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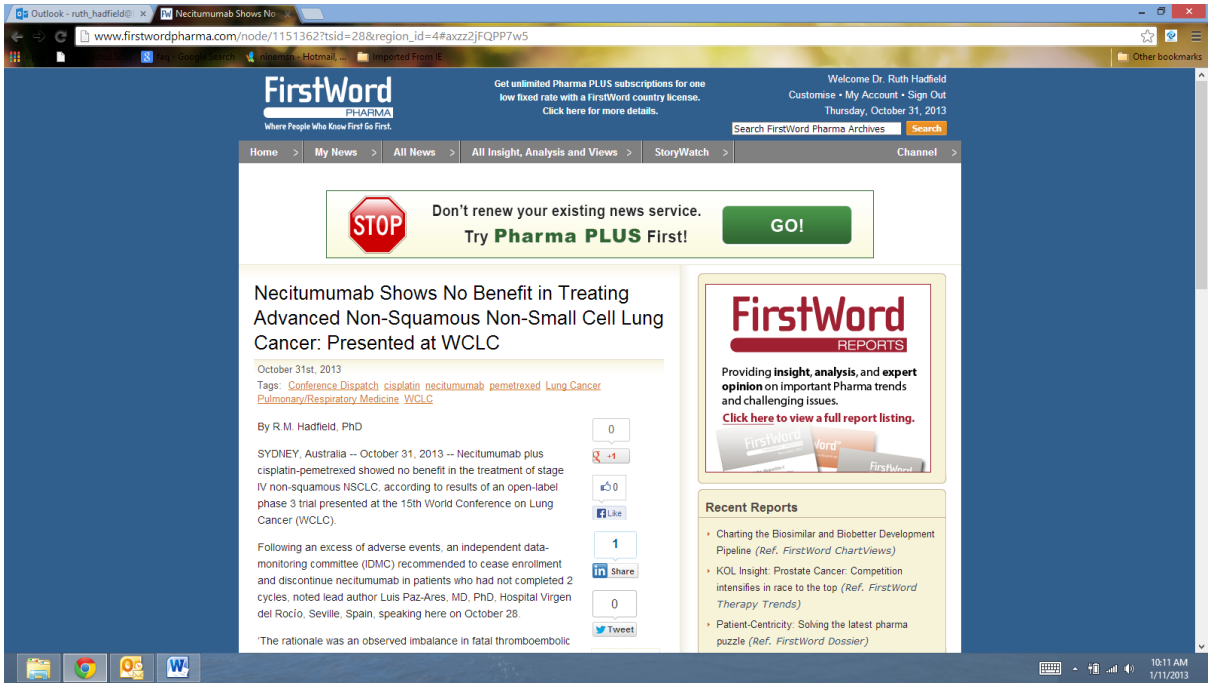

Necitumumab Shows No Benefit in Treating Advanced Non-Squamous Non-Small Cell Lung Cancer: Presented at WCLC

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By R.M. Hadfield, PhD

SYDNEY, Australia -- October 31, 2013 -- Necitumumab plus cisplatin-pemetrexed showed no benefit in the treatment of stage IV non-squamous NSCLC, according to results of an open-label phase 3 trial presented at the 15th World Conference on Lung Cancer (WCLC).

Following an excess of adverse events, an independent data-monitoring committee (IDMC) recommended to cease enrollment and discontinue necitumumab in patients who had not completed 2 cycles, noted lead author Luis Paz-Ares, MD, PhD, Hospital Virgen del Rocío, Seville, Spain, speaking here on October 28.

'The rationale was an observed imbalance in fatal thromboembolic events, and fatal events potentially related to thromboembolism between the cisplatin-pemetrexed + necitumumab arm and the cisplatin-pemetrexed arm, predominantly during the first 2 cycles, assessed within the context of the overall event rate," Dr Paz-Ares explained.

Dr. Paz-Ares and colleagues had randomised 633 patients with histologically or cytologically proven stage-IV, non-squamous NSCLC into the 2 arms of the so-called INSPIRE study.

The team found no significant difference in overall survival (OS) and progression-free survival (PFS) between the 2 arms of the study, with hazard ratios (HR) of 1.01 (P = .956) for OS and 0.96 (P = .664) for PFS. Sub-group analyses were also consistent between groups.

The OS was analysed according to epidermal growth factor receptor (EGFR1) expression in collected tissue samples; 85% of tissue samples were evaluable for H-score. There were no significant differences between high EGFR1 (H-score ≥200 to 300, HR 1.03) and low EGFR1 (H-score 0 to 200, HR 1.07, P = .857). The results suggested that H-score may be a useful prognostic indicator.

Adverse events of grade 3 or higher in the necitumumab arm of the trial were more common with fatigue (11.2% vs 6.1%), hypomagnesia (7.6% vs 2.2%), rash (14.8% vs. 0.3%), venous thromboembolic events (7.6% vs. 3.5%) and sudden or explained death (3.6% vs. 1.6%) all notably increased.

“Development of necitiumumab continues for squamous NSCLC in an ongoing phase 2 trial: SQUIRE,” Dr Paz-Ares noted.

[Presentation title: Randomized Phase-3 trial (INSPIRE) of Necitumumab plus Cisplatin-Pemetrexed versus Cisplatin-Pemetrexed Alone as First-Line Therapy in Stage IV Non-Squamous NSCLC. Abstract O03.02]