



RedHill BioPharma has positive results from anti-MAP Crohn's disease trial

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Technical news (uncommented clippings)

Tags: TAFS, technical news, paratuberculosis, MAP, food safety, Crohn's

Source: johnes.org

First reported by Reuters, Tel Aviv, July 30:

Israel's RedHill Biopharma said on Monday it had positive safety and efficacy results from a late-stage clinical trial with its treatment for Crohn's disease called RHB-104.

The study met its primary endpoint and key secondary endpoints, demonstrating the drug's superiority over a placebo in achieving remission of the gastrointestinal disease at week 26, the company said in a statement.

"The proportion of patients meeting the primary endpoint was significantly greater in the RHB-104 group compared to placebo," RedHill said.

Patients treated with RHB-104 also experienced a statistically significant benefit in achieving early remission at week 16 and in durable remission over weeks 16-52.

RHB-104 was found to be generally safe and well tolerated, said the company, which is focused on proprietary drugs for gastrointestinal diseases.

"Many patients with Crohn's disease do not achieve remission on current standard-of-care therapies, which are accompanied with poor side effects," said David Graham, lead investigator of the Phase III study.

"RHB-104 appears to have the potential to become a promising, new, orally administered therapy for this important debilitating disease."

RHB-104 is a proprietary, antibiotic combination therapy that is based on the hypothesis that Crohn's disease is caused by a bacterial infection in susceptible patients called *Mycobacterium avium* subspecies *paratuberculosis* (MAP).

Comment [by [Johnes.org](http://johnes.org); highlighting by TAFS]: If the final published results of this trial are consistent with the claims in this press release, it represents a final piece of evidence indicating that MAP is a cause of Crohn's disease. **This would heighten the need for veterinary medicine, animal agriculture, and relevant governmental agencies concerned with food safety to limit contamination of food and water by MAP.**

Further reading:

<https://www.pharmaceutical-technology.com/comment/antibiotics-crohns-disease/>

<https://www.redhillbio.com/RedHill/Templates/showpage.asp?DBID=1&LNGID=1&TMID=178&FID=1365&PID=0&IID=5148>

<https://clinicaltrials.gov/ct2/show/NCT01951326>