AzurRx BioPharma

Combination
MS1819 + PERT

MS1819 R&D Update:
Combination Therapy Trial Interim Data
August 11, 2020

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Biotechnology company focused on the development of therapeutic proteins for GI indications

MS1819 recombinant lipase for treatment of Exocrine Pancreatic Insufficiency (EPI)

- Targeting patients with **Cystic Fibrosis (CF)** and **Chronic Pancreatitis (CP)**
- Addressing established global market (>$2 billion) (1)

Synthetic alternative to porcine pancreatic enzyme replacement therapy (PERT)

- Clear unmet medical need
- Established POC in two therapeutic indications in CF and CP

Pursuing parallel monotherapy and combination therapy clinical pathways:

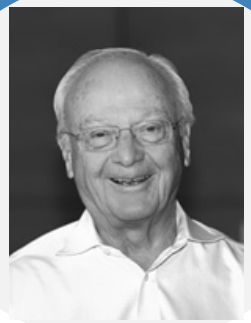
- Topline Phase 2b CF monotherapy data expected 1H 2021
- Topline Phase 2 CF combination (MS1819 + PERT) therapy data expected 1H 2021

(1) The CorStar Group 2019. Symphony Health 2019.

Management Team
Established track record of execution and value creation

James Sapirstein
Chief Executive Officer

serono biotech & beyond
TOBIRA THERAPEUTICS
GILEAD
Roche
Bristol-Myers Squibb



James Pennington, MD
Chief Medical Officer

Bayer HealthCare Pharmaceuticals
CÖTHERIX
InterMune
Anthera
HARVARD MEDICAL SCHOOL

Combined experience in developing and launching over 25 drugs

Combination Therapy: A Second Shot on Goal

Combination
MS1819 + PERT

- **Clinically Meaningful**

  - Significant unmet need for patients with severe EPI who cannot achieve adequate nutrition on standard PERT monotherapy

  - A small daily dose of MS1819 added to daily PERT has the potential to safely help patients meet their nutritional needs, alleviate multiple morbidities caused by EPI, decrease abdominal pain, and achieve a better quality of life

- **Commercially Attractive**

  – Significant niche market opportunity for moderate-severe EPI patients (CF & CP)*

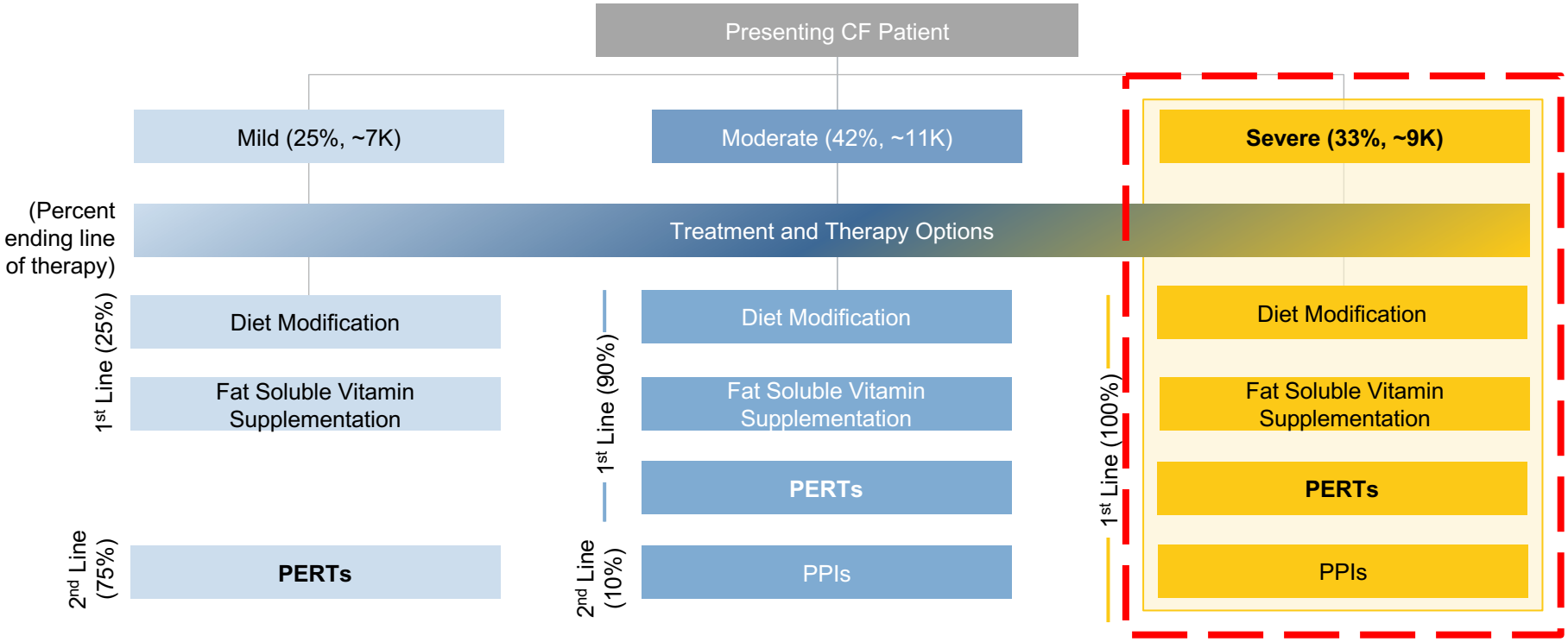
  – Potential to expand the market size of the $2 billion PERT global market for EPI treatment

  – Provides a pathway to safely and gradually shift patients to MS1819 as a replacement to PERT therapy

* Source: The CorStar Group (2019)

CF Treatment Approach

1/3 of CF Patients have Severe EPI, at maximum allowed or tolerated daily dosage of PERT



PPI:Proton-pump inhibitors

Source: Results of interviews of 10 pulmonologists, The CorStar Group 5/2019, and 10 gastroenterologists, Campbell Alliance 8/2014

Combination Study of MS1819 and PERTS in CF Patients with Severe EPI

- Satisfactory PERT should enable the patient to eat a normal to high-fat diet and avoid unpleasant gastrointestinal symptoms
- In practice, a substantial number of CF patients do not achieve normal absorption
- Reasons to add-on MS1819 in patients uncontrolled on porcine PERT
  - Daily dose at, or close to, maximum allowed by guidelines
  - Attempts to increase porcine enzymes not well tolerated
  - Physician, patients, and/or parent may want to keep porcine based products to a minimum

MS1819 Combination Therapy Clinical Trial Efficacy Endpoints

Primary Efficacy Endpoint	
Coefficient of Fat Absorption (CFA)	≥ 80%

Secondary Efficacy Endpoints
• Coefficient of Nitrogen Absorption (CNA)
• Stool Quantity (Weight)
• Steatorrhea
• # Stools per Day
• Body Weight

Phase 2 Combination Therapy (PERT + MS1819) Trial Design
Study Initiated Q4 2019, Anticipated Completion 1H 2021

Combination
MS1819 + PERT

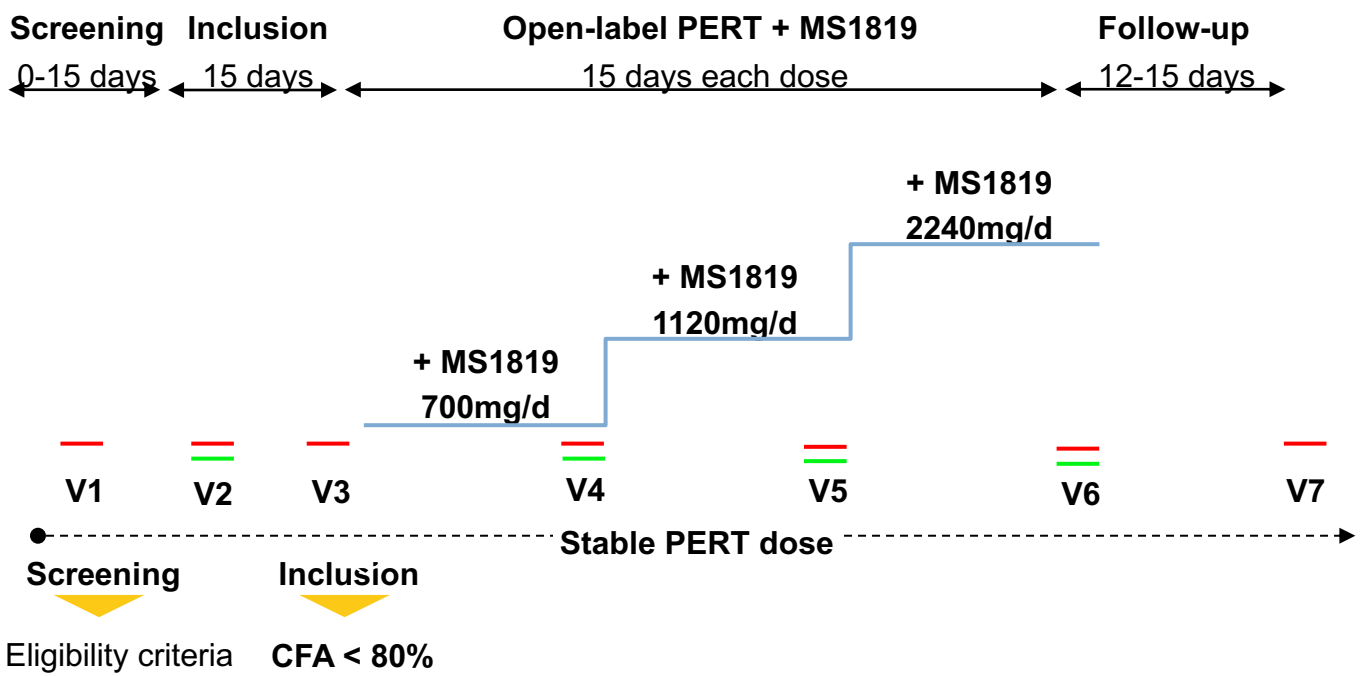
M/F ≥12 years

N = 24 patients

Duration: 100 Days

European Trial Sites

(Hungary, Spain, Turkey)



Visit

Inpatient CFA measurement

Interim Data from the First Five Patients in Combination Study

Combination
MS1819 + PERT

Mean Values	V2 PERT (Baseline)	V4 + 700mg/day MS1819	V5 + 1120mg/day MS1819	V6 + 2240mg/day MS1819
CFA (%)	78.4	88.4	87.2	86.5
CNA (%)	96.6	97.7	98.0*	97.4*
Stool Weight (g/72h)	784.2	566.6	565.0	526.6
Steatorrhea (g/24h)	21.0	11.5	12.7	13.6
# Stools per day	6.8	4.8	4.8	4.8
Body Weight (Kg)	47.6	48.6	48.6	49.4

* CNA data not available for one patient on V5 and one patient on V6.

Interim Data from the First Five Patients in Combination Study
Primary and Secondary Efficacy Endpoints Met

	V2 (Baseline)	AVG V4-V6	Change
CFA (%)	78.4	87.4	9
CNA (%)	96.6	97.7*	1.1
Stool Weight (g/72h)	784.2	552.7	-231.5
Stools/Day	6.8	4.8	-2.0
Steatorrhea (g/24h)	21.0	12.6	-8.5

* CNA data not available for one patient on V5 and one patient on V6.

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What Is a Clinically Meaningful Increase in CFA?

Some Experts Consider a 10% increase in CFA as meaningful

"Absorption of an additional 10% (10 g of a 100 g fat/day diet at 9 calories/g of fat) could lead to an additional 90 calories/day, or 32,850 calories/year, equivalent to slightly more than a 9lb weight gain/year, which is a clinically meaningful weight gain in a patient with CF."

- Konstan et al., *Clin. Invest*. (2013) 3(8), 731–741.

Even a 5% increase in CFA may be meaningful

"Theoretically, 50 kcal/day translates into a potential weight gain of 5 lbs/year, or about 1 full year's growth for a child aged 6 to 10 years (i.e., enough additional energy to promote normal weight gain and prevent growth failure)."

- Brady et al., *Journal of the American Dietetic A*ssociation (2006).

Body Weight increased by 1.8kg (~ 4 lbs.) over the 45 days of MS1819 dosing

	V2 (Baseline)	V6	Change
Body Weight (kg)	47.6	49.4	1.8
Body Weight (lbs)	105	109	4

Clinical Feedback from First Five Patients

Questions to Patients	Patients' Responses
How did you feel after adding MS1819?	4 out of 5 patients who responded said they felt better; had less abdominal pain
Were there any adverse events after starting the add-on, felt to be due to MS1819?	5 out of 5 patients who responded said there were none
What happened after you stopped taking MS1819 and went back to only taking PERT?	2 out 2 patients who responded reported that abdominal pain returned and stool frequency increased back to pre-MS1819 levels.

Combination Therapy Trial Timeline: Topline Data in 1H 2021

- Target enrollment of 24 patients and 20 patients completing the trial
  - First 5 patients have completed
  - 6th patient has completed, results being analyzed
  - 7th patient beginning treatment

- 2H 2020 enrollment completion target

- COVID-19 Risk Mitigation
  - 11 new clinical trial sites in Spain and Turkey

Re-Initiating or Initiating	Countries	# Clinical Trial Sites
July 2020	Hungary	6
September 2020	Spain (new)	5
September 2020	Turkey (new)	6
Total		**17**

Summary of Key Interim Findings

Primary Efficacy Endpoint

- CFA **>** 80% for all patients, across all visits

Secondary Efficacy Endpoints

- Stool Weight decreased
- The number of Stools/Day decreased
- Steatorrhea improved
- Body Weight increased

Safety

- Safe - no Serious Adverse Events