Targeted, Non-Systemic Therapies for Gastrointestinal Diseases

AzurRx BioPharma

Corporate Overview

AzurRx BioPharma, Inc. is a clinical stage biopharmaceutical company specializing in the development of targeted, non-systemic therapies for gastrointestinal (GI) diseases. The Company's pipeline is highlighted by two gut-restricted GI clinical programs:

- MS1819 – a recombinant lipase for the treatment of exocrine pancreatic insufficiency (EPI) in patients with cystic fibrosis (CF) and chronic pancreatitis (CP)
- Niclosamide – a pro-inflammatory pathway inhibitor being developed for COVID-19 gastrointestinal infections (RESERVOIR) and grade 1 Immune Checkpoint Inhibitor-Associated Colitis (ICI-AC) and diarrhea in oncology patients (FW-420)

PROGRAM	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONE
MS1819 LIPASE					
MONOTHERAPY (MS1819)	Exocrine Pancreatic Insufficiency in Cystic Fibrosis				Optimized Formulation
COMBINATION (MS1819 + PERT)	Exocrine Pancreatic Insufficiency in Cystic Fibrosis				Phase 2 Topline Data: Q2'21
NICLOSAMIDE					
FW-1022	COVID-19 GI Infections				Phase 2 Topline Data: Q1'22
FW-420	Immune Checkpoint Inhibitor Associated Colitis				Phase 1b/2a Initiation: 1H'21

MS1819

Yeast derived recombinant lipase enzyme administered as an oral non-systemic capsule for the treatment of EPI

- Designed as a potential improvement over porcine-derived PERT (pancreas enzyme replacement therapy)
- Development strategy: provide CF and CP patients with a safe and effective therapy to control EPI that offers the potential to dramatically reduce their daily pill burden

Monotherapy: MS1819

- Comparing MS1819 against PERT
- Developing encapsulated microbead formulation to optimize delivery of drug
- Next milestone: Optimized formulation pilot study

Combination: MS1819 + PERT

- Phase 2 comparing MS1819 + PERT against PERT
- Primary efficacy endpoint: coefficient of fat absorption
- Next milestone: Topline data in Q2 2021

Niclosamide

Pro-inflammatory pathway inhibitor for COVID-19 GI infection and checkpoint inhibitor colitis

- FDA-approved drug with broad spectrum anti-viral and anti-inflammatory properties; safely used by millions of patients
- Patented micronized formulation improves beneficial properties while maintaining safety profile
- In-licensed from First Wave Bio

RESERVOIR: COVID-19 GI Infections

- Phase 2 for treatment of GI infection caused by SARS-CoV-2
- Potential for accelerated approval via 505(b)(2) pathway
- Next milestone: Topline data in Q1 2022

FW-420: Checkpoint Inhibitor Colitis

- Phase 1b/2a for treatment of ICI-colitis and diarrhea
- Potential for accelerated approval via breakthrough designation
- Next milestone: Trial initiation in 1H 2021

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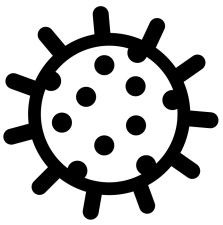
Therapeutic Indications

Exocrine Pancreatic Insufficiency (EPI) in Cystic Fibrosis

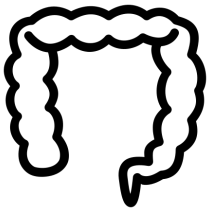
- EPI affects 30,000 cystic fibrosis patients and 90,000 chronic pancreatitis patients in the U.S.
- Pancreas is damaged and does not produce digestive enzymes; patients cannot digest or absorb their food – especially fat
- EPI patients struggle nutritionally, have difficulty gaining and retaining weight, and suffer from weight loss, severe abdominal pains, bloating, and other painful chronic side effects
- High daily PERT pill burden with CF patients currently taking 25 to 40 capsules daily to control symptoms; safety concerns with black box warnings for PERT therapy (risks of fibrosing colonopathy and transmission of animal pathogens)
- ***MS1819 is designed to provide CF and CP patients with a safe and effective therapy to control EPI that offers the potential to dramatically reduce their daily pill burden***

COVID-19 GI Infection



- SARS-CoV-2, the virus that causes COVID-19, has been shown to remain in the GI system following infection, leading to recurrence and fecal spread of the virus
- Data suggests that 18% (almost one in five) COVID-19 patients develop GI symptoms and almost 50% have viral RNA in their stool
- Extrapolated to the 28+ million cases of COVID-19 in the U.S., ~5 million patients experience GI infections. That number is four times larger on a global scale
- There currently is no targeted treatment for COVID GI infections
- ***FW-1022 has the potential to destroy SARS-CoV-2 in the GI tract by decreasing viral load in the gut, treating infection symptoms, and preventing transmission of the virus through fecal spread***

Immune Checkpoint Inhibitor-Associated Colitis (ICI-AC)



- Global market of immune checkpoint inhibitors (ICIs) is significant; >$22 billion in 2019 and growing
- Use of ICIs, particularly higher dose and combinations of ICIs, can cause potentially life-threatening side-effects, including ICI-AC
- ICI-AC can occur in ~25% of patients depending on the type of ICI and if used in combination
- ICI-AC typically begins with diarrhea and progresses to colitis. The progression to colitis is rapid and unpredictable
- Patients who exhibit these issues can become severely debilitated and risk interrupting or stopping their cancer therapy
- ***FW-420 offers the potential to safely treat grade 1 ICI colitis and diarrhea and prevent its progression to more serious and potentially fatal later stages***

Executive Management Team

James Sapirstein	President, CEO and Chairman
Daniel Schneiderman	Chief Financial Officer
James Pennington	Chief Medical Officer
Martin Krusin	SVP, Corporate Development

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