

PFIZER INC.

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PROPRIETARY DRUG NAME®/GENERIC DRUG NAME:

CP-751871

PROTOCOL NO.:

A4021017

EudraCT NUMBER:

2008-004008-30

PROTOCOL TITLE:

Randomized, Open Label, Phase 3 Clinical Study to Evaluate the Effect of the Addition of CP-751,871 to Gemcitabine and Cisplatin in Patients with Advanced Non-Small Cell Lung Cancer

Study Centers

Data not available

Study Initiation and Final Completion Dates

Data not available. This study was cancelled prior to enrollment of any study subjects and therefore no data were collected.

Phase of Development:

Phase 3

Study Objectives:

Gemcitabine and cisplatin given together is a standard treatment option for advanced lung cancer patients. The purpose of this study is to assess if the life span is longer in patients taking the investigational drug CP-751,871 in combination with gemcitabine and cisplatin compared to gemcitabine and cisplatin alone. Considering a 10% rate of drop-outs, 1,210 participants will be required in order to have an adequate sample size (1,100 evaluable patients) and power to detect a 30% prolongation of survival on the experimental arm.

METHODS

Data not available

RESULTS

Subject Disposition and Demography:

Data not available

Efficacy Results:

Data not available

Safety Results:

Data not available

CONCLUSION:

Data not available. This study was cancelled prior to enrollment of any study subjects and therefore no data were collected.