- Immunexpress is a molecular diagnostic company committed to improving outcomes for suspected sepsis patients and healthcare providers
- They are a pioneer in the analysis of the immune system to rapidly detect sepsis
- Their technology uses a gene expression in the blood with a specific algorithm to detect a patient's immune response to a pathogen, rather than the traditional approach of trying to identify a causative pathogen
- Their mission is to develop diagnostic technologies to help clinicians and patients to fight this life-threatening disease
- Headquarter: Seattle, Washington
- https://immunexpress.com/
- Reason for investing in Immunexpress:
    - Debiopharm recognizes that sepsis is one of the biggest killers globally and the rapid diagnosis in sepsis is key to effective management of patients
    - They recognize the power in Imunexpress' approach of measuring the host-response on a quick sample-to-result platform
- In October 2020, Immunexpress' rapid test for sepsis, SeptiCyte® RAPID, launched in Europe on Biocartis' Idylla platform
    - This is a 1 hour molecular diagnostic test that runs on the Biocartis Idylla platform that can swiftly differentiate infection positive (sepsis) from infection negative systemic inflammation in patients
    - This is the first rapid, fully-integrated, immune response-based test to aid clinicians with sepsis diagnosis
    - This launch follows the CE marking announced in March 2020
    - The immediate EU commercialization in partnership with Biocartis NV was intended to support the use of the technology to improve the efficiency with COVID-19 patient triage

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- The test can be used to quickly identify patients with worsening prognoses and ensuring rapid initiation of sepsis management protocols that can increase the potential to save lives

- Agendia is the only molecular diagnostics company focused solely on breast cancer
- They believe in the power of genomic testing to better inform the patient journey as it sheds light on complex treatment decisions, leading to the most relevant and targeted approach for each individual patient
- They create genomic testing that provides patients with actionable insights throughout their breast cancer journey
- They have been on the market since 2004 in Europe and 2008 in the U.S.
- https://agendia.com/
- ***Agendia MammaPrint*** - a test that shows the likelihood of a patient's breast cancer recurring
    - The MammaPrint® test analyzes the 70 most important genes associated with breast cancer recurrence
    - Results are typically available in 6 days or less
    - MammaPrint enables quicker, more informed decisions on pre- and post-operative treatment and can easily be integrated into diagnostic workups
- ***Agendia BluePrint*** **-** a test that determines the underlying genomics driving the growth of a tumour
    - The test looks at 80 genes and the tumour is accurately classified as one of three subtypes, which reveal valuable information about its behavior, long-term prognosis and response to systemic therapy
    - Results are typically available in <6 days

- Eclosion Ventures manages the Exclusion life science investment fund, that helps translate breakthrough science into drugs by providing an incubator and resources for young biotechs

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    - They support portfolio companies from seed to capital stage up to clinical proof of concept
- They focus on highly innovative science and early stage companies developing new approaches to address high unmet medical needs
- Their portfolio companies have developed first-in-class drugs with high potential value in patients in fields such as multiple sclerosis, fibrosis and oncology
- They have 4 portfolio companies, 3 in clinical stage, 1 IPO and 1 merger wit ha public company
- Debiopharm supports programs that support entrepreneurship such as Exclusion