Summit Therapeutics

Small/medium-sized enterprise
Stock exchange: LSE; NASDAQ • Ticker: SUMM; SMMT • HQ: Oxfordshire, UK • Employees: 61

PERFORMANCE

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

R&D: Summit has three antibacterial projects in its pipeline that target priority pathogens, including one late-stage candidate that is considered novel: ridinilazole, for *C. difficile* infections. Reports an access plan with a licensing agreement to expand availability to access countries.

How Summit was evaluated

A R&D

B RM

C AA

C STW

How Summit was evaluated

Revenues

(2018)

43.0 m GBP

SALES AND OPERATIONS

Therapeutic areas: Antibiotics

Products on the market: None

R&D grants received since 2016: At least USD 68.2 million, awarded by two funders (CARB-X; BARDA). Its latest award, from BARDA, was increased in June 2019, bringing the total value to USD 63.7 million to support patient enrolment and dosing in the ongoing Phase III clinical trials of ridinilazole.

Financing and investment structure: Summit is a publicly listed company. It completed its IPO in October 2004 on the London Stock Exchange, raising GBP 15 million. In 2015, it was listed on the NASDAQ stock exchange, raising USD 34 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: 1 clinical project, ridinilazole, a Phase III clinical candidate for the treatment of *C. difficile* infections, and 2 discovery/pre-clinical projects

Novelty: 1 novel project, ridinilazole, a Phase III clinical candidate for the treatment of *C. difficile* 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: Its 1 late-stage R&D project has a project-specific access plan that is a licensing agreement to expand availability to access countries, though this plan does not address affordability.

Stewardship plans: Its 1 late-stage R&D medicine project lacks a project-specific stewardship plan.

* 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.
OCCUPANCIES FOR SUMMIT

Improve access plans and develop stewardship plans for ridinilazole. Summit has committed to ensure access and stewardship plans are in place for its antibacterial candidate in late-stage development, ridinilazole, through its agreement with the Wellcome Trust. So far, Summit has entered into a regional licensing agreement for ridinilazole with Eurofarma Laboratórios for 21 countries in Latin America, including 13 access countries. Summit can improve its access plans for access countries by committing to an equitable pricing strategy and/or looking for licensees across other regions of the world. Summit has not developed worldwide stewardship plans for ridinilazole yet. 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
Summit invested USD 56 million in the development of antibacterial medicines in 2017 and 2018. As with all other small and medium-sized enterprises (SMEs) evaluated, Summit was not scored in this indicator.

A.2.1 Pipeline size of three projects
Summit reports three projects targeting priority pathogens in its pipeline. The company focuses on antibacterial medicine development, with its three projects equally divided between discovery, pre-clinical and clinical (Phase III) stages of development.

A.2.2 One clinical-stage novel project
Summit’s clinical-stage medicine pipeline for priority pathogens consists of one new R&D project. Summit has one late-stage antibacterial medicine project that is considered novel: ridinilazole, for C. difficile infections, which 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
Summit is not eligible for this indicator as it is not active in vaccine development.

A.2.4 Three candidates targeting critical and/or urgent priorities
Summit’s pipeline includes one clinical medicine candidate in Phase III (ridinilazole) that targets C. difficile; one pre-clinical medicine candidate (SMT-571) that targets N. gonorrhoeae; and a discovery platform (DDS-04) that targets Enterobacteriaceae, including ESBL-producing Enterobacteriaceae and CRE. These pathogens are among those that are considered critical and/or urgent R&D priorities for limiting AMR, as identified by WHO and/or the US Centers for Disease Control and Prevention (CDC).

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>DDS-04 Series - Enterobacteriaceae (including ESBL-producing Enterobacteriaceae and CRE)</td>
<td>SMT-571 - N. gonorrhoeae</td>
<td>Ridinilazole (SMT-19969) - C. difficile - Novel</td>
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CHANGES SINCE 2018

- Initiated Phase III clinical trials for ridinilazole in February 2019, with data expected in 2021.
- Expanded its R&D pipeline in April 2019 to include the discovery-stage DDS-04 series project targeting Enterobacteriaceae, identified via its proprietary Discuva Platform.
- Entered into a new exclusive license and commercialisation agreement in December 2017 with Eurofarma Laboratórios SA in Latin America for ridinilazole. Eurofarma is responsible for regulatory approvals in the territory (Brazil and 20 other Latin American countries) and Summit retains commercial rights worldwide.

B RESPONSIBLE MANUFACTURING

As an SME, Summit is not evaluated in this Research Area. Its most advanced antibacterial candidate is ridinilazole, and the Benchmark notes that Summit reports planning its manufacturing programmes to cover the needs of Phase III clinical trials as well as the commercial launch of ridinilazole. Within these plans, two third-party suppliers will be engaged to manufacturer the product. Summit states that it recognises the importance of reducing the impact of manufacturing discharge on antibacterial resistance and expects to develop its environmental risk-management strategy with respect to antibacterial discharge over the coming years. Summit was not scored on these activities.

C APPROPRIATE ACCESS & STEWARDSHIP

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

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