

RedHill Biopharma

12:22 07 Jan 2021

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: \$342.68 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.

action@proactiveinvestors.com

Contact Angela at angela@proactiveinvestors.com

Disclaimer: This content has been provided pursuant to an agreement under which RedHill Biopharma pays an annual fee to the publisher. (<https://www.proactiveinvestors.com/pages/terms>)

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts, journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of RedHill Biopharma named herein, including the promotion by the Company of RedHill Biopharma in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars (\$25,000).