



# Linagliptin Oral Solution (a 505B2 NDA Product)

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## RLD PRODUCT NAME

Tradjenta ® Tablet, 5mg

## API NAME

Linagliptin

## DOSAGE FORM

Oral Solution, 5mg/5ml

## INDICATION

Type 2 diabetes

## 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: Q1 2024
- 6 Month stability completion: Q4 2024
- BE study completion: Q3 2024
- Estimated FDA filing date: Q1 2025
- FDA approval: Q1 2026

## Terms for US Partner:

- Total Milestone payments: \$800,000
  - \$200,000 on signing
  - \$200,000 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 \$4,425)
- Bioequivalence studies: \$300,000
- 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.