DRAFT
QUESTIONS FOR THE ONCOLOGY DRUGS ADVISORY COMMITTEE

SEPTEMBER 13, 2005 MEETING

NDA 21473/S-003 Tarveva (Erlotinib)

Proposed Indication: TARCEVA in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

1. Is the Tarceva survival effect in study PA 3 statistically persuasive?

2. Is the size of the Tarceva survival effect in study PA 3 clinically important?

3. Is the Tarceva risk/benefit ratio in study PA 3 favorable?

4. The FDA Guidance on when evidence of efficacy from a single trial without independent confirmation is adequate for marketing approval indicates that the study must be statistically persuasive (very low p value) such that it would be unethical to repeat the trial. Is a confirmatory trial recommended prior to approval?

5. Is this SNDA approvable?