

Simvastatin Oral Solution (a 505B2 NDA Product)

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Timelines for Developing Brand XXXXXX ®

RLD PRODUCT NAME

Zocor ® Tablet, 5mg, 10mg,
20mg, 40mg, 80mg

API NAME

Simvastatin

DOSAGE FORM

Oral Solution, 20mg/5ml, 40mg/5ml

INDICATION

Cholesterol

PATENT STATUS

Mahashiv owns Patent Pending for the product
and technology

PARAGRAPH IV CERTIFICATION

NA

ANDA FILER

NA

POTENTIAL COMPETITORS

No generic competition

EARLIEST GENERIC LAUNCH

NA

- Definitive Agreement – Q3 2023
- Completion of 3×3 exhibit (pivotal) batches of drug product:Q1 2024
- 6 Month stability completion: Q4 2024
- BE study completion: Q3 2024
- Estimated FDA filing date:Q4 2024
- FDA approval: Q4 2025

Terms for US Partner:

- Total Milestone payments: \$875,000
 - \$200,000 on signing
 - \$225,000 on Bioequivalence study Acceptance
 - \$225,000 on 505(b)(2) filing to FDA
 - \$225,000 on FDA Approval
- Filing Fee: Partner pays upfront (recoup 50% of fee from profits)
- Profit sharing: DP 50%/ 50% Partner
- Length of Term: 10 years

Estimated Remaining Development Costs (50% DP/50% Partner):

- Formulation Development Cost: \$500,000
- Submission batches: \$ 300,000 (India) (5 batches- 3 validation and two feasibility batches; includes API cost of \$2,000)
- Bioequivalence studies: \$250,000
- Stability & non-clinical studies:*\$200,000

+ Please note that the submission batches costs from India, should we move to EU/US CDMO, then costs will increase.

Estimated Commercial Finished Dose Cost

COG: \$10.00 per unit-dose bottle pack (150ml) includes packaging, shipping, insurance etc. Please note that these COGS are based on manufacturing in India, should we move manufacturing to EU/US CDMO, then costs will increase.