Amplex Pharmaceuticals Inc

Small/medium-sized enterprise
Stock exchange: Privately held • Ticker: N/A • HQ: California, USA • Employees: 27

PERFORMANCE

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

R&D: Amplex has one novel project in its clinical pipeline for treatment of invasive antifungal infections, fosmanogepix. Reports a project-specific access plan for an Expanded Access Program for this late-stage project.

SALES AND OPERATIONS

Therapeutic areas: Invasive fungal infections
Products on the market: None
R&D grants received since 2016: At least USD 4.4 million, awarded from one funder (NIH) to support its drug discovery and development efforts.
Financing and investment structure: Amplex is a privately held company. Following three funding series, it has raised a total of USD 118.5 million. Its lead investors were RiverVest and New Enterprise Associates.
M&A since 2018: None in the antibacterial and/or antifungal sectors

PIPELINE for diseases in scope

Pipeline size: 1 project for priority pathogens* (1 antifungal medicine)
Development stages: 1 clinical project, fosmanogepix (APX001), a Phase II clinical candidate for the treatment of invasive fungal infections including invasive candidiasis and invasive aspergillosis
Novelty: 1 novel project, fosmanogepix (APX001), a Phase II clinical candidate for the treatment of invasive fungal infections including invasive candidiasis and invasive aspergillosis, that belongs to a new chemical class of antifungals and has a new drug target, mode of action and no known cross-resistance to other antifungal classes
Regulatory approvals: 0 approvals for priority pathogens
Access plans: Its 1 late-stage R&D project has a project-specific access plan
Stewardship plans: Its 1 late-stage R&D medicine project lacks a project-specific stewardship plan.
OPPORTUNITIES FOR AMPLYX

Operationalise access and stewardship plans for fosmanogepix. Amplyx is developing one antifungal candidate (fosmanogepix) in late-stage clinical development. Amplyx can develop more detailed plans to ensure that fosmanogepix 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 developing companion diagnostics and susceptibility testing devices and/or become involved in antifungal 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, Amplyx was not scored in this indicator.

A.2.1 Pipeline size of one project

Amplyx reports one project targeting a priority pathogen. The company is focused on antifungal medicine development, and its project fosmanogepix (APX001) is currently in Phase II of clinical development.

A.2.2 One clinical-stage novel project

Amplyx’s clinical-stage medicine pipeline for priority pathogens consists of one new R&D project. Amplyx has one clinical-stage antifungal medicine project that is considered novel: fosmanogepix (APX001), for the treatment of invasive candidiasis, invasive aspergillosis and invasive rare mould infections, which belongs to a new chemical class and has a new target and mode of action and no known cross-resistance to existing classes of antifungals.

A.2.3 Vaccines in the pipeline

Amplyx 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

Amplyx’s clinical pipeline includes one new, novel candidate (APX001) in Phase II that targets multi-drug resistant C. auris, which is listed since November 2019 as an urgent pathogen by the US Centers for Disease Control and Prevention (CDC).

A.3 Intellectual capital sharing

Amplyx reports one intellectual capital sharing initiative: it has shared some of its projects for in-vitro testing with different researchers and institutions such as the CDC. As an SME, Amplyx was not scored for this indicator, in line with the external stakeholder consensus defined by the Foundation.

A.4 Specific access plan for one project

Amplyx has one late-stage R&D project targeting a priority pathogen: fosmanogepix (APX001) for Candida spp. and Aspergillus spp. Amplyx is developing its Expanded Access Program as a mechanism to provide access to investigational therapies for clinical trial participants. It intends to follow the 2016 Davos Declaration, and has made a general commitment to help ensure the appropriate access and stewardship of this project.

CHANGES SINCE 2018

This section lists notable changes in companies’ activities since the 2018 Benchmark. Since Amplyx was not in scope for evaluation in 2018, no changes are reported.