**Patient Disposition and Flow Diagram**

**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

**Protocol Number:** NSP-002-2024  
**Study Duration:** March 2, 2024 – September 22, 2024  
**Sponsor:** Novitor Pharmaceuticals Inc.

**1. Overview**

This document summarizes the patient disposition throughout the Phase 2 trial of Novostatin (Novitor). It provides a visual representation of patient progress from screening through to analysis (consistent with CONSORT guidelines) and details the reasons for exclusions and discontinuations.

**2. Patient Disposition Summary**

* **Assessed for Eligibility:** 250 subjects
* **Excluded Prior to Randomization:** 50 subjects
  + **Not meeting inclusion criteria:** 30 subjects
  + **Declined to participate:** 15 subjects
  + **Other reasons:** 5 subjects
* **Randomized:** 200 subjects

**Allocation**

* **Novostatin (Novitor) Group:** 100 subjects
* **Placebo Group:** 100 subjects

**Follow-Up**

* **Novostatin Group:**
  + Completed treatment: 95 subjects
  + Discontinued: 5 subjects
    - Reasons:
      * Adverse events: 2 subjects
      * Withdrew consent: 1 subject
      * Lost to follow-up: 2 subjects
* **Placebo Group:**
  + Completed treatment: 98 subjects
  + Discontinued: 2 subjects
    - Reasons:
      * Withdrew consent: 1 subject
      * Lost to follow-up: 1 subject

**Analysis Populations**

* **Intent-to-Treat (ITT):** 200 subjects (all randomized subjects included in the primary efficacy analysis)
* **Per-Protocol (PP):** 190 subjects (subjects who completed the study without major protocol violations)

**3. Flow Diagram**

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Assessed for Eligibility

(n = 250)

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│ Excluded (n = 50) │

│ - Not meeting criteria (30)│

│ - Declined consent (15) │

│ - Other (5) │

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Randomized (n = 200)

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Allocated to Novostatin (n = 100) Allocated to Placebo (n = 100)

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Completed (n = 95) Discontinued (n = 5) Completed (n = 98) Discontinued (n = 2)

│ │ │ │

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│ └──────── Reasons for discontinuation ─────────┘

│ - Adverse events, - Withdrew consent,

│ - Lost to follow-up, - Lost to follow-up

│ etc. etc.

▼ ▼

Included in ITT Analysis (n = 100) Included in ITT Analysis (n = 100)

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Included in PP Analysis (n = 95) Included in PP Analysis (n = 98)

**4. Narrative Summary**

A total of 250 subjects were assessed for eligibility. Of these, 50 were excluded due to not meeting the study’s inclusion criteria, declining participation, or other reasons. Two hundred subjects were subsequently randomized into the trial, with 100 subjects allocated to receive Novostatin (Novitor) and 100 to receive placebo.

During the treatment phase, 95 subjects in the Novostatin group completed the study, while 5 subjects discontinued due to adverse events, withdrawal of consent, or loss to follow-up. In the placebo group, 98 subjects completed treatment, and 2 subjects discontinued due to withdrawal of consent or loss to follow-up.

All 200 randomized subjects were included in the Intent-to-Treat analysis, and a Per-Protocol analysis was conducted on the 190 subjects who completed the study without major protocol violations.

The overall positive patient disposition, along with the robust efficacy and safety data collected, supports the progression of Novostatin to Phase 3 clinical trials.

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