

## INTRODUCTION

This DMC Charter is for protocol no. \_\_\_\_\_ of *PharmaDrug, Inc.* (“*PharmaDrug*”). This Charter describes the roles and responsibilities of the Board and outlines the plan for communicating study data to the sponsor. The study Synopsis of the clinical trial is provided in Appendix A.

## ROLE OF THE BOARD

The DMC will evaluate the safety parameters of the ongoing study of the study drug in combination with cisplatin for treating non-small cell lung cancer (NSCLC), following the treatment and post-treatment period of each arm of the study. The sponsor can require that the DMC examine the safety data more frequently. The DMC will examine safety issues, and issues relating to the design and administration of, and compliance with the study. The frequency of DMC meetings may be increased, for example, where safety issues arise. Efficacy will also be addressed.

The goals of the DMC will include:

- Protecting patient welfare.
- Monitoring interim safety data.
- Identifying safety issues and suggesting solutions regarding study design and conduct.
- Evaluating the nature and frequency of AEs reported from each treatment arm, including clinical assessments of all AEs and SAEs that could lead to discontinuation of the study drug.
- Advise sponsor on the need for modifying the study design or conduct, based on safety data.
- Provide interim review of adverse events (AEs) observed in each study arm.
- Based on safety data, advise sponsor regarding the need for modifying the study design or conduct.
- Based on safety data, advise sponsor on proposals for dose escalation, dose modification, dose continuation, or termination of the study.

The DMC is not responsible for reviewing the final study results, although such results may be made available to the Board, where found appropriate.

## BOARD MEMBERSHIP

The DMC is an independent body of experts that serves in an advisory capacity to *PharmaDrug* to ensure that clinical trial participants are not exposed to unreasonable or unnecessary risks of the study drug in combination with cisplatin.

The DMC will consist of three voting members: two clinicians with expertise in oncology, one of which will be the DMC Chairperson (“Chair”), and a biostatistician. Each member’s curriculum vitae will be kept in the files at *PharmaDrug*. Current Board membership is disclosed on the title page of this DMC Charter. In the event that a DMC member withdraws from the Board, *PharmaDrug* may appoint a replacement.

## TERM

The duration of membership for the DMC will encompass the analysis of safety data from Clinical Study Protocol no. \_\_\_\_\_. The DMC may be asked to review the final safety study results.