RedHill Biopharma Ltd.

(NASDAQ/ TASE: RDHL)

MAP US Phase III Positive Top-Line Results
RHB-104 for Crohn's Disease

July 30, 2018

RedHill Biopharma

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Agenda

- **Introduction**
  Dror Ben Asher, RedHill CEO
- **RHB-104 Phase III MAP US study for Crohn's disease - Top-line results**
  Ira Kalfus, MD, Medical Director, RedHill
- **Crohn's disease & the MAP infectious etiology paradigm**
  Prof. David Graham, MD, M.A.C.G., Lead Investigator of the RHB-104 MAP US Phase III study
- **Crohn's disease - the unmet medical need & the potential positioning of RHB-104**
  M. Scott Harris, MD, MS, FACP, AGAF, RedHill Advisory Board and consultant
- **Q&A**

INTRODUCTION

Dror Ben Asher

CEO, RedHill Biopharma

RHB-104 Phase III Study in Crohn's Disease - Positive Top-Line Results

- Primary endpoint successfully achieved - superior remission rate at week 26 in patients treated with RHB-104 (p= 0.013)

- Key secondary endpoints also met, demonstrating consistent benefit to Crohn's disease patients treated with RHB-104

The robust results of this study demonstrate that RHB-104 could become a leading therapeutic option for Crohn's disease and bring hope to patients worldwide

RHB-104 Phase III MAP US Study for Crohn's Disease - Top-Line Results

Ira Kalfus, M.D.
Medical Director, RedHill Biopharma

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RHB-104 for Crohn's Disease

- A patent protected combination of 3 antibiotics in a single oral capsule with potent intracellular, anti-mycobacterial and anti-inflammatory properties

- Development based on increasing evidence supporting the hypothesis that Crohn's disease is caused by *Mycobacterium avium paratuberculosis* (MAP) infection in susceptible patients

- Robust global patent portfolio covering RHB-104

RHB-104 MAP US - First Phase III Study for Crohn's Disease

- Multi-center, randomized, double-blind, placebo-controlled, parallel group Phase III study in patients with active disease despite receiving standard-of-care
- 331 subjects completed week 26 assessments
- Over 100 sites: U.S., Canada, Europe, Australia, New Zealand, Israel
- Lead investigator - Professor David Y. Graham MD (Baylor College of Medicine)

RHB-104 MAP US - Main Inclusion Criteria

- 18 to 75 years of age
- CD diagnosed at least 6 months prior to randomization
- CD involving the ileum and/or colon
- *Moderately to severely active CD with CDAI score of ≥220 and ≤450*
- Patients must maintain current treatment with SoC:
  - Oral 5-aminosalicylic acid (5-ASA) compounds
  - Corticosteroid therapy
  - Azathioprine or 6-mercaptopurine (6-MP) or methotrexate
  - Infliximab or adalimumab
- Active Crohn's disease
  - C-reactive protein, fecal calprotectin, radiographic (MRE or CTE) or endoscopic confirmation

RHB-104 MAP US - Demographics

	Statistics	RHB-104 (N=166)	Placebo* (N=165)
Gender Male Female		 91 (55%) 75 (45%)	 98 (59%) 67 (41%)
Age (years)	Mean (SD)	39.0 (12.5)	39.3 (12.6)
BMI (kg/m^2) at BL	Mean (SD)	25.9 (7.1)	26.2 (6.6)
Smoking Yes No		 33 (20%) 133 (80%)	 30 (18%) 135 (82%)
EtOH Consumption Yes No		 63 (38%) 103 (62%)	 49 (30%) 116 (70%)

* Placebo and RHB-104 as add-on to standard-of-care

RHB-104 MAP US - Demographics

	Statistics	RHB-104 (N=166)	Placebo* (N=165)
CDAI Score at BL	Mean (SD)	298 (57.0)	293 (53.2)
Time from Dx to MAP US < 2 years 2-5 years > 5 years	Mean (SD)	10.4 (9.0) 20 (12%) 36 (22%) 110 (66%)	10.8 (9.0) 18 (11%) 37 (22%) 110 (67%)
Site of primary Dx Ileum Colon Other		125 (75%) 93 (56%) 12 (7%)	98 (59%) 106 (64%) 8 (5%)
CRP at BL Normal ≤ 0.999 mg/dL High >0.999 mg/Dl	Mean (SD)	1.34 (1.75)	1.38 (1.87)
Fecal calprotectin at BL Normal ≤ 162.9 mcg/g High >162.9 mcg/g	Mean (SD)	575 (610)	661 (949)

* Placebo and RHB-104 as add-on to standard-of-care

RHB-104 MAP US – Study Endpoints

- **Primary endpoint:** Remission at week 26 (CDAI <150)
- **Key secondary endpoints**:
  - Response at week 26 (decrease in CDAI of at least 100 points)
  - Remission at week 52
  - Durable remission from week 26-52
  - Remission at week 16
  - Durable remission from week 16-52
  - Safety

RHB-104 MAP US – Additional Study Endpoints

Secondary and exploratory endpoints include:

- Onset and duration of remission/response
- CRP and fecal calprotectin
- Health related quality of life using IBDQ and SF 36
- Steroid free remission
- Population PK
- Mucosal healing as measured via CDEIS/SESCD
- MAP Status via culture and PCR
  - Relationship to efficacy
  - Validation of MAP assay

RHB-104 MAP US - Positive Top-Line Efficacy Results

Primary Efficacy Endpoint - Intent-to-Treat (ITT) Population

	RHB-104 N=166 (%)	Placebo** N=165 (%)	Treatment Effect	P-value
Remission at Week 26*	61 (37%)	38 (23%)	14%	**0.0134**

* Remission defined as Crohn's Disease Active Index (CDAI) value of less than 150

** Placebo and RHB-104 as add-on to standard-of-care

RHB-104 MAP US - Positive Top-Line Efficacy Results

Key Secondary Endpoints - ITT Population

	RHB-104 N=166 (%)	Placebo** N=165 (%)	Treatment Effect	P-value
Response at Week 26*	73 (44%)	51 (31%)	13%	**0.028**
Early Remission at Week 16	70 (42%)	48 (29%)	13%	**0.019**

* Response defined as a decrease of ≥ 100 in CDAI from baseline

** Placebo and RHB-104 as add-on to standard-of-care

RHB-104 MAP US - Positive Top-Line Efficacy Results

Secondary and Additional Endpoints - ITT Population

	RHB-104 N=158 (%)	Placebo** N=161 (%)	Treatment Effect	P-value
Remission at Week 52*	43 (27%)	32 (20%)	7%	**0.155**
Durable Remission Weeks 16-52	28 (18%)	14 (9%)	9%	**0.038**
Remission at Weeks 16 and 52	40 (25%)	20 (12%)	13%	**0.007**

* This study was powered for 26 weeks and was not sufficiently powered for 52 weeks

** Placebo and RHB-104 as add-on to standard-of-care

Secondary and Additional Endpoints - ITT Population

	RHB-104 N=158 (%)	Placebo*** N=161 (%)	Treatment Effect	P-value
Durable Remission Weeks 26-52*	29 (18%)	21 (13%)	5%	**0.319**
Durable Remission 75% Weeks 26-52*	44 (28%)	27 (17%)	11%	**0.034**

* This study was powered for 26 weeks and was not sufficiently powered for 52 weeks
** CDAI <150 on at least 3 of 4 visits after week 26
*** Placebo and RHB-104 as add-on to standard-of-care

Safety Endpoints - ITT Population

Subjects with any TEAEs

	RHB-104 N=166 (%)	Placebo** N=165 (%)
Subjects with any TEAEs*	145 (87%)	135 (82%)
Subjects with any Serious TEAEs	31 (19%)	29 (18%)
Subjects with any Serious Drug-related TEAEs	2 (1%)	2 (1%)
Subjects with any TEAEs leading to study drug discontinuation	35 (21%)	30 (18%)

* TEAEs: Treatment-emergent adverse events
** Placebo and RHB-104 as add-on to standard-of-care

RHB-104 MAP US - Top-Line Conclusions

The first global, double-blind placebo-controlled study to demonstrate the efficacy of anti-MAP therapy in Crohn's disease

- Demonstrated consistent treatment effect favoring RHB-104 in both the protocol defined primary endpoint of 26 weeks (Δ14% with p-value = 0.013) and secondary endpoint of early remission at 16 weeks (Δ13% with p-value = 0.019)
- Durable remission from week 16 through week 52 (18% vs. 9%, Δ9%, p-value = 0.038) as well as
- Remission at both weeks 16 and 52 (25% vs. 12%, Δ13% p-value = 0.007) , were twice that of placebo
- RHB-104 was safe and well tolerated
- RHB-104 could lead to a groundbreaking change in the treatment of Crohn's disease

RHB-104 MAP US - Next Steps

- Further data review, including:
  - MAP status via culture with relationship to efficacy
  - Sub-population and pharmacokinetic analyses
  - Quality of Life assessments
  - Mucosal healing evaluation
- KOL discussions
- Meet with FDA to discuss data and path forward
- Accelerate pharma partnership discussions

Ongoing MAP US2 Study - Open Label Phase III Extension Study

- Enrollment completed - 54 patients in total
- 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
- Expands safety and efficacy data set of RHB-104

Crohn's Disease & the MAP Infectious Etiology Paradigm

Prof. David Graham, M.D., M.A.C.G.

Lead Investigator of the MAP US study

Renowned Researcher and Physician at the Baylor College of Medicine

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Crohn's Disease

- Crohn's disease is a devastating illness that has long been in search of a cause which could lead to a cure
- Chronic gastrointestinal disorder characterized by abdominal pain, diarrhea, bleeding, bowel obstruction, and a variety of systemic symptoms
- Approx. 1.5 million people globally suffer from Crohn's disease (2017)
- Annual aggregate economic burden of Crohn's disease in the U.S. from 2003-2013: >$6 Billion*

* Buonthavong M et al. Res Social Adm Pharm. 2017 May - Jun;13(3):530-538

Crohn's Disease - Pathophysiology

Important "Knowns":

- Fundamentally, Crohn's disease is an overzealous immune and inflammatory response in the intestines
- Associated with many genes related to the body's inability to deal with intracellular pathogens such as MAP
- There is also strong evidence of an environmental stimulus

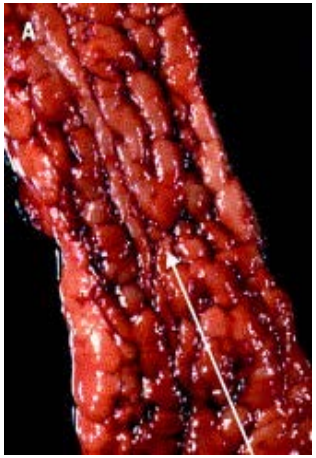
Current Therapy - Biologics

- Current focus has been on modulation of inflammation
  - Not curative
  - Simply turns the inflammation down

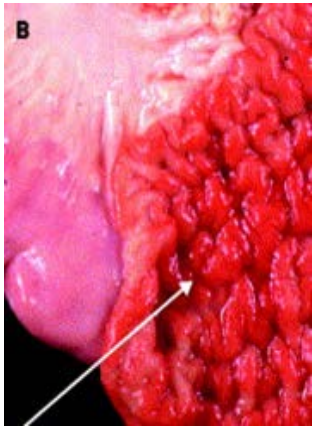
MAP and Johne's Disease

- *Mycobacterium avium paratuberculosis* (MAP) causes a similar disease in ruminants and has been considered as a possibly cause of CD since Crohn's Disease was first described

- This study was designed to test the hypothesis that treatment of MAP would affect the natural history of CD



Crohn's disease



Johne's disease

RHB-104 MAP US Phase III - Top-Line Conclusions

- The results showed that the addition of MAP therapy to standard therapy (plus placebo) definitely had a strong and significant beneficial effect suggesting that it will result in a paradigm shift in therapy

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

Crohn's Disease - The Unmet Medical Need & The Potential Positioning of RHB-104

M. Scott Harris, MD, MS, FACP, AGAF
RedHill Biopharma Advisory Board

Adjunct Professor of Medicine, Georgetown University School of Medicine,
Principal, Middleburg Consultants

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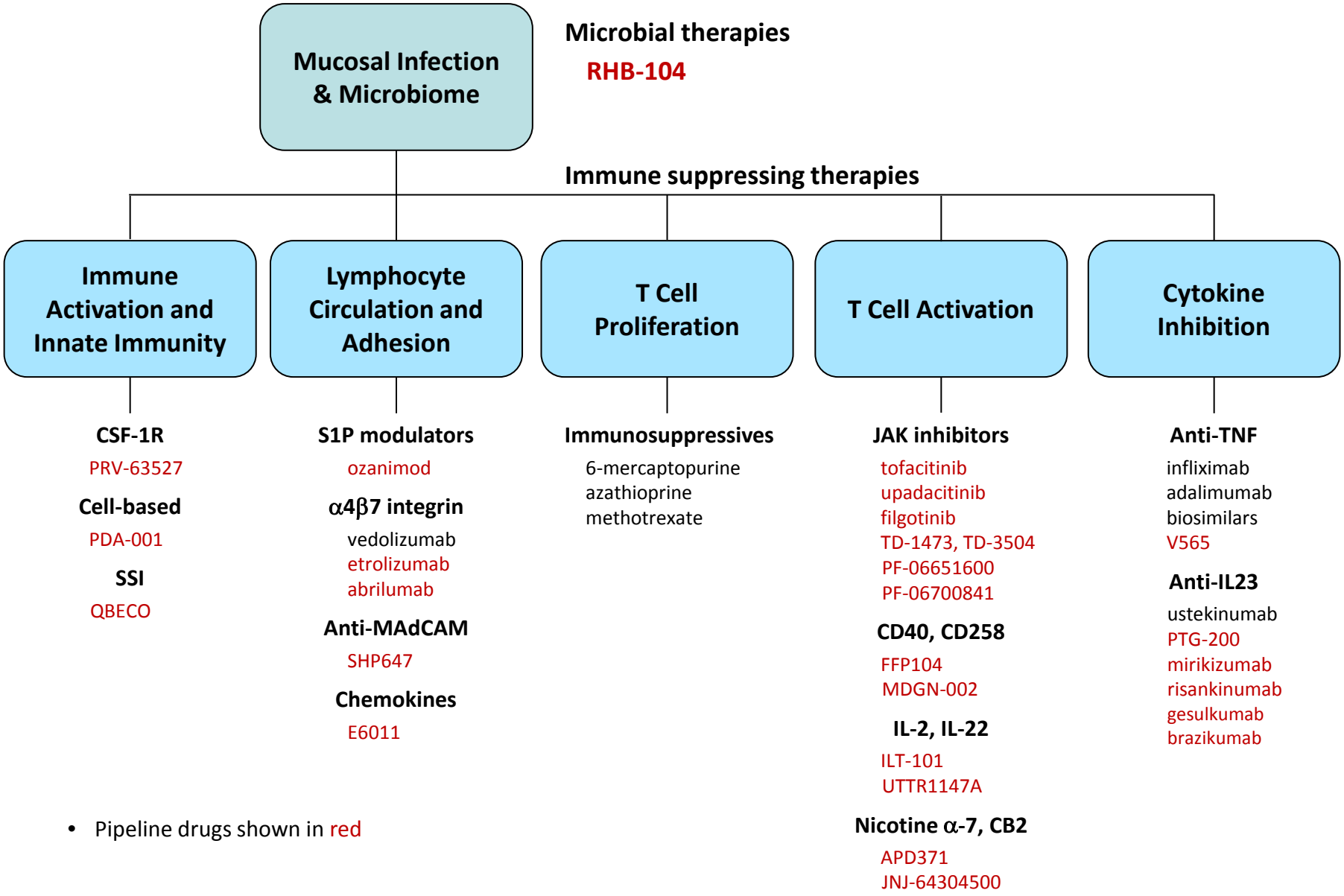
Crohn's Disease - Competitive Landscape



- Pipeline drugs shown in red

IBD Agents Achieve Low Remission Rates

- **Current agents target downstream immune processes after the disease is triggered**
- **At one year, the most effective agents only achieve ~40% clinical remission rates in the subset of patients who experience an initial response to treatment**
- **This equates to an absolute 1-year remission rate of ~ 25% of all patients treated**

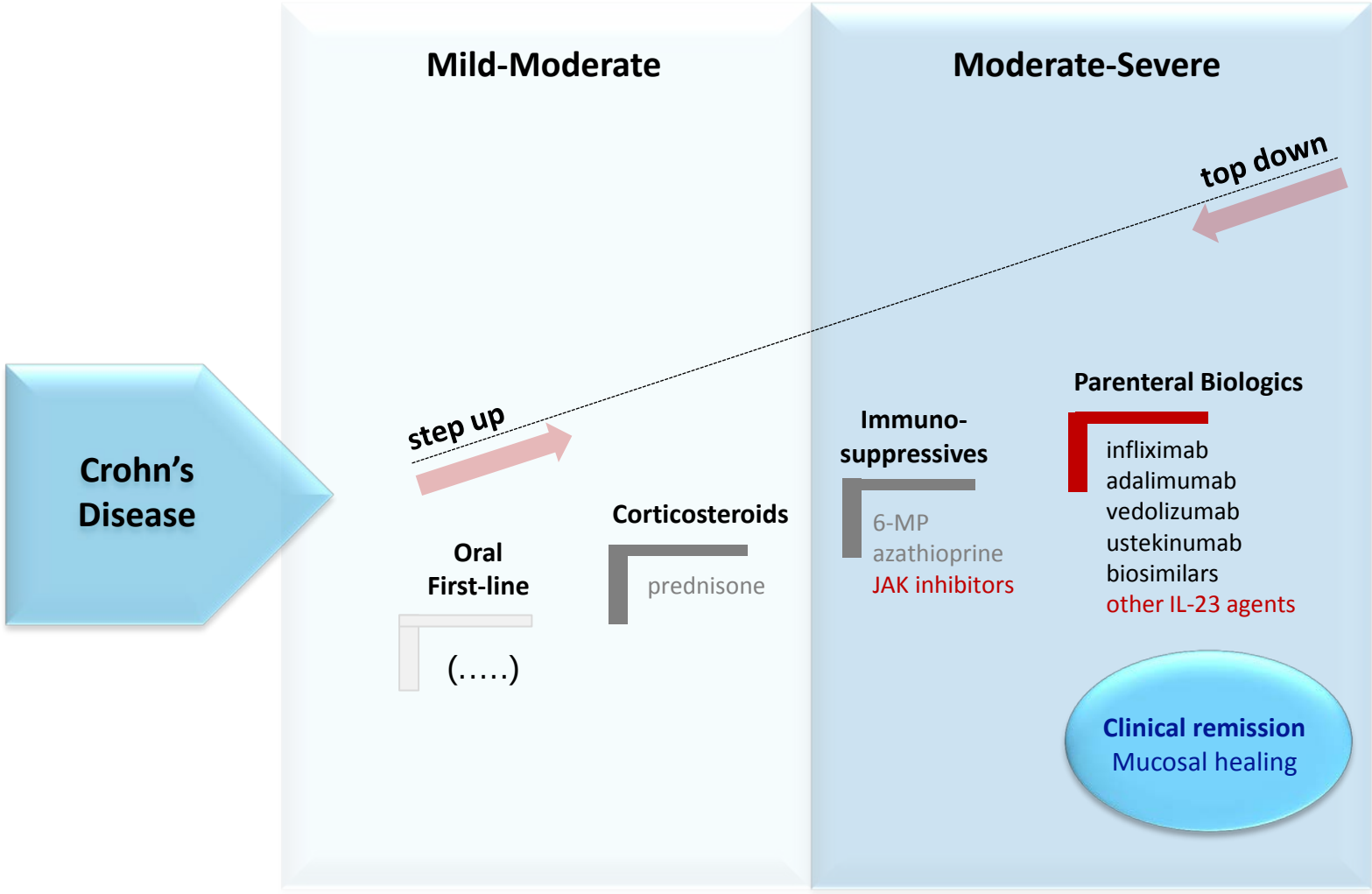
Drug/Study	Route	Endpoint	Mean Remission Rate†
Remicade®(infliximab)	IV	Week 4	**48%**
Humira® (adalimumab)	SC	Week 4	**36%**
Entyvio® (vedolizumab)	IV	Week 6	**15%**
Stelara® (ustekinumab)	IV/SC	Week 8	**31%**

An oral agent targeting a MAP etiology, used alone or in combination with these agents, could alter the natural history of disease and response to treatment

*** Mean remission rates achieved in Phase III trials, not adjusted for background placebo response.**

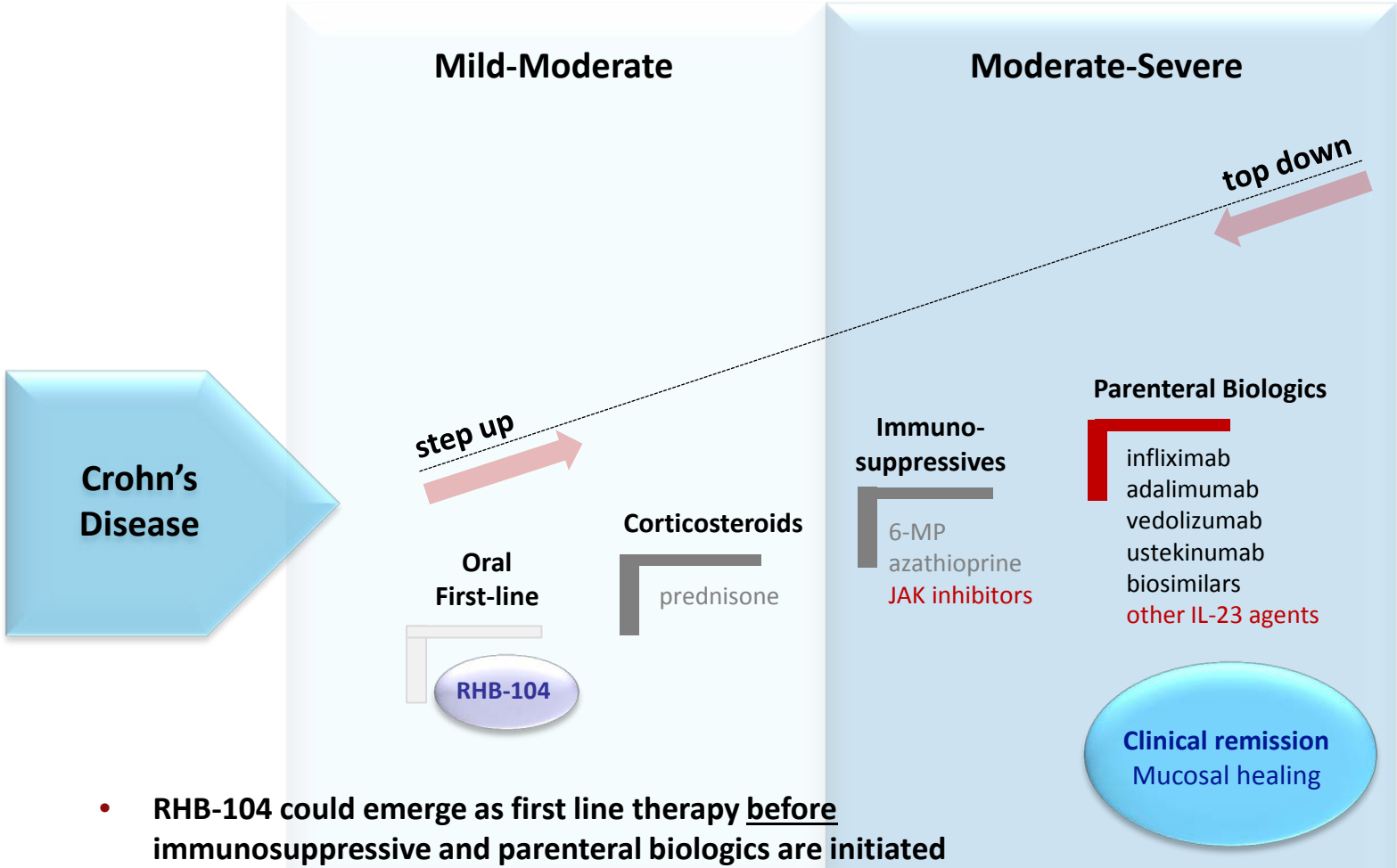
* Sources: Remicade® Targan NEJM 1997, Humira® CLASSIC 1 trial, Entyvio® GEMINI 2, Stelara® UNITI 1 and 2 trials; Hirten Clin Gastro Hep 2018.

Crohn's Disease - The Emerging Treatment Paradigm



- Pipeline drugs shown in red
- Obsolete drugs shown in gray`

RHB-104 - Transforming the Crohn's Treatment Paradigm



- **RHB-104 could emerge as first line therapy before immunosuppressive and parenteral biologics are initiated**
- **Because of its complementary MOA, RHB-104 also could be used in combination with these immune-suppressing agents**

- Pipeline drugs shown in red
- Obsolete drugs shown in gray`

Q&A

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THANK YOU!

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