INFORMED CONSENT FORM

Title of Study : A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Investigational Drug X-123 in Patients with Moderate to Severe Chronic Pain

Sponsor : PharmaFuture Inc.

Principal Investigator : Dr. Jane Doe, MD

Study Site : Clinical Research Institute, 123 Medical Drive, Cityville, USA

Introduction

You are being invited to participate in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family, friends, or healthcare provider if you wish. Ask us if there is anything that is not clear or if you would like more information.

Purpose of the Study

The purpose of this study is to evaluate the safety and effectiveness of an investigational drug called X-123 in treating moderate to severe chronic pain. The study will compare X-123 to a placebo (an inactive substance) to determine if X-123 provides better pain relief.

Study Procedures

If you agree to participate, you will be asked to :

1. Attend up to 10 clinic visits over 6 months.
2. Take the study drug (X-123 or placebo) as directed.
3. Complete pain assessment questionnaires.
4. Provide blood and urine samples for laboratory tests.
5. Report any side effects or changes in your health.

Risks and Discomforts

Possible risks of participating in this study include :

- Mild to moderate side effects such as nausea, headache, or dizziness.

- Rare but serious side effects, including allergic reactions or liver problems.

- Discomfort from blood draws or other procedures.

The study team will monitor your health closely and provide medical care if any issues arise.

Benefits

You may or may not benefit directly from participating in this study. However, your participation may help researchers learn more about treating chronic pain, which could benefit others in the future.

Confidentiality

Your participation in this study is confidential. Your name and personal information will not be shared in any reports or publications. Study records will be stored securely and only accessible to authorized personnel.

Voluntary Participation

Your participation in this study is entirely voluntary. You may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

Compensation

You will receive $50 for each completed study visit to cover travel and time expenses.

Contact Information

If you have any questions or concerns about the study, please contact :

- **Principal Investigator :** Dr. Jane Doe, MD

Phone : (555) 123-4567

Email : jane.doe@clinicalresearchinstitute.com

- **IRB Contact :** Institutional Review Board, Cityville

Phone : (555) 987-6543

Email : irb@cityville.org

Statement of Consent

By signing below, you confirm that :

- You have read and understood the information provided.
- You voluntarily agree to participate in this study.
- You may withdraw from the study at any time without penalty.

Participant’s Name (Print) : _____

Participant’s Signature : _____

Date : _____

Investigator’s Name (Print) : _____

Investigator’s Signature : _____

Date : _____