**Ethics Committee/IRB Approval Document**

**Institution:**  
Biotech City Hospital Institutional Review Board (IRB)

**IRB Reference Number:** IRB-2024-NSP002

**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  
**Investigational Product:** Novostatin (Trade Name: Novitor)  
**Study Duration:** March 2, 2024 – September 22, 2024

**1. IRB Review and Approval**

The Biotech City Hospital IRB has reviewed the complete study protocol, including the Investigator’s Brochure, Informed Consent Form, Statistical Analysis Plan, and all other relevant documents for the above-referenced study.

**Approval Details**

* **Date of Initial Review:** March 15, 2024
* **Date of Approval:** March 20, 2024
* **Approval Status:** Approved with Minor Comments (All comments have been addressed by the Sponsor prior to study initiation)

**2. Summary of IRB Findings**

The IRB reviewed the following aspects of the study:

* **Scientific Rationale and Design:**  
  The study protocol for Novostatin (Novitor) has been found to be scientifically sound, with clearly defined objectives, endpoints, and appropriate patient safety monitoring procedures.
* **Risk/Benefit Assessment:**  
  Based on the preclinical and Phase 1 data, the anticipated benefits of improved lipid lowering with reduced side effects outweigh the potential risks. The IRB noted that the low dosage administration strategy is a significant advancement over existing statin therapies.
* **Informed Consent Process:**  
  The Informed Consent Form provides clear and concise information about the study purpose, procedures, potential risks, and benefits. The IRB confirmed that the consent process adequately protects patient rights and autonomy.
* **Privacy and Confidentiality:**  
  Measures to ensure patient confidentiality and data security were reviewed and approved. All collected data will be coded and stored in compliance with applicable data protection regulations.
* **Safety Monitoring:**  
  The study includes robust safety monitoring protocols, including regular laboratory assessments and an independent Data Monitoring Committee (DMC) review at Week 12, ensuring ongoing protection of participant safety.

**3. IRB Conditions and Requirements**

The IRB approval is subject to the following conditions:

* **Ongoing Reporting:**  
  The Sponsor must provide periodic progress reports and a final study report, including any unanticipated problems, adverse events, or protocol deviations.
* **Amendment Submission:**  
  Any protocol amendments, including revisions to the informed consent form, must be submitted to the IRB for review and approval before implementation.
* **Continuing Review:**  
  A continuing review will be conducted annually, or more frequently if deemed necessary by the IRB, until study completion.
* **Adverse Event Reporting:**  
  All serious adverse events (SAEs) must be reported to the IRB within 24 hours of awareness.

**4. IRB Approval Statement**

The Biotech City Hospital IRB hereby approves the study titled “A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Novostatin (Novitor) in Patients with Hypercholesterolemia” under Protocol NSP-002-2024. The study may commence on or after March 2, 2024, provided that all sponsor and site-specific conditions have been met.

**IRB Chair Signature:**

Dr. Michael Reed, MD  
IRB Chair, Biotech City Hospital  
Date: March 20, 2024

**IRB Administrator Signature:**

Lisa Nguyen, IRB Administrator  
Date: March 20, 2024