with afatinib plus paclitaxel, overall survival did not show any statistical difference between the 2 treatment arms (12.2 months in each arm; HR, 1.00; 95% CI, 0.70 to 1.43; $P = .994$), possibly attributed to differences in postprogression treatment between the arms. More patients in the ICC arm received 2 postprogression lines of therapy compared with the afatinib plus paclitaxel arm (36% vs 15%).

Despite prolonged exposure time to afatinib plus paclitaxel compared with ICC (133 vs 51 days), discontinuation due to treatment-related adverse events was low, and quality of life was comparable between arms (HR, 0.97; 95% CI, 0.6 to 1.5). The most common adverse events in afatinib plus paclitaxel vs ICC arms included diarrhea (53.8% vs 6.7%), alopecia (32.6% vs 15%), and asthenia (27.3% vs 28.3%).

Prof Schuler concluded that afatinib plus paclitaxel was superior to ICC and improved outcomes in patients who had an acquired resistance to erlotinib/gefitinib and had disease progression on afatinib monotherapy after an initial benefit. It should, however, be noted that this study did not include a mutational analysis. Future studies should include a mutational status analysis (including *EGFR* mutations) to evaluate how the efficacy of treatments differs based on mutational status.

Age-Stratified Subgroup Analysis of SQUIRE in Patients With Stage IV Squamous NSCLC

Written by Anita Misra-Press, PhD

The current treatment for advanced non–small cell lung cancer (NSCLC), the leading cause of cancer death, is a combination of a platinum agent with third-generation therapies [Socinski MA et al. *J Clin Oncol.* 2012]. However, with survival differences related to histology, the paucity of data for patients with squamous NSCLC underscores an unmet need for more effective treatment.

Nicholas Thatcher, PhD, The Christie NHS Foundation Trust, Manchester, United Kingdom, previously reported results from the SQUIRE trial [Thatcher N et al. *J Clin Oncol.* 2014], a multinational, randomized, open-label, phase 3 study demonstrating increased overall survival (OS), progression-free survival (PFS), and disease control rates by adding necitumumab (N) to gemcitabine/cisplatin (GC) as first-line treatment for stage IV squamous NSCLC.

Changing the prevalence of comorbidities (and associated toxicities) across the age spectrum may influence outcomes, particularly for the elderly squamous NSCLC population [Piccirillo JF et al. *Crit Rev Oncol Hematol.* 2008]. In the present poster, Prof Thatcher presented efficacy results from an age-stratified subgroup analysis of the SQUIRE trial (N + GC or GC alone) in elderly patients with stage IV squamous NSCLC [Thatcher N et al. *Ann Oncol.* 2015].

Prespecified subgroup analyses (< 70 years: N + GC [n = 437], GC [n = 451] vs ≥ 70 years: N + GC [n = 108], GC [n = 97]) for efficacy were based on the randomized intent-to-treat population. Baseline patient characteristics were comparable between the subgroups. Exposure to N and GC treatment cycles was slightly lower in the ≥ 70-year subgroup; N continuation monotherapy was initiated in 53% of the < 70-year subgroup and in 43% of the ≥ 70-year subgroup. Both subgroups showed predictable toxicities with similar grade ≥ 3 adverse events (AEs) in both arms; however, the higher incidence of serious AEs in the N plus GC arm in both age groups was likely responsible for the higher proportion of patients discontinuing treatment in that arm.

Kaplan–Meier curves for OS of the < 70-year subgroup demonstrated a significant increase from 9.9 months (GC) to 11.7 months (N + GC; HR, 0.81; 95% CI, 0.70 to 0.94; $P = .006$). However, OS in the ≥ 70-year subgroup showed no significant benefit from the addition of N (9.7 months GC vs 10 months N + GC; HR, 1.03; 95% CI, 0.75 to 1.42; $P = .858$).

PFS in the < 70-year subgroup increased slightly (5.5 months GC to 5.7 months N + GC; HR, 0.82; 95% CI, 0.70 to 0.95; $P = .007$). However, PFS in the ≥ 70-year subgroup demonstrated no change in the 2 treatment arms (5.5 months GC vs 5.6 months N + GC; HR, 1.07; 95% CI, 0.77 to 1.49; $P = .686$). This age-related decrease in survival response is consistent with previous studies in patients with advanced NSCLC [Pirker R et al. *Lancet.* 2009; Ramalingam SS et al. *J Clin Oncol.* 2008].

Prof Thatcher concluded that treatment benefit with N plus GC was observed for patients aged < 70 years; however, for the ≥ 70-year subgroup of elderly patients (representing 19% of the SQUIRE population), there was no significant difference in OS or PFS between the treatment arms.

Novel Compound Beneficial as Adjunct to Antibody-Based Therapy for Stage IV NSCLC Patients

Written by Anita Misra-Press, PhD

Recent reports show that PGG beta-glucan, a novel immune cell modulator, increased objective response rates in patients with stage IV non–small cell lung cancer (NSCLC) when added to the first-line regimen of carboplatin/paclitaxel (C/P) chemotherapy and cetuximab, an EGFR-targeted antibody [Schneller F. *J Thorac Oncol.* 2014]. Bevacizumab is a vascular endothelial growth factor