

# Fexofenadine Oral Suspension (a 505B2 NDA Product)

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## 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: \$750,000
  - \$175,000 on signing
  - \$175,000 on Bioequivalence study Acceptance
  - \$200,000 on 505(b)(2) filing to FDA
  - \$200,000 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: \$ 250,000 (India) (5 batches- 3 validation and two feasibility batches; includes API cost of \$9,000)
- Bioequivalence studies: \$200,000
- Stability & non-clinical studies: \*\$100,000

+ 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.

### **RLD PRODUCT NAME**

Alegra ® Tablet, 30mg, 120mg  
and 180mg

### **API NAME**

Fexofenadine Hydrochloride

### **DOSAGE FORM**

Oral Suspension, 180mg/5ml

### **INDICATION**

Antihistamine

### **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

