**Efficacy Analysis Summaries**

**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.

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**1. Introduction**

This document summarizes the efficacy analysis for the Phase 2 clinical trial of Novostatin (Novitor). The primary endpoint was the mean percentage change in LDL cholesterol from baseline to Week 24. Secondary endpoints included changes in total cholesterol, HDL cholesterol, and triglyceride levels. The analyses were conducted on the Intent-to-Treat (ITT) population, and the results demonstrate statistically significant improvements in lipid parameters for subjects treated with Novostatin compared to placebo. Based on these positive findings, it is recommended to proceed to Phase 3 clinical trials.

**2. Methods**

**2.1 Analysis Population**

* **Intent-to-Treat (ITT) Population:**  
  All randomized subjects who received at least one dose of study medication and had at least one post-baseline lipid measurement.

**2.2 Statistical Methods**

* **Primary Analysis:**  
  Analysis of covariance (ANCOVA) was used with the percentage change in LDL cholesterol as the dependent variable, adjusted for baseline LDL levels and treatment group.
* **Secondary Analyses:**  
  Descriptive statistics and ANCOVA models were used for changes in total cholesterol, HDL cholesterol, and triglycerides. A two-sided significance level of 0.05 was applied.

**3. Results**

**3.1 Primary Endpoint**

**Table 1: Summary of Primary Endpoint – Mean Percentage Change in LDL Cholesterol (Week 24)**

| **Treatment Group** | **n** | **Baseline LDL (mg/dL)** | **Mean % Change in LDL** | **Standard Deviation** | **p-value** |
| --- | --- | --- | --- | --- | --- |
| Novostatin (Novitor) | 100 | 160.0 ± 15.0 | -20.5% | 6.0% | < 0.001 |
| Placebo | 100 | 158.0 ± 16.0 | -4.8% | 4.5% | – |

**Text Summary:**  
Subjects treated with Novostatin experienced a mean LDL cholesterol reduction of 20.5% from baseline to Week 24, compared to a 4.8% reduction in the placebo group. The between-group difference was statistically significant (p < 0.001).

**Figure 1: Mean Percentage Change in LDL Cholesterol Over Time**

*(A line graph depicts the progressive decline in LDL cholesterol levels in the Novostatin group compared to a minimal change in the placebo group from baseline through Week 24.)*

**3.2 Secondary Endpoints**

**Table 2: Summary of Secondary Endpoints – Lipid Parameter Changes at Week 24**

| **Parameter** | **Novostatin (Novitor)** | **Placebo** | **Between-Group Difference** | **p-value** |
| --- | --- | --- | --- | --- |
| Total Cholesterol | -15.0% | -3.5% | -11.5% | < 0.001 |
| HDL Cholesterol | +5.0% | +1.0% | +4.0% | 0.002 |
| Triglycerides | -12.0% | -2.0% | -10.0% | < 0.001 |

**Text Summary:**  
In addition to LDL reduction, Novostatin significantly improved other lipid parameters. Total cholesterol was reduced by 15.0% in the Novostatin group compared to a 3.5% reduction in the placebo group. HDL cholesterol increased by 5.0% with Novostatin versus 1.0% in the placebo group, while triglycerides decreased by 12.0% compared to a 2.0% reduction with placebo. All differences were statistically significant.

**3.3 Additional Findings**

* **Subgroup Analysis:**  
  Subgroup analyses based on age, gender, and baseline cardiovascular risk factors showed consistent efficacy across all groups.
* **Responder Analysis:**  
  A responder analysis indicated that 75% of subjects in the Novostatin arm achieved a ≥15% reduction in LDL cholesterol, compared to 20% in the placebo arm.
* **Safety and Tolerability:**  
  Efficacy findings were accompanied by a favorable safety profile, with minimal adverse events reported and no serious safety concerns, supporting the overall positive benefit-risk assessment of Novostatin.

**4. Conclusion**

The efficacy analysis of the Phase 2 trial demonstrates that Novostatin (Novitor) significantly reduces LDL cholesterol levels and improves other lipid parameters compared to placebo. The robust efficacy signal, combined with an acceptable safety profile, supports the decision to advance to Phase 3 clinical trials for further evaluation in a larger patient population.

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