

Rezdiffra: SWOT Analysis and Strategic Evaluation

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SWOT Analysis

S Strengths

- 1st to market
- Favourable Label
- Simple Dosing
- Reasonable pricing
- Adequate Launch Funding
- Improvement in Comorbid Conditions

Weaknesses **W**

- Company lacks experience in commercialization
- Unclear EU launch strategy
- Lack of long-term safety data
- Relatively weak efficacy data

T Threats

- Competition to intensify in next 2-3 yrs
- Competitors with better clinical data
- Full approval is yet to be granted
- Not yet developed treatment paradigm
- Limited awareness and diagnosis
- Biopsy required for VA* coverage

Opportunities **O**

- Only approved Tx for next 1yr
- Inclusion in guidelines
- Indication/Geographic expansion
- Robust US launch strategy
- Favourable HCP perception



*Veterans Affairs



Rezdiffra's Strengths



1st to Market

- The first and only medication approved by the FDA for MASH F2 and F3 treatment



Clean label

- Liver biopsy not required for diagnosis
- No contraindications; no boxed warning
- No monitoring requirements beyond the SoC



Simple dosing

- Oral
- Once-daily



Reasonable Pricing

- WAC pricing of \$47,400 (*falls within ICER's recommended range*)



Adequate Launch Funding

- \$690M raised from public offering
- \$1.1B of cash as of March end
- Positive indicators of launch execution



Improvement in Comorbid Conditions

- Showed benefits in cardiometabolic biomarkers, including improvements in lipoproteins (LDL, ApoB, triglycerides)

Rezdifra's Weaknesses



Company lacks experience in commercialization

- Madrigal is transitioning to a commercial organization with no prior marketed product



Unclear EU launch strategy

- It is not clear if Madrigal will launch in the EU alone or with a partner



Lack of long-term safety data

- Though the safety profile looks favorable at 52 weeks, confirmatory and long-term studies are still ongoing
- Long-term sex hormone-binding elevations need to be looked out for



Relatively weak efficacy data

- FGF21 and GLP1 analogs have better preliminary results for MASH resolution and liver fibrosis improvement



Rezdiffra's Opportunities



**Only
approved Tx
for next 1yr**

- Expected to be the only marketed therapy till 2H'25 before the next expected launch



**Inclusion in
guidelines**

- Revision in MASH guidelines expected to include Rezdiffra. This may position it as a Foundational Therapy in MASH



**Indication &
Geographic
Expansion**

- Possibility of securing approval for F4-compensated patients
- Expected approval in the EU in 2025



**Well laid out
commercial
strategy**

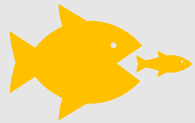
- Hired experienced commercial personnel with prior Hep/GI experience
- Well defined HCP and patient targets



**Favorable
HCP
Perception**

- Market research supports high demand for Rezdiffra

Rezdiffra's Threats



**Competition
to intensify in
next 2-3 years**

- Several late-stage competitors (Novo Nordisk, Inventiva, Akerio, 89Bio) to enter the market by 2029



**Competitors
with better
clinical data**

- Preliminary data from FGF21 and GLP1 analogs have shown better MASH resolution and fibrosis improvement



**Veterans Affairs
requiring a
biopsy**

- The Veterans Affairs (VA) instituted a policy that requires a biopsy to qualify for Rezdiffra coverage



**MASH treatment
pathway not
developed**

- Healthcare system needs to be primed and there is no prior benchmark to follow



**Full approval
yet to be
granted**

- Data from confirmatory studies (MAESTRO-NASH and MAESTRO-NASH OUTCOMES) yet to be reported



Competitive Intelligence
Launch Strategy
AI Platform

Dive deeper into the evolving landscape of **MASH**

Email us at  info@atacana.com