BRISTOL-MYERS SQUIBB COMPANY

KOS-1584

Synoptic Clinical Study Report for Study BMS KOS-1584-203

SYNOPTIC REPORT

Open Label, Multi-Center, Phase 2 Study of KOS-1584 in Patients with Advanced or Metastatic Stage IIIB/IV Non-Small Cell Lung Cancer Previously Treated with First-Line Chemotherapy

Indication:	Non-small cell lung cancer
Phase:	2
Study Initiation Date:	4 April 2008
Study Completion Date:	28 November 2008
Report Date:	31 March 2009
Previous Version(s) of this Report	None

THIS STUDY WAS CONDUCTED IN ACCORDANCE WITH GOOD CLINICAL PRACTICE

Sponsor's Responsible Medical Officer:

[redacted]

Bristol-Myers Squibb
5 Research Parkway, Wallingford, CT 06492

SYNOPSIS

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TITLE OF STUDY: Open Label, Multi Center, Phase 2 Study of KOS 1584 in Patients with Advanced or Metastatic Stage IIIB/IV Non Small Cell Lung Cancer Previously Treated with First Line Chemotherapy

PURPOSE: This study was intended to evaluate KOS 1584 as a single agent administered intravenously (IV) weekly for 2 weeks of every 3 weeks in patients with stage IIIB/IV non small cell lung cancer (NSCLC) whose disease had progressed following initial chemotherapy. The study was terminated early because the sponsor decided not to pursue development of KOS 1584.

NUMBER OF SUBJECTS: 1 patient was treated

DISPOSITION, DEMOGRAPHICS AND OTHER PERTINENT BASELINE CHARACTERISTICS: The patient treated was [redacted] with stage IV NSCLC. [redacted] had previously been treated with one chemotherapy regimen of gemcitabine, docetaxel, and cetuximab. [redacted] received KOS 1584 for 5 treatment cycles and discontinued the study due to sensory neuropathy.

SUMMARY OF SAFETY RESULTS: No serious adverse events were reported. The patient experienced 12 sensory neuropathy events, all of which were nonserious and considered possibly related to study drug. Two of those events, which were reported before and during Cycle 4, were severe and led to dose reduction from 50.5 mg in the first three cycles to 38.8 mg in the fourth and fifth cycles and delay in dosing. Among the non neuropathy adverse events bone pain, myalgias, and arthralgias were considered severe, possibly related to study drug, and contributed to the dose reduction and delay. Other adverse events considered possibly related to study drug were fatigue, diarrhea, anorexia, alteration in taste, alopecia, and insomnia. Low eosinophil values and platelet counts were the only laboratory parameters that were consistently outside the normal range after the prestudy visit.

DATE OF REPORT: 31 March 2009