



# Barclays Global Healthcare Conference

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**BAUSCH** Health

# Forward-Looking Statements



## Forward-Looking Statements

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# Key Salix Pipeline Overview<sup>1</sup>

	Investigational Formulation	Proposed Indications	Pre-Clinical	Phase I	Phase 2	Phase 3
Hepatology	Rifaximin SSD (Solid Soluble Dispersion) in a tablet (low-dose)	RED-C Program - Reduction of Early Decompensation in Cirrhosis  Prevention of the first occurrence of hepatic encephalopathy (HE) in mild cirrhosis				Rifaximin SSD IR
Gastrointestinal	Amiselimod Capsules	Mild to Moderate UC (Ulcerative Colitis)			Amiselimod (S1P Modulator)	
	Combination of Rifaximin with a Mucolytic Agent	Irritable Bowel Syndrome - Diarrhea Cedars-Sinai Collaboration	Rifaximin / Mucolytic Agent			
	Rifaximin Liquid Gel Capsules (novel formulation, low-dose)	Small Intestinal Bacterial Overgrowth (SIBO)		Rifaximin		
Hematology	Rifaximin Timed Release Coated Beads in Capsules (novel formulation, low-dose)	Sickle Cell Anemia			Rifaximin	

# Amiselimod Capsules<sup>1</sup>

*Mild to Moderate Ulcerative Colitis*

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- Amiselimod is a new oral selective S1P<sup>2</sup> receptor modulator
- Amiselimod shows potent selectivity for S1P1 receptor and no distinct agonist activity for S1P2 or S1P3 receptors
- Thorough QT/QTc trial demonstrated clean cardiac profile; data presented at AIBD (Advances in Inflammatory Bowel Diseases) and Crohn's and Colitis Foundation Meeting
- Differentiated from ozanimod
  - No dose titration regimen
  - Greater effect for lymphocyte reduction than ozanimod
  - Mild to Moderate indication

## Timeline

- Phase 2 start was delayed in 2020 due to COVID-19; first patient to be dosed 2Q21
  - 3-arm study, 336 patients, approximately 175 investigative sites
  - 12 weeks of blinded treatment; up to 36 weeks of open-label extension
  - Primary endpoint - Change from Baseline in the modified Mayo Score at Day 85
- Dependent on positive Phase 2 data, Phase 3 study estimated to start 1H24 (2 large trials) and estimated completion 2027
- New drug application (NDA) anticipated to be submitted 2028

## 4 Novel Rifaximin Formulations

*Unique and novel rifaximin formulations are in development to address unmet medical needs*

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Rifaximin solid soluble dispersion (SSD) in a tablet

Combination of rifaximin with a mucolytic agent

Rifaximin liquid gel capsules

Rifaximin timed release coated beads in capsules

# Rifaximin Solid Soluble Dispersion (SSD) in a Tablet

## *RED-C Program*

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- RED-C Program - Reduction of Early Decompensation in Cirrhosis
- “Upstream” approach intended to prevent the first occurrence of hepatic encephalopathy (HE) in mild cirrhosis
  - Will also investigate: Spontaneous bacterial peritonitis (SBP), hepato-renal syndrome (HRS), Variceal bleed
- Proof of concept demonstrated in two Phase 2 trials
- Agreement with FDA obtained regarding design and primary endpoint of pivotal Phase 3 trials in January 2021
  - Would be first drug in this indication

## Timeline

- Phase 3 program estimated to commence 2H21
  - SSD twice a day vs. placebo
  - ~1,000 patients, approximately 200 investigative sites
  - 72-week treatment period
  - Primary endpoint—time to first occurrence of hepatic encephalopathy
- New drug application (NDA) planned to be submitted 2026

# Combination of Rifaximin with a Mucolytic Agent

*Irritable Bowel Syndrome - Diarrhea Cedars-Sinai Collaboration*

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- Collaboration with Cedars-Sinai
- Combination of rifaximin with a mucolytic agent (N-acetyl cysteine)
  - Liberation of resident noxious bacteria in mucous layer will result in better kill rates and improved efficacy in irritable bowel syndrome - diarrhea predominant (IBS-D)

## Timeline

- Preclinical (in vitro and animal studies) have been completed and support the hypothesis
- Proof of Concept study start was delayed in 2020 due to COVID-19 and is approximately 50% enrolled
- Phase 2 study start anticipated in 2022, dependent on meeting with FDA
- Phase 3 start estimated in 2023, dependent upon successful Phase 2 study
- New drug application (NDA) submission planned for 2025

# Rifaximin Liquid Gel Capsules

## *Small Intestinal Bacterial Overgrowth (SIBO)*

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- Targeted for small intestine bacterial overgrowth (SIBO)
  - Currently there is no approved medication indicated for SIBO
- Designed to release in the small bowel

### Timeline

- Working with FDA on the development of proprietary Patient Reported Outcome (PRO) tool
- To be validated in Phase 2 for use in Phase 3 studies



# Rifaximin Timed Release Coated Beads in Capsules












## *Sickle Cell Anemia*

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- Orphan disease designation granted October 2020
- Dysbiosis (disordered gut microbiome) in sickle cell patients is associated with more frequent episodes where “sickled” red blood cells and circulating activated neutrophils (CANs) occlude blood vessels (vaso-occlusive crises, VOCs); these VOCs are extremely painful and often require IV opioids and can result in organ damage
- Rifaximin, by its effect on the microbiome, decreases circulating activated neutrophils (CANs) and consequently vaso-occlusive crises (VOCs)
- Proof of Concept study demonstrated benefit in sickle cell patients
  - Decreased VOCs and opioid usage

### Timeline

- Phase 1b / 2a study expected to commence 2H21
- Phase 2b / 3 adaptive design study anticipated to start 1H23, dependent upon agreement with FDA
- New drug application (NDA) planned to be submitted 2026

	2019	2020	2021	2022	2023	2024	2025	2026	2027
Rifaximin solid soluble dispersion (SSD) in a tablet <sup>1</sup> <b>RED-C</b>			 Phase 3 Trial Start Expected					 NDA Approval Expected	
Combination of rifaximin with a mucolytic agent <sup>1</sup> <b>Irritable Bowel Syndrome - Diarrhea Cedars-Sinai Collaboration</b>				 Phase 2 Trial Start Expected	 Phase 3 Trial Start Expected			 NDA Approval Expected	
Rifaximin liquid gel capsules <sup>1</sup> <b>Small Intestinal Bacterial Overgrowth (SIBO)</b>				 Phase 2 Trial Start Expected	 Phase 3 Trial Start Expected			 NDA Approval Expected	
Rifaximin timed release coated beads in capsules <sup>1</sup> <b>Sickle Cell Anemia</b>			 Phase 1b/2a Trial Start Expected		 Phase 2b/3 Trial Start Expected				 NDA Approval Expected