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

W Weaknesses

- 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

O Opportunities

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

*Veterans Affairs

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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)

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Rezdiffra'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

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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

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Rezdiffra's Threats

Competition to intensify in next 2-3 years	• Several late-stage competitors (Novo Nordisk, Inventiva, Akero, 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 form confirmatory studies (MAESTRO-NASH and MAESTRO-NASH OUTCOMES) yet to be reported

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