RedHill Biopharma Ltd.

(NASDAQ/ TASE: RDHL)

RHB-104 Phase III Crohn's Disease Program Update

October 2, 2017

RedHill Biopharma

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Pipeline*

	Product**	Indication	Pre-Clinical / Phase I/II / Phase III / NDA/ Marketed
GI & Inflammation	Donnatal®	IBS and acute enterocolitis***	U.S. CO-PROMOTION
	EnteraGam®	Chronic diarrhea and loose stools****	U.S. EXCLUSIVE LICENSE
	Esomeprazole Strontium DR Capsules	GERD and other GI conditions*****	U.S. COMMERCIALIZATION LICENSE
	TALICIA™ (RHB-105)	*H. pylori* infection	Successful first U.S. Phase III completed; Confirmatory U.S. Phase III ongoing
	RHB-104	Crohn's disease	Phase III MAP US study and Phase III MAP US2 extension study are ongoing
		NTM infections	Pivotal Phase III study planned
	BEKINDA® (RHB-102)	Gastroenteritis	Successful top-line results from Phase III U.S. study
		IBS-D	Phase II U.S. study ongoing
	RHB-106	Bowel cleanser	Worldwide rights licensed to Salix Pharmaceuticals
Oncology /GI Inflammation	YELIVA® (ABC294640)	Multiple indications	Multiple Phase I/II studies ongoing and planned
	MESUPRON	Pancreatic cancer	Completed Phase II studies including in pancreatic cancer
Other	RIZAPORT® (RHB-103)	Migraine	U.S. NDA filed - re-submission of NDA planned following CRL EUROPEAN MAA APPROVED UNDER THE EUROPEAN DECENTRALIZED PROCEDURE

** Estimated timeline/indication in the pipeline is subject to changes in development plans and regulatory requirements/clarifications, including complementary /additional studies ** BEKINDA®, YELIVA®, RIZAPORT® and TALICIA™ are proposed tradenames which are subject to FDA review and approval *** For further information see slide 10. For full prescribing information see: www.Donnatal.com; ****EnteraGam® (a serum-derived bovine immunoglobulin/protein isolate, SBI) is a medical food which must be administered under medical supervision ***** for full information see slide 12; for full prescribing information see: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=53240ab5-98e7-4050-b640-e09c1271899a&type=display*

RHB-104 Phase III - Update

RedHill accelerates RHB-104 Phase III study in Crohn's Disease with Top-Line Results Expected Mid-2018

RedHill has curtailed the target sample size in the ongoing first Phase III study with RHB-104 for Crohn's disease (MAP US) from 410 to approximately 325 subjects, of which 322 have been enrolled to date, while maintaining statistical power of over 80% with a treatment effect of 15%

We have concluded that the study has sufficient enrollment to potentially demonstrate efficacy within the protocol-defined 15% treatment effect

Company remains blinded to the data

RHB-104 Indications

- A ground breaking anti-mycobacterial combination antibiotic targeting:
  - *Mycobacterium avium paratuberculosis (MAP) for treatment of Crohn's disease*
  - *Non-Tuberculous Mycobacteria (NTM) – a pathogen that causes pulmonary disease that resemble tuberculosis*
  - *Potentially other auto-immune diseases*
- First Phase III ongoing in Crohn's disease

Where There is Inflammation, Look for Infection

- Crohn's disease is increasingly associated with a pathological response to alterations in gut flora
- RHB-104 is a combination antibiotic designed to treat *Mycobacterium avium paratuberculosis* (MAP) - a putative cause of Crohn's disease
- Paradigm shift in pathophysiology not unlike *H. pylori* and peptic ulcer disease

Crohn's Disease - Current Therapies

- Worldwide market for Crohn's disease therapies estimated at over $7.6B in 2016
- U.S. prevalent cases estimated at over 604,000 in 2016

Current therapies -

- Not curative
- Focus on modulation of inflammation
  - Simply turn down the volume

Crohn's Disease - Pathogenesis Hypothesis

Genetic susceptibility:

difficulty with intracellular parasites

Mycobacterium avium subsp. Paratuberculosis

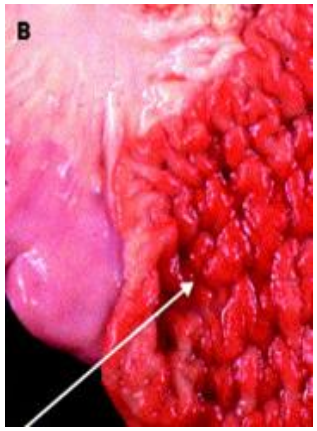
via food, water (environment)

Crohn's disease

Johne's Disease and Crohn's Disease

- Intestinal diseases - Johne's disease in cattle and Crohn's in humans
- Severe chronic diarrhea, weight loss
- Characterized by granuloma formation
- Pathognomonic cobblestoning
- MAP is the infectious agent of Johne's
- MAP is difficult to identify in humans

Crohn's disease



Johne's disease

RHB-104 First Phase III MAP US Study

- Multi-center, randomized, double-blind, placebo-controlled, parallel group study
- 410 subjects randomized 1:1, 322 enrolled to date
- Up to 150 sites: U.S., Canada, Europe, Australia, New Zealand, Israel
- Primary endpoint:
  - Remission at 26 weeks
- Secondary endpoints include:
  - Response at 26 weeks
- Exploratory endpoint
  - MAP status via PCR and culture
  - Relationship to efficacy
- Two pre-planned independent DSMB meetings provided unanimous recommendations to continue the study

MAP US - Additional Study Endpoints

- **Secondary and exploratory endpoints include:**
  - Maintenance of remission through week 52
  - Time and duration of remission/response
  - CRP and fecal calprotectin
- Health related quality of life using IBDQ and SF 36
- Steroid discontinuation
- Safety
- Population PK
- CDEIS/SESCD
- Validation of MAP assay
- Lead investigator - Professor David Y. Graham MD (Baylor College of Medicine)

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MAP US Study – Prior Major Amendments

- 50 sites, 240 subjects, 61.6% RHB-104 vs. 40% placebo
  - 21.6% treatment effect
  - Increased to 88 then 100 sites

- 120 sites, 270 subjects, 61.6% RHB-104 vs. 40% placebo
  - 21.6% treatment effect

- 150 sites, 410 subjects, 36% RHB-104 vs. 21% placebo
  - 15% treatment effect
  - Interim efficacy look for overwhelming superiority at $p<0.003$
  - O'Brien Fleming final analysis p-value <0.049

MAP US2 Study Ongoing - Open Label Phase III Extension Study

- All subjects with CDAI>150 at 26 weeks eligible for up to one year of treatment with RHB-104
  - Provides investigator and patient requested treatment option
- Separate study - will not impact MAP US timelines
- Expands safety and efficacy data set of RHB-104

MAP US Study - Status Before Curtailment

- 322/410 subjects enrolled = >75% of targeted enrollment
- Given recruitment challenges, targeted Last Patient In (LPI) may not occur until December 2018 (410 patients)
- Consistent blinded blended remission rate superior to pre-specified protocol assumptions support study curtailment with potential study success
- External expert review of subject accrual and powering assumptions
- **RedHill & external expert review remain blinded to study data**

MAP US Study - External Review Summary

- Advisors recommended against interim analysis for efficacy at DSMB 3 with 75% of subjects at week 26 CDAI
  - Involves statistical spend (penalty) of p-value given O'Brien Fleming calculations
- Curtailing the study to approximately 325 maintains >80% power if pre-specified 36% RHB-104 and 21% Placebo remission rates are unchanged

Curtailment of the MAP US Study

- Curtailment of the number of subjects in the MAP US study to a target sample size of approximately 325 subjects
  - Maintaining statistical power of over 80% with a treatment effect of 15%
  - Final statistical analysis remains unchanged with 15% treatment effect
- Consistent blinded blended remission rate superior to pre-specified protocol assumptions support study curtailment with potential study success
- Targeted placebo remission rates in line with approved Crohn's disease treatments
- Completion of enrollment for the study expected by November 2017; Top-line results expected in mid-2018

MAP US Study - Expected Benefits of Curtailment

- Avoids extended timelines and learning curve associated with new sites and countries
- Eliminates concerns of study fatigue at long term sites that have exhausted potential patient populations
- Avoids further use of advertising for subjects
- Provides preferred expedited development path assuming blinded blended remission rates remain constant
- Maintains protocol defined two sided p-value of 0.049 significance level using the O'Brien-Fleming method
- Development plan shortened by approximately 1 year
- Estimated cost saving of approximately $14M

Conclusion

"We have concluded that the study has sufficient enrollment to potentially demonstrate efficacy within the protocol-defined 15% treatment effect"

"We are excited about the significant progress achieved with RHB-104 and look forward to top-line results from the MAP US Phase III study, expected in mid-2018"

Thank You!

RedHill Biopharma

RedHill Biopharma Ltd.
21 Ha'arba'a St. Tel-Aviv,
6473921. Israel
E:mail: info@redhillbio.com
Web: www.redhillbio.com
Tel: +972-3-541-3131