Polyphor Ltd

Small/medium-sized enterprise
Stock exchange: SWX • Ticker: POLN • HQ: Allschwil, Switzerland • Employees: 70

PERFORMANCE

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

R&D: Polyphor has three antibacterial projects in its pipeline that target priority pathogens. Reports no project-specific plans for access or stewardship.

SALES AND OPERATIONS

Therapeutic areas: Antibiotics; Immuno-oncology compounds
Products on the market: None
R&D grants received since 2016: Up to USD 13.4 million, awarded by three funders (CARB-X, Innovative Medicines Initiative; Wellcome Trust). Its latest award, from CARB-X, worth USD 5.6 million, came in February 2019 to support the pre-clinical and early clinical development of Polyphor’s OMPTA candidate, through the completion of the Phase I clinical trial.
Financing and investment structure: Polyphor is a publicly listed company. It completed its IPO in May 2018, raising CHF 155 million following three venture rounds raising CHF 59 million. Post IPO equity by Novo Holdings’ Repair Impact Fund amounts to CHF 6.8 million.
M&A since 2018: None in the antibacterial and/or antifungal sectors

PIPELINE for diseases in scope

Pipeline size: 3 projects for priority pathogens* (3 antibacterial medicines)
Development stages: 3 pre-clinical projects, incl. murepavadin, formerly in Phase III clinical stage for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia caused by P. aeruginosa infections
Novelty: 1 novel project, murepavadin, in development for the treatment of P. aeruginosa 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: At analysis, its 1 late-stage R&D project lacked a project-specific access plan.
Stewardship plans: At analysis, its 1 late-stage R&D medicine project lacked a project-specific stewardship plan.

* Priority pathogens: 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 POLYPHOR

Develop access and stewardship plans for its R&D projects when they reach Phase II in clinical development. After the end of the period of analysis (in July 2019), Polyphor closed the Phase III clinical studies for its antibacterial candidate murepavadin (on account of higher than expected rates of acute kidney injury). During the period of analysis, while the project was still in Phase III, Polyphor did not report any access or stewardship plans. When its R&D antibacterial projects (murepavadin and others from its OMPTA platform) reach Phase II in clinical development, Polyphor can work with partners and funders (including the Wellcome Trust and CARB-X) to develop plans to ensure that these products will be available, affordable and appropriately used 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.

CHANGES SINCE 2018

- Halted Phase III trials for murepavadin for HABP and VABP in May 2019 due to high incidence of acute kidney injury in patients; re-started pre-clinical trials.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT Evaluated: medicine & vaccine pipelines for priority* bacteria & fungi

A.1 R&D investments

Polyphor reports it invested between USD 21 and 50 million in its entire pipeline, including the development of antibacterial medicines and one oncology project.

A.2.1 Pipeline size of three projects

Polyphor reports three projects targeting priority pathogens in its pipeline. The company is focused on antibacterial medicine development, and has two of its projects in pre-clinical development and a third one which, at analysis, is in Phase III of clinical development. After the end of the period of analysis (in July 2019), the clinical studies were closed and the project reverted back to pre-clinical development, on account of higher than expected rates of acute kidney injury.

A.2.2 One novel project

At analysis, Polyphor’s candidate murepavadin, in development for the treatment of bacterial infections caused by P. aeruginosa, including hospital-acquired and ventilator-associated bacterial pneumonia, was in Phase III clinical development. This candidate was considered novel, since it met 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

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

A.2.4 Two candidates targeting critical and/or urgent priorities

Polyphor’s pre-clinical pipeline includes a medicine (murepavadin) that targets CRPA and an adapted project to develop an aerosol formulation of this same product. Its project POL7306, also in pre-clinical development, targets Gram-negative ESKAPE critical priority pathogens.

Pipeline targeting priority pathogens: 3 As at 16 October 2019

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murepavadin - P. aeruginosa - HABP and VABP - Novel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Murepavadin - P. aeruginosa - Adaptation (additional indication and new aerosol formulation) - Respiratory infections in cystic fibrosis and bronchiectasis patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OMPTA new antibiotics platform (POL7306) - GNB (including colistin-resistant strains and CRE, ESBL-producing Enterobacteriaceae, A. baumannii and P. aeruginosa)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CRE = Carbapenem-resistant Enterobacteriaceae
CRPA = Carbapenem-resistant Pseudomonas aeruginosa
ESBL = Extended-spectrum beta-lactamase
GNB = Gram-negative bacteria
HABP = Hospital-acquired bacterial pneumonia
OMPTA = Outer Membrane Protein Targeting Antibiotics
VABP = Ventilator-associated bacterial pneumonia

* 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.
B RESPONSIBLE MANUFACTURING

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

C APPROPRIATE ACCESS & STEWARDSHIP

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