

Randomisation



Arm 1

OSI-744 (Tarceva™) – 150 mg PO daily

Gemcitabine – 1000 mg/m² IV weekly

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Placebo – 150 mg PO daily

Gemcitabine – 1000 mg/m² IV weekly

Response evaluation day 1 of cycle 2 and every 2 cycles

Continue treatment until progression or until unmanageable side-effects
End of treatment assessment four weeks after final dose of study drug

Survival follow-up