

(PS 0-1), never smoker, and development of skin rash with gefitinib ($p < 0.001$, $p = 0.031$, $p < 0.001$, respectively).

Conclusion: This analysis suggests that patients with good performance status and never smoker and development of skin rash may benefit from gefitinib treatment in terms of tumor response as well as survival.

P3-110 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6

Tumor histology and N-score predict survival with gefitinib in patients with advanced non-small cell lung cancer

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Background: Gefitinib (Iressa) is active as a single agent in the treatment of select patients with recurrent non-small cell lung cancer (NSCLC). The clinical characteristics of patients treated with gefitinib at our department identified predictive variables associated with survival.

Methods: Patients ($n = 60$) with advanced NSCLC were treated with gefitinib (250 mg) upon progression with chemotherapy. N-score=0 is defined as N0,N1 or no-bulky and single N2,N-score=1 is defined as bulky or multiple N2 or N3 or distant lymph node.

Results: Partial responses were noted in 18 patients (30%) and disease stabilization in 25 (41.7%) patients. The median survival (MS) was 51 weeks and median time to progression was 24 weeks. The predictive factors analyzed were gender, age, tumor histology, T,N, N-score, performance status (PS) and weight lost. Tumor histology ($p = 0.008$) and N-score ($P < 0.001$) (not N) were predict factors in Cox regression model.

Conclusions: Tumor histology and N-score could predict survival time for recurrent NSCLC patients treated with gefitinib

P3-111 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6

Cutaneous side-effects of erlotinib treatment in lung cancer patients

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A new class of drugs that have the ability to inhibit the epidermal growth factor receptor (EGFR), namely gefitinib, erlotinib and cetuximab, is being used for treatment of patients with colorectal, head and neck, or non-small cell lung cancer (NSCLC) refractory or intolerant to chemotherapy.

Erlotinib (EGFR-specific tyrosine kinase inhibitor) is currently been used for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one previous chemotherapy regimen, it is taken orally and its most frequent undesirable side-effects are gastrointestinal disturbance and, cutaneous alterations (acneiform rash, skin dryness, paronychia, nasal or oral ulcers, urticariform rash and seborrhoeic dermatitis), that are observed in 56% and 75%, respectively. This skin toxicity is a pharmacologic class effect rather than a hypersensitivity reaction to the drug. It appears to imply a better response from the tumor to erlotinib and is dose dependent but not correlated with duration of therapy.

Dermatologists have now the responsibility to assist usage of this new therapy without lowering of dosis so an effective oncologic management is achieved.

We present 5 cases of patients that underwent erlotinib treatment for NSCLC that presented cutaneous alterations, namely an acneiform reaction, hirsutism and paronychia and how we manage them. We'll emphasize on cumulative dosis of the drug, delay to the appearance of the cutaneous side effects and time needed for their remission after treatment.

This work intends to point out the need for dermatologists to be aware of the new oncologic drugs that are being developed, the alterations they cause in the skin and the need for a consensus in how to treat them so we can help the patient comply with the oncologic treatment and hopefully improve its quality of life and survival.

P3-112 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6

Initial phase 1 results of gemcitabine, carboplatin and IMO-2055, a toll like receptor 9 (TLR9) agonist, in patients (pts) with advanced solid tumors

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Introduction: IMO-2055 is a novel synthetic oligonucleotide agonist of TLR9 that stimulates innate and adaptive immune responses in preclinical studies. IMO-2055 was well tolerated in a phase 1 monotherapy study in refractory solid tumor patients at dosages up to 0.64 mg/kg/week SC, with optimal immune system activation, based on the parameters evaluated, demonstrated between 0.16 and 0.32 mg/kg/week. Mild, transitory lymphocytopenia on day 2 (d2) was an expected pharmacology. Adverse events (AEs) were mild-moderate injection site reactions and flu-like symptoms. In preclinical studies, IMO-2055 was shown to potentiate the activity of standard oncology therapies, including chemotherapy, monoclonal antibodies and targeted agents. Combining IMO-2055 with gemcitabine in a mouse NSCLC model (A549) led to greater suppression of tumor growth than either agent alone. The carboplatin-gemcitabine combination had acceptable activity and a different safety profile vs. standard cisplatin-gemcitabine in NSCLC (Zatloukal et al, Lung Can 2003). Based on these data, we investigated the combination of IMO-2055, gemcitabine and carboplatin in advanced solid tumor patients.

Methods: We combined IMO-2055 at 4, 8 or 12mg total dose per SC injection with gemcitabine 1000mg d1 and 8 IV plus carboplatin AUC5 d1 IV q3w. The initial IMO-2055 schedule was d1, 8, 15; schedules of d2, 9 and d9, 16 were added to optimize IMO-2055 administration relative to the nadirs of chemotherapy-induced hematological toxicity. Pts had refractory solid tumors with ≤ 2 prior regimens and fulfilled standard phase 1 entry criteria. The primary endpoint was to identify MTD; secondary endpoints included safety and response rate (RECIST).

Results: 18 pts were treated from November 2005 to February 2007 for a median of 3 cycles (1-15) in 17 evaluable pts (7 male; 10 female): 7 NSCLC, 3 neuroendocrine, 2 unknown primary, 1 each of melanoma, esophagus, head and neck, breast and cholangio- carcinomas. Median ECOG PS was 1 (0-1) with median 1 prior chemotherapy and 53% prior radiotherapy. Grade 4 neutropenia or thrombocytopenia have been identified as DLTs in 2/5 pts at IMO-2055 12mg d1, 8, 15; 2/3 pts at 8mg d2, 9; 1/2 pts at 12mg d9, 16; and 0/3 pts at 8mg d9, 16. Most