

RedHill Biopharma

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RedHill Biopharma says orphan lung disease therapy RHB-204 granted Fast Track designation by US Food and Drug Administration

RedHill Biopharma Ltd (NASDAQ:RDHL) has said its drug candidate RHB-204 has been granted Fast Track designation by the US Food & Drug Administration (FDA).

The specialty biopharmaceutical company said it is being developed as a potential first-line, stand-alone, oral treatment of pulmonary nontuberculous mycobacteria (NTM) disease caused by Mycobacterium Avium Complex.

NTM lung disease, is a chronic and debilitating condition caused by environmental bacteria found in soil, as well as natural and engineered water systems. There is no FDA-approved first-line therapy for this disease. The incidence and prevalence of pulmonary NTM disease are increasing in many areas of the world. There were an estimated 110,000 pulmonary NTM disease patients in the US in 2017, with US market potential estimated at over \$500 million.

READ: RedHill Biopharma says its Phase 2/3 COVID-19 drug candidate opaganib reduces thrombosis in preclinical study

The US regulator's Fast Track designation for RHB-204 means RedHill will have "access to early and frequent communications with the FDA, to expedite the RHB-204 development program, and to a rolling review of a new drug application".

The drug candidate has already been granted Qualified Infectious Disease Product (QIDP) accreditation, which means RHB-204, which recently entered the phase III clinical trial stage, is also eligible for New Drug Application Priority Review and Accelerated Approval.

The previous award of orphan status extends US market exclusivity for RHB-204 to a potential total of 12 years following FDA approval.

"Given the urgent need to improve therapeutic options for patients with NTM disease, we welcome this Fast Track designation and the regulatory support it provides in expediting the ongoing phase III development program for RHB-204 and any subsequent potential approvals," said Patricia Anderson, RedHill's senior vice president of regulatory affairs in a statement.

"NTM disease is thankfully rare but its prevalence is increasing in many areas of the world. It is a notoriously difficult to treat disease and, if not effectively treated, can cause scarring and fibrosis in the lungs - potentially leading to respiratory failure. Many patients fail current therapies, and more than half will have either recurring disease or a new infection after completing treatment."

Angela Harmantas contributed to this report

Price: 9.23

Market Cap: \$383.85 m

1 Year Share Price Graph



March 2020 August 2020 February 2021

Share Information

Code: RDHL

Listing: NASDAQ

52 week	High	Low
	11.5	3.275

Sector: Pharma & Biotech

Website: www.redhillbio.com

Company Synopsis:

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases. RedHill promotes three FDA-approved gastrointestinal drugs: Movantik® for opioid-induced constipation in adults, Talicia® for Helicobacter pylori (H. pylori) infection in adults, and Aemcolo® for travellers' diarrhoea in adults.

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