Clinical Study Report: Phase 3 Registrational Trial of OncoRelief

Submitted by Pharmatech Corporation to the FDA

# 1. Synopsis

Study Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of OncoRelief in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)

Investigational Product: OncoRelief

Indication: Advanced Non-Small Cell Lung Cancer (NSCLC)

Study Phase: Phase 3

Study Design:

- Randomized, double-blind, placebo-controlled

- Parallel-group design

- Patients stratified by disease stage and prior therapy

Objectives:

- Primary: To evaluate the efficacy of OncoRelief in improving overall survival (OS) in patients with advanced NSCLC

- Secondary: To evaluate the safety profile of OncoRelief

Study Duration: [Placeholder for Duration]

Number of Participants: [Placeholder for Number]

Study Centers: Multi-center, conducted at [Placeholder for Number] locations

Primary Endpoint: Overall survival (OS)

Secondary Endpoints:

- Progression-free survival (PFS)

- Objective response rate (ORR)

- Quality of life (QoL)

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# 3. List of Abbreviations

* NSCLC: Non-Small Cell Lung Cancer
* OS: Overall Survival
* PFS: Progression-Free Survival
* ORR: Objective Response Rate
* QoL: Quality of Life
* FDA: Food and Drug Administration
* ICH: International Council for Harmonisation

# 4. Ethics

Ethical Conduct of Study: The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. Written informed consent was obtained from all participants prior to their inclusion in the study.

# 5. Investigators and Study Administrative Structure

Principal Investigator: Dr. [Placeholder Name], [Placeholder Institution]

Study Coordinator: [Placeholder Name], [Placeholder Institution]

# 6. Introduction

Background: OncoRelief is an investigational product developed by Pharmatech Corporation for the treatment of advanced NSCLC. This Phase 3 trial aims to confirm the efficacy and safety of OncoRelief in an expanded patient population.

# 7. Study Objectives

Primary Objective: To evaluate the efficacy of OncoRelief in improving overall survival (OS) in patients with advanced NSCLC.

Secondary Objectives: To evaluate the safety profile of OncoRelief, progression-free survival (PFS), objective response rate (ORR), and quality of life (QoL).

# 8. Study Design

Design Overview: This is a randomized, double-blind, placebo-controlled, parallel-group trial.

Randomization and Blinding: Patients were randomly assigned to receive either OncoRelief or placebo, with blinding maintained throughout the study.

# 9. Study Population

Inclusion Criteria:

* Adults aged 18 years and older
* Diagnosis of advanced NSCLC
* ECOG performance status of 0 or 1
* Measurable disease per RECIST criteria

Exclusion Criteria:

* Previous treatment with OncoRelief
* Uncontrolled medical conditions
* Pregnancy or breastfeeding

# 10. Study Treatment

Investigational Product: OncoRelief administered intravenously.

Control Product: Placebo administered intravenously.

# 11. Measurements and Evaluations

Efficacy Assessments:

* Overall survival (OS)
* Progression-free survival (PFS)
* Objective response rate (ORR)

Safety Assessments:

* Incidence of adverse events
* Laboratory parameters
* Vital signs

# 12. Statistical Methods

Sample Size Calculation: [Placeholder for Calculation]

Statistical Analysis Plan: [Placeholder for Detailed Plan]

# 13. Study Results

## 13.1 Demographic and Baseline Characteristics:

|  |  |  |
| --- | --- | --- |
| Characteristic | OncoRelief Group | Placebo Group |
| Age (years) | [Placeholder] | [Placeholder] |
| Gender | [Placeholder] | [Placeholder] |
| ECOG Performance Status | [Placeholder] | [Placeholder] |

## 13.2 Efficacy Results:

|  |  |  |
| --- | --- | --- |
| Endpoint | OncoRelief Group | Placebo Group |
| Overall Survival (OS) | [Placeholder] | [Placeholder] |
| Progression-Free Survival (PFS) | [Placeholder] | [Placeholder] |
| Objective Response Rate (ORR) | [Placeholder] | [Placeholder] |

## 13.3 Safety Results:

|  |  |  |
| --- | --- | --- |
| Adverse Event | OncoRelief Group | Placebo Group |
| Any Adverse Event | [Placeholder] | [Placeholder] |
| Serious Adverse Events | [Placeholder] | [Placeholder] |

# 14. Discussion and Overall Conclusions

Discussion: The results of this Phase 3 trial suggest that OncoRelief may improve overall survival and progression-free survival in patients with advanced NSCLC. However, further analysis and validation are required.

Conclusions: OncoRelief shows promise as a therapeutic option for advanced NSCLC. The safety profile is consistent with previous clinical trials.

# 15. References

* [Placeholder for Reference 1]
* [Placeholder for Reference 2]
* [Placeholder for Reference 3]