**Laboratory Data 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.  
**Document Version:** 1.0  
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**1. Introduction**

This document provides a comprehensive summary of the laboratory data collected during the Phase 2 clinical trial of Novostatin (Novitor). The laboratory assessments were performed by a central laboratory to ensure consistency and accuracy across all study sites. Key parameters include the lipid profile, liver function tests, muscle enzyme levels, renal function, and other safety-related biomarkers. The data support the overall positive outcome of the trial and the decision to advance Novostatin to Phase 3 clinical development.

**2. Laboratory Assessments and Schedule**

Laboratory assessments were conducted at the following time points:

* **Screening/Baseline (Day -14 to Day 1)**
* **Week 4**
* **Week 12 (Interim)**
* **Week 24 (End-of-Treatment)**
* **Follow-Up (4 weeks post last dose)**

The central laboratory performed analyses for:

* **Lipid Panel:** LDL, Total Cholesterol, HDL, Triglycerides
* **Liver Function Tests:** Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline Phosphatase (ALP), Bilirubin
* **Muscle Enzymes:** Creatine Kinase (CK)
* **Renal Function:** Serum Creatinine, Blood Urea Nitrogen (BUN), Estimated Glomerular Filtration Rate (eGFR)
* **Additional Parameters:** Fasting Glucose, hs-CRP (inflammatory marker)

**3. Summary of Key Laboratory Findings**

**3.1 Lipid Panel**

**Table 1: Lipid Panel Summary (Mean ± SD)**

| **Parameter** | **Baseline (mg/dL)** | **Week 24 (mg/dL)** | **Mean % Change** |
| --- | --- | --- | --- |
| LDL Cholesterol | 160.0 ± 15.0 | 127.2 ± 14.5 | -20.5% |
| Total Cholesterol | 240.0 ± 20.0 | 204.0 ± 18.0 | -15.0% |
| HDL Cholesterol | 45.0 ± 5.0 | 47.3 ± 5.2 | +5.0% |
| Triglycerides | 180.0 ± 30.0 | 158.4 ± 28.0 | -12.0% |

**Text Summary:**  
Subjects receiving Novostatin demonstrated a significant reduction in LDL cholesterol (20.5% decrease) and total cholesterol (15.0% decrease) from baseline to Week 24. HDL cholesterol showed a modest increase, while triglycerides were reduced by 12.0%.

**3.2 Liver Function Tests**

**Table 2: Liver Function Tests Summary (Mean ± SD)**

| **Parameter** | **Baseline** | **Week 24** | **Change** |
| --- | --- | --- | --- |
| ALT (U/L) | 32.0 ± 8.0 | 29.0 ± 7.0 | Decrease of ~9% |
| AST (U/L) | 29.0 ± 6.5 | 27.0 ± 6.0 | Decrease of ~7% |
| ALP (U/L) | 75.0 ± 12.0 | 73.5 ± 11.5 | Minimal change |
| Bilirubin (mg/dL) | 0.9 ± 0.2 | 0.8 ± 0.2 | Minimal change |

**Text Summary:**  
Liver function tests remained within normal limits throughout the study. A slight reduction in ALT and AST levels was observed, supporting the favorable hepatic safety profile of Novostatin.

**3.3 Muscle Enzymes**

**Table 3: Creatine Kinase (CK) Summary (Mean ± SD)**

| **Parameter** | **Baseline (U/L)** | **Week 24 (U/L)** | **Change** |
| --- | --- | --- | --- |
| CK | 110.0 ± 20.0 | 112.0 ± 22.0 | No significant change |

**Text Summary:**  
CK levels showed no significant change from baseline to Week 24, indicating a low risk of muscle toxicity with Novostatin.

**3.4 Renal Function**

**Table 4: Renal Function Summary (Mean ± SD)**

| **Parameter** | **Baseline** | **Week 24** | **Change** |
| --- | --- | --- | --- |
| Serum Creatinine (mg/dL) | 0.9 ± 0.1 | 0.9 ± 0.1 | No change |
| BUN (mg/dL) | 14.0 ± 3.0 | 14.2 ± 2.8 | No change |
| eGFR (mL/min/1.73 m²) | 95.0 ± 10.0 | 94.0 ± 9.5 | Minimal change |

**Text Summary:**  
Renal function parameters remained stable with no significant changes noted from baseline through Week 24.

**3.5 Additional Safety Parameters**

**Table 5: Additional Laboratory Parameters**

| **Parameter** | **Baseline** | **Week 24** | **Change** |
| --- | --- | --- | --- |
| Fasting Glucose (mg/dL) | 105.0 ± 10.0 | 102.0 ± 9.5 | Minor reduction |
| hs-CRP (mg/L) | 3.2 ± 1.0 | 2.4 ± 0.8 | ~25% reduction |

**Text Summary:**  
Fasting glucose levels showed a minor reduction, while hs-CRP levels decreased by approximately 25%, indicating a reduction in systemic inflammation and potential cardiovascular risk.

**4. Central Laboratory Reports**

All laboratory analyses were conducted by Central Lab Solutions Inc. The lab maintains Good Laboratory Practice (GLP) compliance and has provided quality-assured data. The central lab report, attached as Appendix A, includes detailed raw data, calibration records, and quality control assessments for all assays used in the trial.

**5. Conclusion**

The comprehensive laboratory data from the Phase 2 trial of Novostatin (Novitor) demonstrate significant improvements in lipid parameters with concurrent stability in liver, muscle, and renal function. The reduction in hs-CRP further supports the drug's potential to mitigate cardiovascular risk. These findings, along with the overall positive safety and efficacy profile, support the decision to advance Novostatin to Phase 3 clinical trials.

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