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**Phase II clinical trial chemotherapy naïve patients greater than and equal to 75 years of age treated with erlotinib for advanced non-small cell lung cancer**

**Reviewed by Dr. Charles Butts**

Jackman DM *et al.* [JCO 2007; 25\(7\):760-6](#)

This is a phase II trial of Erlotinib as first line therapy for elderly patients without selection based on clinical or molecular predictors of response to EGFR TKI's. This is a rather large 80 patient phase II trial done by the Dana Farber/ Brigham and Women's Group. The results of this trial show a partial response rate of 10% with 41% of patients having stable disease, median time to progression of 3.5 months and a median overall survival of 10.9 months. One in two year survival rates were 46 and 19% respectively. These are results that are very similar to those seen with first line platinum based chemotherapy. This suggests that Erlotinib may be reasonable first line therapy in the elderly based on its favorable toxicity profile but this would require confirmation in a phase III trial. It is interesting to note that there was no selection to enhance the population for response to EGRF TKI's. Attempts were made to assess tumor for EGFR mutations as well as KRAS mutations. As typical for lung cancer population, only about 50% of patients had tissue samples available or suitable for analysis. In this sub-set EGFR mutations were only marginally associated with clinical response but were closely correlated with disease control and prolonged TTP and survival. KRAS mutations were detected in 6 of 41 patients all of whom had a history of tobacco use. There were no clinical responses in the group with KRAS mutations and median time on study for these patients was only 2.5 months.