2 cycles of chemotherapy. Common non-hematologic toxicities of all grades during consolidation chemotherapy were anorexia (45%), alopecia (41%), asthenia (35%), and esophagitis (41%). Hematologic toxicities were mild. Although Grade 3–4 neutropenia occurred in 5 cycles out of 65 cycles, there was no treatment-related mortality

**Conclusions:** These results suggest that CCRT with weekly docetaxel and cisplatin is feasible and consolidation chemotherapy with same agents after CCRT is also well tolerated. Further data will be updated on presentation.

**PD4-1-5 Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

**Docetaxel, carboplatin and thoracic radiotherapy in unresectable stage III non-small cell lung cancer (NSCLC): A safety report of the first 100 patients treated with this concurrent chemoradiation as part of a multicenter web-based trial, D0410**


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**Background:** Concurrent chemoradiotherapy (chemoRT) is the preferred treatment for patients with unresectable stage III NSCLC. Limited safety information is available on the use of concurrent docetaxel, carboplatin and thoracic RT. We report the safety information on the initial 100 patients (pts) treated with this chemoRT as part of an ongoing US randomized web-based phase III trial (D0410) evaluating the role of erlotinib/placebo following this concurrent chemoRT treatment. The sample size is 400 pts and the primary endpoint is progression-free survival.

**Methods:** Pts with unresectable pathologically confirmed stage III NSCLC are randomized to receive either erlotinib 150 mg or placebo orally daily for 2 years following concurrent chemoRT with docetaxel 20 mg/m², carboplatin AUC=2 intravenously weekly for 6 wks with thoracic RT of at least 61 Gy in 33 fractions over 6.5 weeks. The planned total lung volume exceeding 20 Gy (V20) was less than 32%. Only the chemoradiation safety information is being reported. This data was reviewed by an independent safety and data monitoring committee.

**Results:** Pt characteristics: 59% males, median age 69 years (range 38 to 86), 21% adenocarcinoma, 48% squamous cell, 94% EGFR PS0-1, 49% stage IIIA, 15% weight loss ≥ 10%. Of 600 planned chemotherapy treatments, 500 were administered (93 wk 1, 86 wk 2, 83 wk 3, 82 wk 4, 80 wk 5, 76 wk 6). There were 27 chemotherapy dose reductions; most commonly for esophagitis (8), neutropenia (5), renal dysfunction (3), hypersensitivity (2). There were no treatment-related deaths. There were 25 grade 3 and 3 grade 4 treatment-related adverse events. The most common grade 3/4 events were esophagitis (7), fatigue (3), dysphagia (2), odynophagia (2), neutropenia (1), thrombocytopenia (1), dermatitis (1).

**Conclusions:** This concurrent chemoradiation regimen appears to be safe. Enrollment to the phase III trial continues. There is a planned interim efficacy evaluation at 150 events (deaths or disease progression). Funded in part by Sanofi-Aventis, Genentech, and OSI Pharmaceuticals.

**PD4-1-6 Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

**Acute esophageal reactions from proton beam therapy and concurrent chemoradiotherapy for non-small cell lung cancer (NSCLC): Reduction in incidence and severity despite higher doses**

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**Purpose and Objective(s):** To assess the incidence and severity of acute esophageal reactions from concurrent chemotherapy and 3-dimensional proton beam therapy (PBT) in the context of previous results with concurrent chemotherapy and 3-dimensional photon therapy (XT) for NSCLC.

**Materials and Methods:** Twenty-five consecutive patients with NSCLC (stages IIB [1], IIIA [8], IIIB [8], IV [2], post-operative recurrent [6], underwent PBT and concurrent chemotheraphy with curative intent on IRB approved protocols. Chemotherapy was platinum-based in all patients, most frequently carboplatin/paclitaxel (16 patients). There were 16 males/9 females ranging in age from 49 to 81 years (median 67 years). Histopathologic diagnosis was squamous cell carcinoma in 9 and non-squamous in 16 patients. All patients were evaluable for acute (< or ≥ 90 days from first treatment) reactions. Toxicity was based on NCI common toxicity criteria vs. 3.0. XT comparisons were based on published data from our institution (215 patients) (Wei X et al, Int J Radiat Oncol Biol Phys 2006)

**Results:** Total doses with PBT ranged from 63 cobalt-gray equivalent (CGE) (using RBE of 1.1 vs. cobalt gamma rays) to 74 CGE (60-69.6 Gy with XT) in 33 to 37 fractions (30-58 fractions with XT). The median total dose was 74 CGE vs. 63 Gy for XT. Acute esophageal reactions were observed in 60% of PBT patients (200 of 215/93% with XT). Seven (28%) of patients had grade 2 esophageal reactions (97 of 215/45.1% with XT). Four (16%) of patients had grade 3 esophageal reactions (43 of 215/20.0% with XT). No patient had a grade 4 reaction (1of 215/0.5% with XT).

**Conclusions:** Proton beam therapy permitted higher total doses (17%-+) with concurrent chemotherapy yet were associated with reduced esophageal reactions compared with 3-dimensional conformal photon therapy.

**PD4-1-7 Combined Modality Therapy in NSCLC, Tue, 16:00 - 17:30**

**Consolidation chemotherapy with monthly Paclitaxel and Cisplatin (PC) or observation after concurrent chemoradiotherapy for locally advanced non-small cell lung cancer (NSCLC): Randomized phase II study**

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**Purpose and Objective:** To compare the efficacy and toxicity of consolidation chemotherapy with paclitaxel and cisplatin with observation after concurrent chemoradiotherapy for locally advanced NSCLC.

**Background:** Consolidation chemotherapy after concurrent chemoradiotherapy is important for improving the outcome of patients with locally advanced NSCLC. However, there is no established consensus on the efficacy of chemotherapy following chemoradiotherapy. Therefore, we designed a randomized phase II study to compare the efficacy and toxicity of consolidation chemotherapy with paclitaxel and cisplatin with observation after concurrent chemoradiotherapy for locally advanced NSCLC.

**Methods:** Patients with locally advanced NSCLC (stage IIIA/B with N2 disease or stage IIIB disease) were eligible for the study. Patients were randomly assigned to receive consolidation chemotherapy with paclitaxel and cisplatin or observation after concurrent chemoradiotherapy. The primary endpoint was overall survival.

**Results:** A total of 41 patients were enrolled in the study. At a median follow-up of 24 months, the median overall survival in the consolidation chemotherapy group was 22 months (95% CI: 16.2-27.8) and 18 months (95% CI: 12.3-23.7) in the observation group. The median progression-free survival was 12 months (95% CI: 8.7-15.3) in the consolidation chemotherapy group and 9 months (95% CI: 6.7-11.3) in the observation group. The most common grade 3/4 toxicities in the consolidation chemotherapy group were neutropenia (29%), anemia (11%), and peripheral neuropathy (11%). There were no treatment-related deaths.

**Conclusions:** Consolidation chemotherapy with paclitaxel and cisplatin after concurrent chemoradiotherapy for locally advanced NSCLC is effective and well tolerated. Further studies are needed to confirm these results.