Sertraline ODT
(a 505B2 NDA Product)

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RLD PRODUCT NAME
Zoloft ® Tablet, 25mg, 50mg, 100mg

API NAME
Sertraline Hydrochloride

DOSAGE FORM
ODT, 25mg,50mg,100mg

INDICATION
Antidepressant (SSRI)

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

Timelines for Developing Brand XXXXXX ®

- Definitive Agreement – Q3 2023
- Completion of 3×3 exhibit (pivotal) batches of drug product:Q4 2023
- 6 Month stability completion: Q3 2024
- BE study completion: Q2 2024
- Estimated FDA filing date:Q3-4 2024
- FDA approval: Q4 2025

Terms for US Partner:

- Total Milestone payments: $950,000
  - $200.000 on signing
  - $250,000 on Bioequivalence study Acceptance
  - $250,000 on 505(b)(2) filing to FDA
  - $250,000 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: $ 400,000 (India) (10 batches- 9 validation and one feasibility batches; includes API cost of $36,000)

- Bioequivalence studies: $200,000
- Stability & non-clinical studies:*$250,000

+ 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: $15.00 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.**