July 8, 2019

R&D UPDATE CALL

(NASDAQ:AZRX)

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R&D Update – MS1819

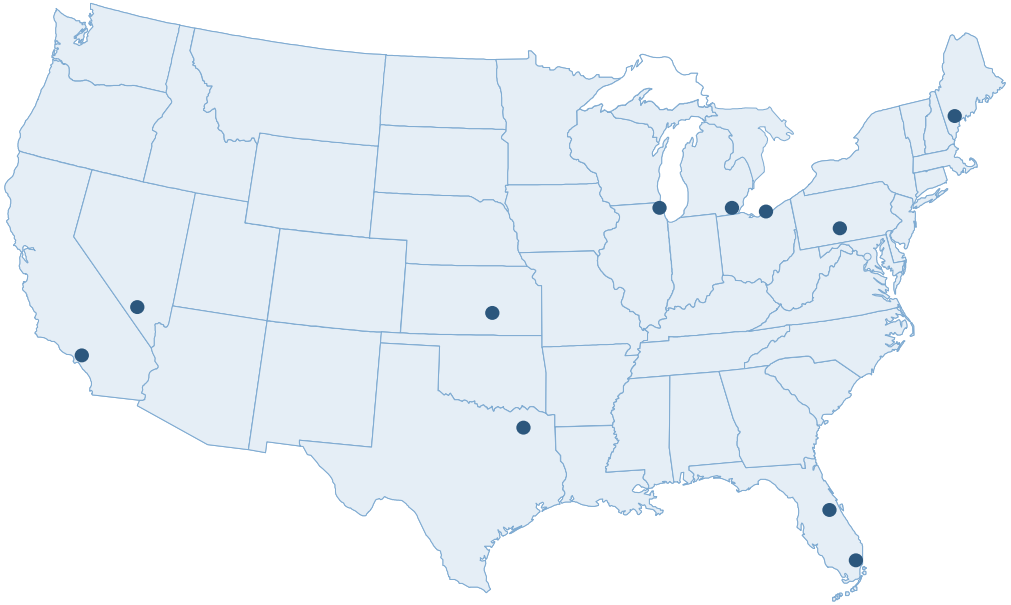
- Phase 2 Cystic Fibrosis (CF) Study Status
- Phase 2 Combination Trial in Cystic Fibrosis Patients with Severe Exocrine Pancreatic Insufficiency
- Phase 2 Chronic Pancreatitis Study Results Recap

Phase 2 Cystic Fibrosis (CF) Study Update

- All 14 sites have participated in enrollment
- Serious protocol deviations have been rare, attesting to excellent site conduct
- Safety has been excellent, with no serious adverse events related to MS1819
- Withdrawal rates have been low, compatible with, or below, other trials of synthetic enzymes
- Final data analysis is planned for September release

Study Sites for Phase 2 OPTION Study of MS1819

Option

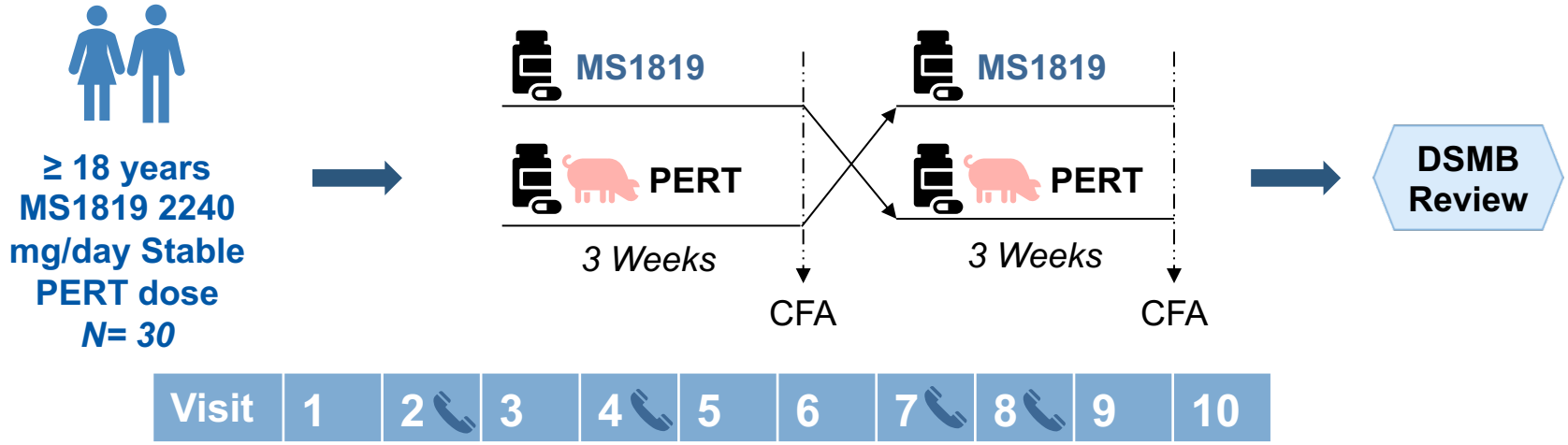


US sites

Polish sites

Phase 2 U.S. and E.U. Study in Cystic Fibrosis Has Completed Enrollment

A Phase 2 Open-Label, Multicenter, 2x2 Crossover Trial to assess the Safety and Efficacy of MS1819-SD in Patients with Exocrine Pancreatic Insufficiency due to Cystic Fibrosis



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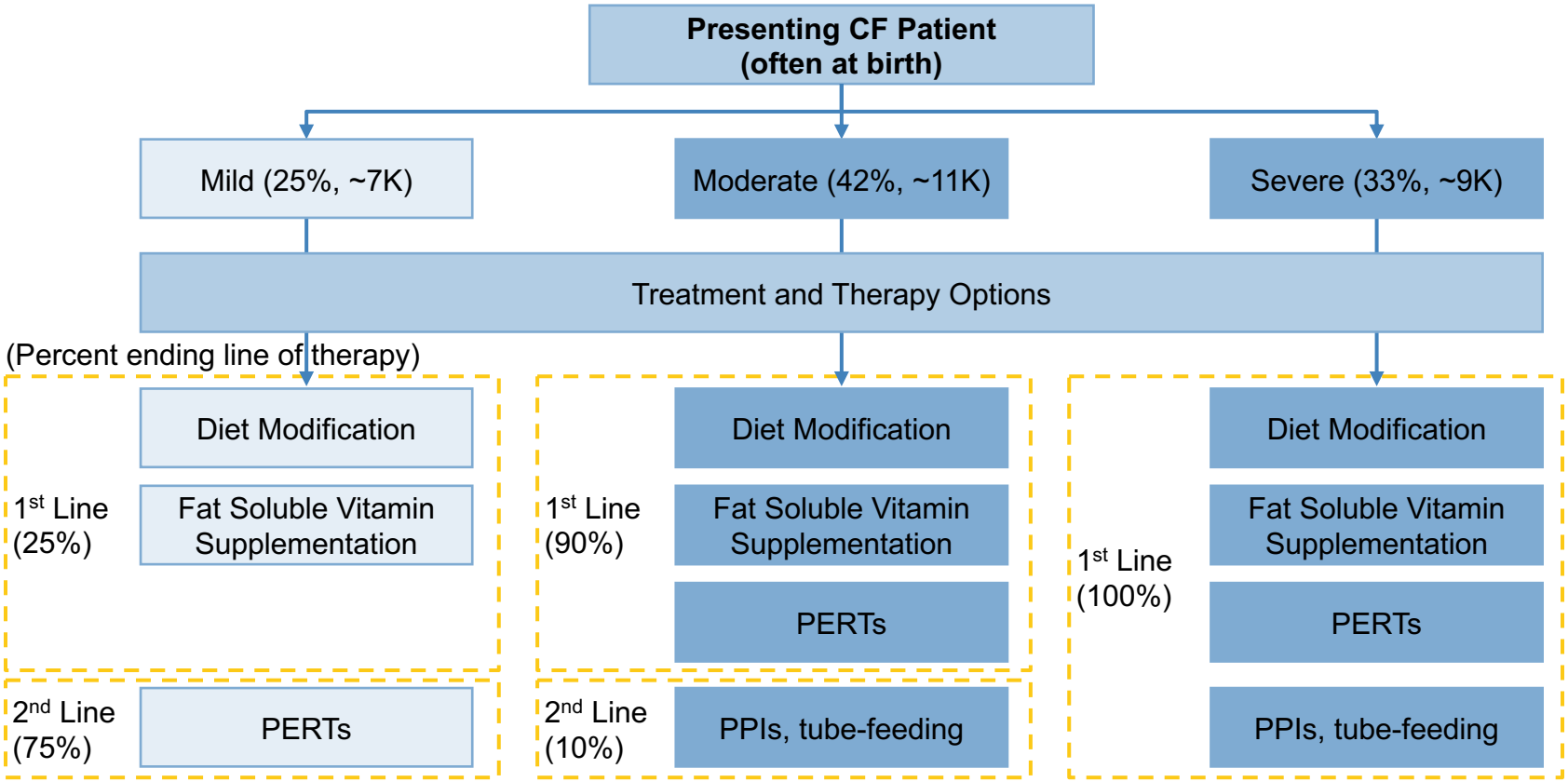
Combination Trial of MS1819 and PERT in CF Patients with Severe EPI

- Satisfactory PERT should enable the patient to eat a normal to high-fat diet and abolish unpleasant gastrointestinal symptoms
- Control of fat and protein malabsorption can be achieved in many patients[1]
- These aims should be possible in many patients with CF, using present-day enzyme preparations however there is a dose limit of up to 10,000 IU lipase/kg/day.
- In practice, a substantial number of CF patients do not achieve entirely normal fat absorption within these guidelines
- Even at specialist CF centers where there is a particular interest in the gastroenterological aspects of CF treatment, a third of CF patients achieved CFA's less than 80%[2]

1 Freedman S.D., *American Journal of Managed Care,* 2017; 23:S220-S2228
2 Littlewood, J.M. et al., *Pediatric Pulmonology,* 2006, 41:35-49

CF Digestive Problems – Treatment Approach

CF EPI patients progress through different lines of therapy.
Progressive EPI requires enzyme replacement therapy to treat the underlying deficiency.

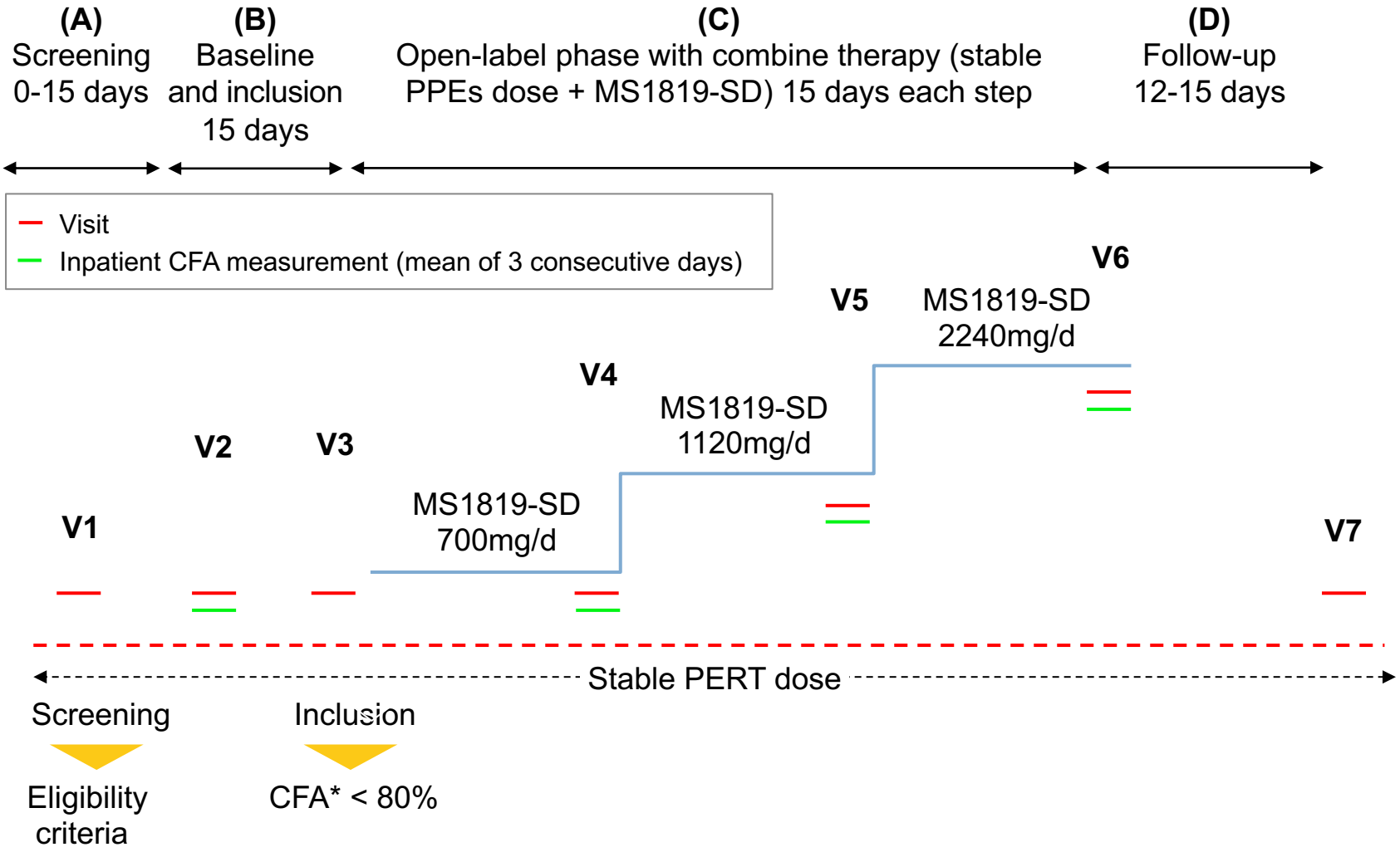


PPI: Proton-pump inhibitors
Source: Results of interviews of 10 pulmonologists, The CorStar Group 5/2019, and 10 gastroenterologists, Campbell Alliance 8/2014

Combination Trial (MS1819 & PERT) in CF Patients with Severe EPI

- Patients on ***maximum*** PERT therapy will receive increasing doses MS1819 as per the following: 700mg/day, 1120mg/day and 2240mg/day
- The total study duration will be approximately 100 days
- Enrollment target of 28 patients, with 24 patients expected to complete all dosing periods
- Trial will be conducted at six sites in Hungary
- Primary endpoints are safety and coefficient fat absorption (CFA)
- Expect preliminary data in early 2020

Phase II Clinical Study Overview: Combination Study (PERT & MS1819) Has Been Initiated



* Baseline CFA < 80% with a maximum daily dose of 10,000 lipase units/kg/day

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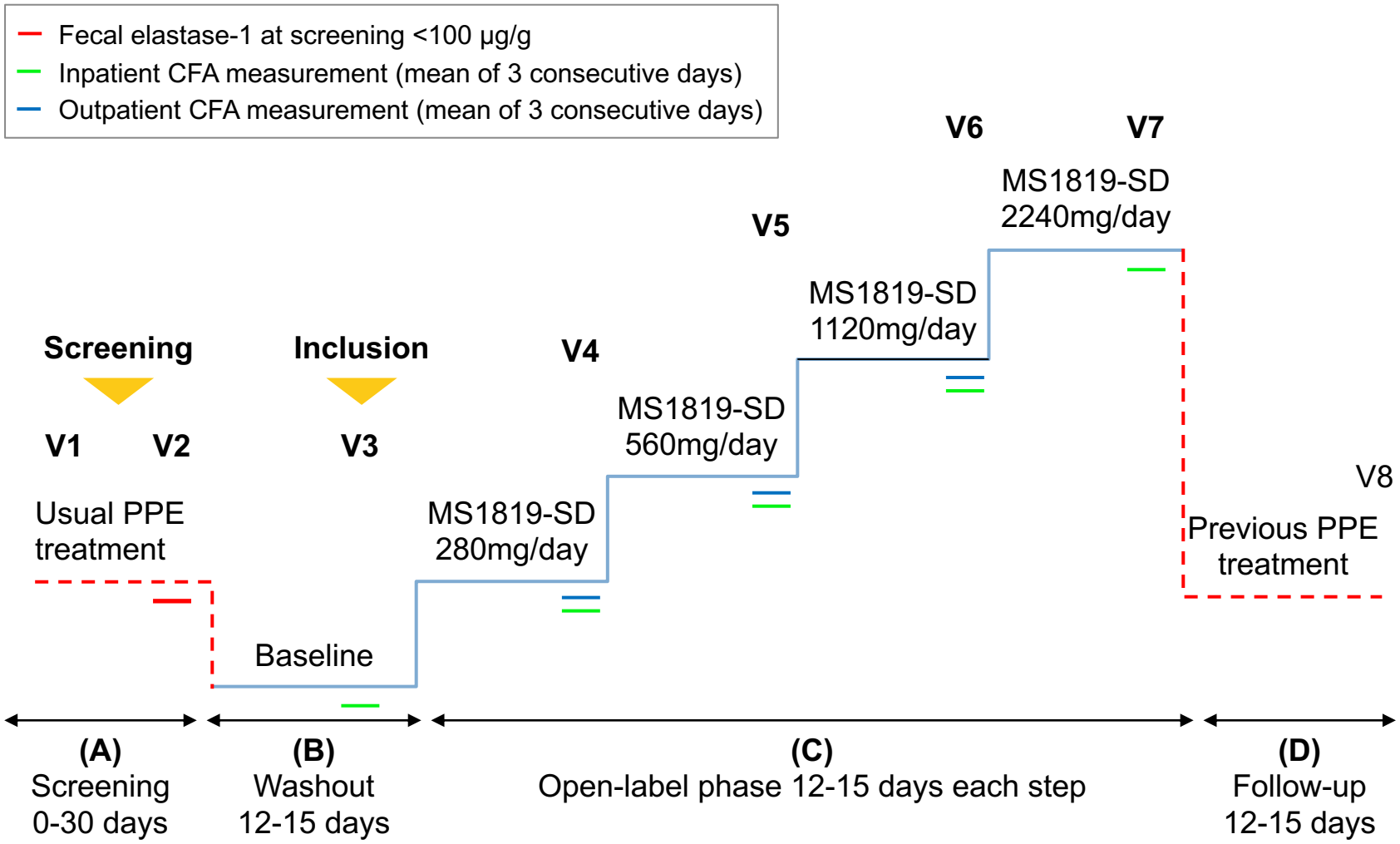
Clinical Trial Design for MS1819 Phase 2a in Chronic Pancreatitis

Trial conducted in France, Australia and New Zealand; 11 patients enrolled



Phase 2 Chronic Pancreatitis Study Recap

- 11 chronic pancreatitis patients underwent a wash-out period and then ascending doses of MS1819, with the highest daily dose being 2.2 grams per day.
- The primary efficacy endpoint was CFA change from baseline, while safety was the study's primary endpoint.
- Statistically significant improvements in CFA on an ITT and PP basis.
- Key secondary endpoints, number of bowel movements, stool consistency and steatorrhea, also showing statistically significant and clinically meaningful improvements with MS1819 treatment.
- MS1819 was shown to have a favorable safety profile with no problematic drug related adverse events.

MS1819-SD Phase 2 Study in Chronic Pancreatitis: Secondary Efficacy Endpoints

	Baseline	@ Highest Dose of MS1819-SD (2240 mg)	Mean Change	p value
Coefficient of Fat Absorption (CFA)			21.8%	0.002
Stool Consistency (Bristol Scale)	5.1	4.1	-19.6%	0.006
Bowel Movements	2.8	1.9	-32%	0.006
Steatorrhea	12.3	10.1	-18%	0.008
Abdominal Discomfort (Visual Analog Scale)	21.0	14.5	-31%	0.148

1. University of Adelaide, Adelaide, Australia; 2. AzurRx, Langlade, France; 3. Syneos Health, London, UK; 4. AzurRx, New York, NY, USA

Source: **Nam Q Nguyen**,[1] Luc Lebreton,[2] Gary Smith,[3] Philippe Jais,[2] Mathieu Schue,[2] and Thijs Spoor[4] "Impact of a spray dried recombinant lipase, MS1819, For the treatment of exocrine pancreatic insufficiency in patients with chronic pancreatitis: Results of a multicenter, Phase II, open-label, non-randomized study". Presented by Dr. Nam Q. Nguyen, et al., at Digestive Disease Week on May 20, 2019.

GI Therapeutic Product Pipeline

Product	Description	Indication	Development Phase				
			Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3
MS1819	Yeast recombinant lipase (*Yarrowia lipolytica* LIP2)	Treatment of EPI in CP patients					
		Treatment of EPI in CF patients[1] **OPTION Cross-Over Study**					
		Treatment of severe EPI in CF patients[1] **Combination PERT-MS1819 Study**					
AZX1103	Synthetic β-Lactamase	Prevention of nosocomial infections and antibiotic associated diarrhea					
MTAN	Bacterial enzyme inhibition	Treatment of *h.pylori* infections					