**Background:** In patients with advanced (stage IIIb/IV) NSCLC, the addition of cetuximab to chemotherapy has demonstrated increased activity compared with chemotherapy alone. Furthermore, the addition of cetuximab to RT in patients with locally advanced squamous cell head & neck carcinoma significantly prolongs the duration of locoregional control and median overall survival compared to radiotherapy alone. Therefore, the SCRATCH study was designed to assess the safety of synchronous cetuximab with radical RT in patients with Stage III NSCLC. The safety results of cohort I from this phase I study are presented below.

**Methods:** Twelve patients with inoperable stage III NSCLC were enrolled into cohort I. Inclusion criteria were performance status 0-1, adequate organ function, and disease encompassable within a radical RT volume. Exclusion criteria were previous malignancy, thoracic RT or treatment with EGFR (epidermal growth factor receptor) targeted therapy. Patients received platinum-based induction chemotherapy, followed by weekly intravenous cetuximab (initial dose 400mg/m²; maintenance dose 250mg/m²) and concomitant RT (64Gy/32fractions/45days). The primary end-point was toxicity. NCI Common Toxicity Criteria (CTC) V3.0 assessments were performed weekly during radiotherapy, and at regular follow-up visits.

**Results:** Complete data from the first ten patients is available. The final 2 patients were still receiving concomitant cetuximab and RT at the time of abstract submission, and so only provide acute toxicity data. Two patients stopped receiving concomitant cetuximab due to toxicity. One experienced grade 3 fatigue following the initial dose, and the other declined further treatment after developing grade 2 skin toxicity. Two patients have died, one from disease progression and one from thromboembolic disease. Both deaths occurred between months 2 and 4 post RT and were not attributed to the cetuximab therapy. Of the 8 living patients, 4 have survived at least 1 year (measured from the first day of induction chemotherapy). The maximum NCI CTC v3.0 scores are summarised in the table below:

<table>
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<tr>
<th>Grade</th>
<th>Lung</th>
<th>Lung</th>
<th>Esophagus</th>
<th>Esophagus</th>
<th>Skin</th>
<th>Skin</th>
<th>Chest Pain</th>
<th>Chest Pain</th>
<th>Sys-tmic</th>
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</tbody>
</table>

RT = During RT; FU = During Follow-Up Post RT; NA = not yet available

**Conclusions:** The results suggest that the early and late toxicities of synchronous cetuximab and radical RT are acceptable. Complete data on all twelve patients will be available by September 2007. SCRATCH Study cohorts II-IV follow on and will recruit sequentially. They will assess the safety of adding concomitant cisplatin and vinorelbine to cetuximab and radical RT. Early data from cohort II will also be available by September 2007.