Protocol Title: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XYZ-123 in Patients with Type 2 Diabetes

Protocol Number: XYZ-123-002
Sponsor: XYZ Pharmaceuticals Inc.
Study Phase: Phase II
Indication: Type 2 Diabetes Mellitus

Study Design:
- Type: Randomized, double-blind, placebo-controlled
- Duration: 24 weeks treatment + 4 weeks follow-up
- Number of Arms: 3 (XYZ-123 low dose, XYZ-123 high dose, placebo)
- Target Enrollment: 300 patients

Primary Objectives:
- To evaluate the efficacy of XYZ-123 compared to placebo in reducing HbA1c levels

Primary Endpoints:
- Change from baseline in HbA1c at week 24

Secondary Objectives:
- To evaluate safety and tolerability of XYZ-123
- To assess impact on fasting glucose levels

Secondary Endpoints:
- Incidence of adverse events
- Change from baseline in fasting glucose at week 24

Study Population:
- Adults aged 18-75 years
- Type 2 diabetes mellitus diagnosis
- HbA1c between 7.0% and 10.5%

Visit Schedule:
- Screening: Day -28 to -1
- Baseline: Day 1
- Treatment visits: Weeks 2, 4, 8, 12, 16, 20, 24
- Follow-up: Week 28

Key Inclusion Criteria:
- Adults aged 18-75 years
- Diagnosis of type 2 diabetes mellitus
- HbA1c 7.0% to 10.5% at screening
- Stable antidiabetic medication for ≥3 months

Key Exclusion Criteria:
- Type 1 diabetes mellitus
- Recent cardiovascular events
- Significant kidney or liver disease
- Pregnancy or breastfeeding