**Novostatin (Novitor) Phase 2 Electronic Case Report Form (eCRF)**

**Protocol Number:** NSP-002-2024  
**Study Title:** A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Novostatin (Novitor) in Patients with Hypercholesterolemia  
**Study Duration:** March 2, 2024 – September 22, 2024

**Page 1: Subject Identification and Screening Information**

**Subject ID:** NS-102  
**Date of Informed Consent:** 02/25/2024  
**Screening Date:** 02/26/2024

**Demographics**

* **Age:** 56 years
* **Sex:** Male
* **Race/Ethnicity:** Caucasian
* **Height:** 175 cm
* **Weight:** 88 kg
* **BMI:** 28.7 kg/m²

**Medical History**

* **Primary Diagnosis:** Hypercholesterolemia
* **Concomitant Conditions:** Hypertension, Mild Type 2 Diabetes
* **Previous Statin Use:** Yes (Atorvastatin 20 mg; discontinued due to myalgia)

**Inclusion/Exclusion Criteria Check**

* **Inclusion:**
  + LDL ≥ 130 mg/dL (Measured LDL: 165 mg/dL) ✓
  + Age 18–75 years ✓
  + BMI between 18 and 35 kg/m² ✓
* **Exclusion:**
  + History of statin intolerance (subject reports mild intolerance to previous statin use, but meets current protocol criteria) ✓
  + Abnormal liver function tests (ALT: 32 U/L; AST: 29 U/L; within normal limits) ✓

**Investigator’s Comments:**  
Patient meets all screening criteria. Eligible for randomization.

**Page 2: Baseline Assessments and Randomization**

**Baseline Visit Date:** 03/02/2024

**Vital Signs and Physical Examination**

* **Blood Pressure:** 132/82 mmHg
* **Heart Rate:** 72 bpm
* **Temperature:** 36.8 °C
* **General Physical Exam:** No abnormalities detected

**Laboratory Assessments**

* **Lipid Panel:**
  + LDL Cholesterol: 165 mg/dL
  + Total Cholesterol: 240 mg/dL
  + HDL Cholesterol: 45 mg/dL
  + Triglycerides: 180 mg/dL
* **Liver Function Tests:**
  + ALT: 32 U/L
  + AST: 29 U/L
* **Creatine Kinase (CK):** 110 U/L
* **Fasting Glucose:** 105 mg/dL

**Randomization**

* **Randomization Date:** 03/02/2024
* **Treatment Assignment:** Novostatin 10 mg (Active Treatment)
* **Randomization Code:** A-102

**Investigator’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Date:** 03/02/2024

**Page 3: Treatment Administration and Follow-Up Visit (Week 4)**

**Visit Date:** 03/30/2024  
**Visit Number:** Week 4

**Medication Compliance**

* **Study Drug:** Novostatin 10 mg once daily
* **Dosing Compliance:** 100% (Patient self-reported; pill count verified)

**Vital Signs**

* **Blood Pressure:** 130/80 mmHg
* **Heart Rate:** 70 bpm
* **Weight:** 87.5 kg

**Laboratory Assessments**

* **Lipid Panel (Interim):**
  + LDL Cholesterol: 150 mg/dL (↓9% from baseline)
  + Total Cholesterol: 230 mg/dL
  + HDL Cholesterol: 47 mg/dL
  + Triglycerides: 175 mg/dL
* **Liver Function Tests:**
  + ALT: 30 U/L
  + AST: 28 U/L
* **Creatine Kinase (CK):** 115 U/L

**Adverse Events Reporting**

* **Reported Adverse Event:** Mild headache reported on 03/28/2024.
* **Severity:** Mild
* **Relationship to Study Drug:** Possibly related
* **Action Taken:** Symptomatic treatment; continued study drug

**Investigator’s Comments:**  
Patient tolerating study drug well with gradual improvements in LDL levels.

**Investigator’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Date:** 03/30/2024

**Page 4: Efficacy Endpoint Assessment (Week 24 / End-of-Treatment)**

**Visit Date:** 09/22/2024  
**Visit Number:** Week 24

**Final Efficacy Assessments**

* **Lipid Panel:**
  + **LDL Cholesterol:** 135 mg/dL (Mean percentage reduction: ~18% from baseline)
  + **Total Cholesterol:** 210 mg/dL
  + **HDL Cholesterol:** 50 mg/dL
  + **Triglycerides:** 160 mg/dL

**Safety Assessments**

* **Liver Function Tests:**
  + ALT: 29 U/L
  + AST: 27 U/L
* **Creatine Kinase (CK):** 112 U/L

**Patient Global Assessment**

* **Overall Tolerability:** Good
* **Quality of Life Score (Questionnaire):** Improved from baseline

**Investigator’s Summary**

* **Clinical Impression:**  
  The subject has demonstrated a significant reduction in LDL cholesterol, meeting the primary endpoint of the study. No serious adverse events have been recorded. The subject’s safety and tolerability profile is consistent with expectations for Novostatin.
* **Study Outcome:** Positive result; supports advancement to Phase 3 trials.

**Investigator’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
**Date:** 09/22/2024