**Adverse Event (AE) and Serious Adverse Event (SAE) Report**

**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.  
**Report Version:** 1.0  
**Report Date:** September 30, 2024

**1. Introduction**

This report provides a detailed summary of all Adverse Events (AEs) and Serious Adverse Events (SAEs) observed during the Phase 2 clinical trial of Novostatin (Novitor). The purpose is to ensure comprehensive documentation of safety events, assess the risk/benefit profile of the investigational product, and support the decision to progress to Phase 3 trials. All reported events were monitored, documented, and evaluated for severity, relationship to study drug, and outcome.

**2. Overall Summary of Adverse Events**

**2.1. Adverse Event Summary Table**

| **AE ID** | **Subject ID** | **Event Description** | **Onset Date** | **Severity** | **Relationship to Study Drug** | **Outcome** |
| --- | --- | --- | --- | --- | --- | --- |
| AE-001 | NS-102 | Mild headache | 03/28/2024 | Mild | Possibly related | Resolved |
| AE-002 | NS-105 | Transient gastrointestinal discomfort | 04/05/2024 | Mild | Possibly related | Resolved |
| AE-003 | NS-110 | Mild dizziness | 04/15/2024 | Mild | Unlikely related | Resolved |
| AE-004 | NS-115 | Muscle cramps | 05/02/2024 | Moderate | Possibly related | Ongoing (Improving) |
| AE-005 | NS-120 | Mild rash | 05/20/2024 | Mild | Unlikely related | Resolved |
| AE-006 | NS-128 | Elevated liver enzymes (ALT, AST) | 05/07/2024 | Moderate | Possibly related | Resolved after dose adjustment |

**2.2. Serious Adverse Event Summary Table**

| **SAE ID** | **Subject ID** | **Event Description** | **Onset Date** | **Severity** | **Relationship to Study Drug** | **Action Taken** | **Outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SAE-001 | NS-107 | Acute allergic reaction | 04/25/2024 | Severe | Possibly related | Hospitalization, medication discontinued, supportive care provided | Recovered; Resolved |

**3. Detailed Adverse Event Listings**

**AE-001 – Mild Headache (Subject NS-102)**

* **Event Description:**  
  Subject NS-102 reported experiencing a mild headache on 03/28/2024.
* **Severity:** Mild
* **Relationship to Study Drug:** Possibly related
* **Action Taken:**  
  Subject was advised to use over-the-counter analgesics; no study drug discontinuation required.
* **Outcome:** Resolved by 03/30/2024.

**AE-002 – Transient Gastrointestinal Discomfort (Subject NS-105)**

* **Event Description:**  
  Subject NS-105 experienced transient gastrointestinal discomfort, characterized by mild nausea and abdominal pain.
* **Severity:** Mild
* **Relationship to Study Drug:** Possibly related
* **Action Taken:**  
  Symptomatic treatment provided; study drug continued.
* **Outcome:** Symptoms resolved within 48 hours.

**AE-003 – Mild Dizziness (Subject NS-110)**

* **Event Description:**  
  Subject NS-110 reported an episode of mild dizziness during a post-dose observation.
* **Severity:** Mild
* **Relationship to Study Drug:** Unlikely related
* **Action Taken:**  
  Patient was monitored; no additional interventions required.
* **Outcome:** Resolved spontaneously.

**AE-004 – Muscle Cramps (Subject NS-115)**

* **Event Description:**  
  Subject NS-115 experienced muscle cramps beginning on 05/02/2024.
* **Severity:** Moderate
* **Relationship to Study Drug:** Possibly related
* **Action Taken:**  
  Dose maintained with close monitoring; subject advised on hydration and stretching.
* **Outcome:** Ongoing, with gradual improvement noted at last follow-up.

**AE-005 – Mild Rash (Subject NS-120)**

* **Event Description:**  
  A mild, transient rash was observed in subject NS-120 on 05/20/2024.
* **Severity:** Mild
* **Relationship to Study Drug:** Unlikely related
* **Action Taken:**  
  Topical treatment prescribed; study drug continued.
* **Outcome:** Resolved within one week.

**AE-006 – Elevated Liver Enzymes (Subject NS-128)**

* **Event Description:**  
  Subject NS-128 showed an increase in ALT and AST levels on 05/07/2024.
* **Severity:** Moderate
* **Relationship to Study Drug:** Possibly related
* **Action Taken:**  
  Dose adjustment implemented; additional liver function tests performed.
* **Outcome:** Enzyme levels returned to baseline by 05/14/2024.

**4. Detailed Serious Adverse Event Listing**

**SAE-001 – Acute Allergic Reaction (Subject NS-107)**

* **Event Description:**  
  On 04/25/2024, subject NS-107 developed an acute allergic reaction characterized by urticaria, facial swelling, and difficulty breathing shortly after receiving the study drug.
* **Severity:** Severe
* **Relationship to Study Drug:** Possibly related
* **Action Taken:**
  + Immediate hospitalization for observation and treatment.
  + Administration of antihistamines and corticosteroids.
  + Study drug permanently discontinued for this subject.
* **Outcome:**  
  The subject recovered fully following treatment and supportive care. The event was classified as resolved with no lasting sequelae.
* **Follow-Up:**  
  Detailed follow-up visits were conducted post-recovery, and the subject was advised to avoid re-exposure to the investigational product.

**5. Summary and Conclusion**

A total of six Adverse Events (AEs) and one Serious Adverse Event (SAE) were reported during the trial:

* **AEs:** The majority were mild to moderate in severity with appropriate management and resolution.
* **SAE:** One severe allergic reaction was managed promptly with full recovery and no long-term impact.
* **Overall Safety Profile:**  
  The safety data from the Phase 2 trial of Novostatin (Novitor) indicate a favorable risk/benefit profile, supporting the advancement to Phase 3 trials. The incidence and severity of events were consistent with expectations for a statin drug administered at low dosages.

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