MEDIA FACT SHEET

We develop tomorrow's standard of care
To cure cancer and infectious diseases
And to improve patient quality of life

1. Debiopharm in short

Debiopharm is an innovation-focused, Swiss biopharmaceutical company that aims to develop innovative therapies to target high unmet medical needs in oncology and infectious diseases. We establish partnerships with academic, biotech, and pharmaceutical institutions to bridge the gap between disruptive discovery products and international patient reach. We seek out and identify high-potential compounds for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally. Our ultimate purpose is to develop tomorrow's standard of care to cure cancer and infectious diseases and to improve patient quality of life.

2. Company history

Debiopharm was created over 40 years ago by Dr. Rolland-Yves Mauvernay, who was convinced that many useful therapeutic products were abandoned before reaching their full potential. He therefore launched a unique business model in which Debiopharm in-licenses innovative compounds, adds value and finances their development into medicines and then seeks a commercialization partner for out-licensing. Today, Debiopharm consists of a group of three companies, led by his son Thierry Mauvernay: Debiopharm International (DPI), Debiopharm Research & Manufacturing (DPRM), and Debiopharm Innovation Fund (DPIF). The group counts over 400 employees with a broad range of expertise, who are active in drug development, drug manufacturing, investment in digital health and smart data start-ups.

3. Debiopharm - Success stories

These two oncology products sold worldwide showcase Debiopharm's success in developing efficient treatments for patients.

The GnRH agonist analogue triptorelin, with international brand names including Decapeptyl®/Trelstar®/Pamorelin®/Triptodur®, is a standard-of-care treatment for advanced prostate cancer and an emerging therapy for endometriosis, in-vitro fertilization programs, uterine fibroids, precocious puberty. This product was the first worldwide registered sustained release formulation of a gonadotropin releasing hormone (GnRH) agonist in 1986 and is marketed throughout the world through our international alliance partnerships. More information

The Platinum-based chemotherapy oxaliplatin, marketed under the brand names Eloxatin®/Elplat®/Dacotin®/Dacplat®, is a diaminocyclohexane (DACH) platin, for the treatment of colorectal cancer. Combination of oxaliplatin with 5-FU and leucovorin (FOLFOX) allowed to more than double the survival of patients with metastatic disease. Since its approval in the 2000's, it has become a worldwide standard treatment in metastatic colorectal cancer and in adjuvant settings has significantly increased the number of patients cured. More information

4. Debiopharm – Oncology, Antibiotic & Rare Diseases Pipeline

With patients in mind and to continue providing treatments, Debiopharm has a growing number of products in our development pipeline, focusing on its specialty areas including oncology, infectious diseases, rare diseases and antibody-drug conjugate (ADC) drug technology. Here is a selection of

compounds in development for the following indications: DNA damage response (DDR), radiotherapy, ADC linkers, and antibiotics. Full pipeline

Oncology

Debio 0123:
Debio 0123 is an oral and highly selective WEE1 inhibitor, currently being investigated as a monotherapy and as a combination agent for the treatment of solid tumors. Debio 0123 targets the DNA damage response (DDR) of cancer cells through the WEE1 checkpoint, preventing cells from repairing DNA damage, ultimately leading to cell death. In a preclinical setting, Debio 0123 has shown good anti-tumor efficacy across many tumor types, providing opportunity for a variety of treatment options. Initial Phase I clinical data suggest a better safety profile than competitors, coupled with early anti-tumor signals and consistent observation of target engagement. Debio 0123 has the potential to be a best-in-class WEE1 inhibitor, which can be combined with a wide array of cancer therapies in multiple indications to address unmet medical need. More Information

Debio 0228/0328:
Debio 0228/0328 (also known as ITM-91/ITM-94D) is the first peptide-based theranostic pair targeting CAIX to approach clinical development. With the potential to treat multiple tumor types, it is initially being developed for patients with unresectable locally advanced or metastatic renal, pancreatic, or colorectal cancer. This investigational pair, now exclusively licensed to ITM, leverages a theranostic approach to both identify and deliver radiation to diseased tissues, allowing for imaging-based pre-identification of patients who have the necessary receptors to respond to the targeted radioligand. Debio 0328 (ITM-94D) ([68Ga]Ga-DPI-4452), a PET imaging agent, is designed to independently identify patients whose cancers overexpress CAIX. Once identified, these patients can then be treated with Debio 0228 (ITM-91) ([177Lu]Lu-DPI-4452), a lutetium-labelled radioligand that delivers targeted radiation directly to the tumor, aiming to destroy it from within. The GaLuCi™ study, a multi-center, non-randomized phase I/II clinical trial, was recently launched to investigate the potential of this theranostic pair in patients with locally advanced or metastatic renal, pancreatic, and colorectal cancer. More Information

Debio 0432:
Debio 0432 (formerly FT-3171) is a small molecule USP1 inhibitor that targets a novel DNA damage repair (DDR) pathway and is currently in late preclinical development. Through its potent and selective inhibition of USP1, a critical player in this pathway, Debio 0432 may be particularly effective in tumor types with underlying defects in DNA repair genes, such as BRCA1. This compound could potentially be deployed to combat multiple tumor types in both poly ADP ribose pathway inhibitor-sensitive and resistant settings. Debiopharm obtained global rights for this product in March 2023 from Novo Nordisk, which acquired Forma Therapeutics, in 2022. More Information

Debio 1562M:
Debio 1562M is a next generation antibody-drug conjugate (ADC) directed against CD37 developed to be first in class therapy in Acute Myeloid Leukemia (AML) and Myelodysplastic syndrome (MDS). Debio 1562M is constructed with naratuximab, an anti-CD37 monoclonal antibody, Debiopharm proprietary linker Multilink™ technology and a microtubule inhibitor as cytotoxic payload. The compound has shown good antitumor activity and tolerability in several in vivo AML models. In preclinical settings, Debio 1562M has proven affinity and specificity to the target, successful internalization, antiproliferative activity in vitro and significant improvement of survival in multiple in vivo models. More Information

Debio 0532:
Debio 0532 program leverages our Multilink™ linker technology and an in-licensed antibody from **SunRock** to create innovative antibody drug conjugates (ADCs). These novel ADCs will target tumor-specific antigens to fight cancers with high unmet need, including those tumor types expressing HER3. More Information

Debio 0633:
The Debio 0633 program leverages our Multilink™ linker technology and an in-licensed antibody from Genome & Company to create an innovative antibody-drug conjugate (ADC). This novel ADC is designed to target tumor-specific antigens to combat cancer in areas with high unmet medical needs. Debio 0633

aims to enhance the precision and efficacy of cancer treatment by delivering targeted therapy directly to malignant cells. More Information

Debio 4228:
We are currently developing sustained-release formulations designed to improve the performance and convenience of cancer treatments. Our efforts include a compound that is currently in Phase II, focusing on enhancing therapeutic outcomes while streamlining administration. By optimizing these formulations, we aim to improve patient adherence and overall quality of life during cancer therapy. More Information

Infectious Diseases

Debio 1450:
Afabicin (Debio 1450) is a first in class FabI inhibitor antibiotic with pathogen-specific activity against staphylococcus species. The novel FabI inhibitor's mode of action (MoA) allows pathogen-specific antibacterial activity and reducing off-target selection of the human microbiota. Use of pathogen-specific antimicrobials is expected to reduce the spread of antimicrobial resistance (AMR) and prevent antibiotic-induced infections. The compound currently is in Phase II clinical trial for the treatment of Bone and Joint infections (BJI) due to staphylococci and is also being researched in staphylococcal acute bacterial skin and skin structure infections (ABSSSI). More Information

Debio 1453:
Debio 1453 is a FabI inhibitor specifically targeting Neisseria gonorrhoeae, the causative bacteria of the sexually transmitted disease, gonorrhea. This compound belongs to a family of pathogen-specific antibiotics that exhibit potent activity against pathogens of interest while sparing other bacterial strains that constitute the microbiome. Developed with the support of the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), Debio 1453 demonstrates high efficacy against N. gonorrhoeae, alongside several potential benefits, including:

- A favorable resistance profile
- No cross-resistance to existing antibiotics
- Encouragement of stewardship
- Appropriate antibiotic prescribing due to its targeted spectrum
- Suitability for both intramuscular and oral administration.

More Information

Debio 1455:
The Debio 1455 program includes novel microbiome therapeutics for the treatment of gastrointestinal (GI) disorders. Currently in drug candidate identification stage, the program aims to identify effective treatment against inflammatory bowel disease (IBD) and other GI disorders. The program is focused on novel, narrow spectrum, microbiome remodeling agents targeting a combination of intestinal pathobiont bacterial species. Drug candidates will be evaluated for their effectiveness against specific disease-causing microorganisms while preserving the natural balance of the microbiota. More Information

Rare Diseases

Debio 4126:
Debio 4126 is a novel sustained-release formulation designed to improve the performance and convenience of octreotide therapy for the treatment of Acromegaly. The safety and efficacy of this octreotide 3-month formulation is currently under investigation. The application of Debiopharm's injectable sustained release expertise could help Acromegaly patients reduce their number of injections from 12 to 4 per year. Debiopharm is seeking partners with expertise in rare diseases/orphan drugs and/or in endocrinology or oncology for the further development of this compound in order to dramatically improve convenience for patients. More Information

Debio 4326:
Debio 4326 is a unique injectable, biodegradable 12-month extended-release formulation of triptorelin currently in development for the treatment of Central Precocious Puberty (CPP). This product has been designed to further reduce the frequency of injections, thereby lightening the treatment administration burden for children affected by this rare disorder. Based on favorable efficacy and safety data from currently marketed triptorelin 1-, 3-, and 6-month formulations, this new formulation aims to provide improved long-term compliance and reduced stress for children and their parents. Debio 4326 is currently in Phase III, investigated by the LIBELULA study, an open-label, single-arm trial assessing the efficacy of this formulation . Debiopharm is seeking partners with expertise in rare diseases, orphan drugs, endocrinology, or oncology for the further development of this compound to dramatically improve convenience for patients. More Information

Technologies

Multilink™ linker technology allows the loading of multiple payloads on an antibody for an enhanced therapeutic effect. This highly effective and well-tolerated linker technology is available for use by other specialty biotech or pharmaceutical companies to generate proprietary, clinical-stage ADCs . Multilink™ linker technology allows for the creation of high DAR and high stability ADCs. More Information

AbYlink™ conjugation technology is a proprietary and innovative technology enabling the rapid, selective and covalent labelling of any off-the-shelf antibody in a single step for diagnostic purposes and antibody drug conjugate (ADC) preparation. Thanks to the AbYlink™ conjugation technology, cytotoxic or imaging cargos can be selectively attached to a defined and invariable conjugation site without the need for prior modification or purification of the antibody. More Information

FibroTrap™ fibrinogen-based technology is able to concentrate microorganisms (bacteria and yeasts) from whole blood in about 60 minutes. Combined with a molecular method, FibroTrap™ fibrinogen-based technology accelerates the identification of pathogen and resistance genes in 3 hours, compared to 24-48 h or more with conventional methods. Aside being exceptionally fast, this unique clotting-based technology is also characterized by a high reliability and simplicity of utilization. Using the FibroTrap™ fibrinogen-based technology will increase the chances of saving lives and providing the right treatment, for the right patient, in a timely manner. More Information

5. Debiopharm Business Model

Debiopharm is a privately owned, unlisted biopharmaceutical company with the capability to finance the development of the candidates we in-license.

Debiopharm bridges the gap between disruptive discovery products and international patient reach.

How? By identifying high-potential discovery or early-stage compounds in for in-licensing at universities and biotechs worldwide. Once identified, Debiopharm forms a partnership to secure the in-licensing and then adds value to the in-licensed compound by conducting smart clinical development, advancing it from the candidate stage to clinical phase II.

Decisions to in-license and develop specific drug candidates are based on science. Our qualified team of scientists rigorously evaluate the potential of each candidate and the benefit to patients before they are taken in for development. Ultimately Debiopharm selects large pharmaceutical commercialization partners to maximize access of the commercialized drugs to as many patients as possible across the globe. Partners include universities, biotech, and big pharma.

Additional information about Debiopharm
Website / LinkedIn / Facebook / X / YouTube
Contact us