Debiopharm

Small/medium-sized enterprise
Stock exchange: Privately held • Ticker: N/A • HQ: Lausanne, Switzerland • Employees: 420

PERFORMANCE

Debiopharm performs on average in Research & Development when compared to other small and medium-sized enterprises in scope.

R&D: Debiopharm has four antibacterial projects for priority pathogens in its pipeline, including one novel clinical-stage candidate, afabicin, for acute bacterial skin and skin structure infections (ABSSSI).

<table>
<thead>
<tr>
<th>How Debiopharm was evaluated</th>
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<td>A</td>
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Each indicator is worth a max score of 5. Indicators are not applicable to every company. See Appendix for full overview.

SALES AND OPERATIONS

Therapeutic areas: Oncology; infectious diseases

Products on the market: Two non-antimicrobial medicines: oxaliplatin (Eloxatin®/Elplat®/Dacola®) used to treat colorectal cancer, and triptorelin (Decapeptyl®/Trelstar®/Pamorelin®/Triptodur®) a hormonal therapy drug used to treat prostate cancer.

R&D grants received since 2016: At least USD 4.7 million, awarded by one funder (CARB-X). Its latest award, worth USD 2.1 million, was granted by CARB-X in May 2019 to advance the development of its antibiotic programme Debio 1454, targeting multi-drug-resistant (MDR) A. baumannii. Debio 1454 compound inhibits bacterial fatty acid biosynthesis, an essential pathway in many bacterial species including Gram-negative, drug-resistant strains.

Financing and investment structure: Family-owned company

M&A since 2018: None in the antibacterial and/or antifungal sectors

PIPELINE for diseases in scope

Pipeline size: 4 projects for priority pathogens* (4 antibacterial medicines)

Development stages: 2 clinical projects, including afabicin, a Phase II clinical candidate for the treatment of ABSSSI, with an additional indication for bone and joint infections also in development, and 2 pre-clinical projects

Novelty: 1 novel project, afabicin, a Phase II clinical candidate for the treatment of acute bacterial skin and skin structure infections that belongs to a new chemical class of antibacterials and has a new drug target, mode of action and no known cross-resistance to other antibacterial classes

Regulatory approvals: 0 approvals for priority pathogens

Access plans: Neither of its 2 late-stage R&D projects have project-specific access plans.

Stewardship plans: Neither of its 2 late-stage R&D medicine projects have project-specific stewardship plans.

* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.
OPPORTUNITIES FOR DEBIOPHARM

Develop access and stewardship plans for afabicin. Debiopharm is developing one antibacterial candidate (afabicin) in late-stage clinical development. Debiopharm can develop plans to ensure that afabicin will be available and affordable in low- and middle-income countries and appropriately used globally after market approval. As examples of access plans, the company can commit to an equitable pricing strategy and/or look for out-licensing opportunities with multiple manufacturers in low- and middle-income countries. As examples of stewardship plans, the company can commit to decouple sales incentives from sales volumes and/or become involved in antibacterial surveillance activities.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

Evaluated: medicine & vaccine pipelines for priority* bacteria & fungi

A.1 R&D investments

As with all other small and medium-sized enterprises (SMEs) evaluated, Debiopharm was not scored in this indicator.

A.2.1 Pipeline size of four projects

Debiopharm reports four projects targeting priority pathogens in its pipeline. The company focuses on antibacterial medicine development, and has two projects in clinical development (Phase II) and two in pre-clinical development.

A.2.2 One clinical-stage novel project

Debiopharm’s clinical-stage medicine pipeline for priority pathogens consists of both new and adapted R&D projects. Debiopharm has one clinical-stage antibacterial medicine project that is considered novel: afabicin, for ABSSSI. It meets all criteria set by WHO for innovativeness, including belonging to a new chemical class and having a new target, mode of action and no cross-resistance to other antibacterial classes.

A.2.3 Vaccines in the pipeline

Debiopharm is not eligible for this indicator as it is not active in vaccine development.

A.2.4 One candidate targeting critical and/or urgent priorities

Debiopharm has one pre-clinical candidate that targets N. gonorrhoeae, which is considered an urgent R&D priority for limiting AMR, as identified by the US Centers for Disease Control and Prevention (CDC). Further details were provided on the basis of confidentiality.

A.3 Intellectual capital sharing

As an SME, Debiopharm was not scored for this indicator, in line with the external stakeholder consensus defined by the Foundation.

A.4 No access or stewardship plans for late-stage R&D projects targeting priority pathogens

Debiopharm has two such R&D projects. It currently reports no plans that address either the stewardship of or appropriate access to the products, upon reaching the market.

Pipeline targeting priority pathogens: 4

As at 16 October 2019

<table>
<thead>
<tr>
<th>Pipeline stage</th>
<th>Project targets</th>
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<tbody>
<tr>
<td>Discovery</td>
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<tr>
<td>Pre-clinical</td>
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<tr>
<td>Phase I</td>
<td>Afabin (Debio-1450) - Staphylococcus spp. (including MRSA) - ABSSSI - Novel</td>
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<tr>
<td>Phase II</td>
<td>Afabin (Debio-1450) - N. gonorrhoeae</td>
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<tr>
<td>Phase III</td>
<td>Afabin (Debio-1450) - A. baumannii and Enterobacteriaceae</td>
</tr>
<tr>
<td>Approval</td>
<td>Afabin (Debio-1450) - Staphylococcus spp. (including MRSA) - Adaptation (additional indication) - Bone and joint infections</td>
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ABSSSI = Acute bacterial skin and skin structure infection
MRSA = Methicillin-resistant S. aureus

B RESPONSIBLE MANUFACTURING

As an SME, Debiopharm is not evaluated in this Research Area. It has no antibacterial products on the market.

C APPROPRIATE ACCESS & STEWARDSHIP

As an SME, Debiopharm is not evaluated in this Research Area. It has no antibacterial and/or antifungal products on the market.

DIAGNOSTICS, ANIMAL HEALTH & AGRICULTURE

Activities in this area are not scored by the Benchmark. This information is provided given the importance of diagnostics, animal health and agriculture on the topic of AMR.

Debiopharm is developing an antimicrobial susceptibility testing (AST) device for its antibacterial afabicin, which is in Phase II of clinical development. It is also developing a sample preparation technology for direct blood testing, which could shorten the time to identify pathogens and enable appropriate use of antibacterials.