males. There were 7 with adenocarcinoma, 3 squamous cell cancer, 1 with large cell and 1 with poorly differentiated non small cell cancer. One of the 12 patients had assessable but no measurable disease. Eight patients (66%) achieved a partial response, one achieved a minor response, two had stable disease, and one had progressive disease in one site with tumor regression in all other sites. Median survival was 16.5 months and 5 patients are still being followed. The number of cycles was 1-6, median of 3. There was one case of grade 4 thrombocytopenia without bleeding, 2 cases of line related sepsis; 2 patients with neutropenic infection, 2 patients with DVT (1 related to central line) and 1 of peripheral neuropathy related to Taxotere requiring discontinuation; 1 patient had a bleeding peptic ulcer successfully treated. There was no evidence of skin rashes, headaches, unexplained leukocytosis or other findings suggestive of retinoic acid syndrome. There was no case of pancreatitis. No dose modification of the retinoids was needed. The combination of brief periods of RAR and RXR agonists given together, along with chemotherapy appears to produce promising responses and survival in this group of patients. The brief period of administration of both agents may limit side effects reported with retinoids. This raises the hypothesis that the high response rate observed is due to increased anti-tumor activity through cross-talk and heterodimerization of the RAR and RXR receptors. A follow up trial has been initiated.

P3-120 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6

Response rates of erlotinib or gefitinib compared to docetaxel as subsequent line therapy in advanced non-small cell lung cancer (NSCLC) in clinical practice

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Background: In randomized trials, docetaxel has been shown to have activity as second-line therapy in advanced NSCLC; and erlotinib in the third-line setting after failure of first-line platinum-based chemotherapy. The role of epidermal growth factor receptor tyrosine kinase inhibitors (EGFRTKI) as second-line treatment prior to docetaxel chemotherapy remains ill defined and is currently the subject of several ongoing trials. Here we explore the outcomes of these agents’ uses in clinical practice.

Method: A retrospective review of the NSCLC database at Princess Margaret Hospital in Toronto, Canada was undertaken. Patients who have previously received docetaxel after failure of platinum-based chemotherapy were identified and a chart review was undertaken to further identify those who also received erlotinib or gefitinib to assess the clinical benefit of these drugs. The primary outcome assessed was response rate and secondary outcomes were time to progression and survival.

Results: 77 patients received docetaxel for advanced NSCLC from 2001 to Dec 2006. Of these, 55 (71%) were administered as second-line treatment following failure of platinum-based chemotherapy, 20 (26%) received it in the third-line setting and two (3%) as four-line treatment (see Table 1). Assessable response rates to second line docetaxel were partial response (PR) of 4%, stable disease (SD) of 47% and progressive disease (PD) in 49%. Of these 55 patients, 26 subsequently went to receive an EGFRTKI. Assessable response rates in these patients to third-line EGFRTKI were CR in 4% (1/23), PR in 9% (2/23), SD in 26% (6/23) and PD in 61% (14/23). Three patients were not assessable for response due to death and withdrawal from medication prior to assessment.

In the 20 patients who received docetaxel in the third line setting, 17 received prior EGFRTKI therapy. Response rates to an EGFRTKI in second line were PR of 12% (2/17), SD of 6% (1/17) and PD of 82% (14/17) while responses to third-line docetaxel were PR of 8% (1/13), SD of 69% (9/13) and PD of 23% (3/13). Seven were not assessable for response due to death or withdrawal prior to assessment.

Updated data on demographics and secondary outcomes will be presented at the meeting.

Conclusions: In this retrospective non-randomized review of patients with advanced NSCLC who progressed following first-line platinum-based chemotherapy, the use of an EGFRTKI as second-line therapy did not appear to be superior to when it is administered in the third-line setting following docetaxel chemotherapy. However, this may be confounded by selection bias. Randomized studies are required to directly test this hypothesis.

Table 1. Response rates of EGFRTKI and docetaxel in 2nd and 3rd line setting

<table>
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<tr>
<th></th>
<th>CR</th>
<th>PR</th>
<th>SD</th>
<th>PD</th>
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<tbody>
<tr>
<td>2nd line therapy</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>EGFRTKI</td>
<td>0%</td>
<td>12%</td>
<td>6%</td>
<td>82%</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>0%</td>
<td>4%</td>
<td>47%</td>
<td>49%</td>
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<tr>
<td>3rd line therapy</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>EGFRTKI</td>
<td>4%</td>
<td>9%</td>
<td>26%</td>
<td>61%</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>0%</td>
<td>8%</td>
<td>69%</td>
<td>23%</td>
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</table>

P3-121 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6

Phase II study of gefitinib as a first-line therapy in elderly patients with lung adenocarcinoma (WJTOG 0402-DI)

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Background: Elderly patients with advanced non-small-cell lung cancer (NSCLC) are often unsuitable for platinum-based chemotherapy due to comorbidity. Monotherapy, for example docetaxel, is the preferred treatment for elderly patients (Kudoh. J Clin Oncol 2006). EGFR tyrosine kinase inhibitors, such as gefitinib and erlotinib, show remarkable responses in some patients with NSCLC. Adenocarcinoma histology and Asian origin are predictors of these responses. Therefore, we conducted a phase II study of gefitinib as a first-line therapy in elderly patients with lung adenocarcinoma in Japan.

Methods: Eligible patients with stage IIB/IV lung adenocarcinoma were 70 years or older, chemotherapy-naïve, and had a performance status of 2 or lower. Patients with interstitial pneumonitis that was detectable on a chest computed tomogram were ineligible. Eligible