Non small cell lung cancer; squamous (SqNSCLC)

Study: «Randomized phase III trial of erlotinib vs. docetaxel in patients with advanced squamous cell non-small cell lung cancer (SqNSCLC) failing first line platinum based doublet chemotherapy stratified by VeriStrat Good vs VeriStrat Poor: The European Thoracic Oncology Platform (ETOPEMPHASIS trial).»

First Author: Solange Peters, University Hospital of Lausanne (CHUV), Lausanne # 8049 Poster Session (Board #372)

Background: Docetaxel (D) or Erlotinib (E) are registered second-line treatments for EGFR wild type NSCLC. Previous studies suggested a predictive value of the serum proteomic VeriStrat test (VS), assigning a good (VSG) or poor (VSP) classification in second-line therapy of patients (pts.) with NSCLC. EMPHASIS aimed at exploring a predictive interaction in SqNSCLC pts. The trial closed prematurely due to low accrual.

Methods: EMPHASIS is a randomized phase III multicenter trial exploring the differential activity of second line E vs. D on progression-free survival (PFS) in VSG vs. VSP SqNSCLC. The expected hazard ratio (HR) of E vs. D was 0.675 for the VSG patients (median PFS, E: 4.0 and D: 2.7 mo.), and 1.23 for the VSP patients (median PFS, E: 2.2 and D: 2.7 mo.). A sample size of 500 was needed to achieve 86% power for testing the expected interaction HR of 1.82 at a two-sided p-value of 0.05. Pts were randomized to receive treatment E150 mg p.o. daily or D 75 mg/m² i.v. on day 1 of each 21 day cycle.

Results: From 1/2013 to 1/2014, a total of 80 patients were randomized to the study, with 72.5% categorized as VSG. Median age was 69 years with the majority being male (83%), smokers (94%), and having good performance status (91%). No unexpected serious adverse events (SAEs) were observed in either treatment arm. All pts are off treatment (median time to treatment failure: 2.1 mo.), while 73 progression events (median PFS: 2.7 mo.) and 56 deaths (median OS: 7.1 mo.) were observed. Median PFS for VSG is 4.1 and 1.6 mo. under D and E respectively, and 1.9 and 2.1 mo. for VSP pts (HR = 1.04, interaction p-value = 0.94). Median OS for VSG is 7.8 and 8.4 mo. for D and E and 4.4 and 5.2 mo. for VSP.

Conclusions: The final analysis of EMPHASIS did not show a differential activity on PFS & OS. The results are at variance with trial assumptions and previous studies. In addition to the EMPHASIS results (PFS & OS), we will present a combined PFS/OS analysis with the subgroup of SqNSCLC from the PROSE study.

EudraCT number: 2012-001896-35.
Clinical trial information: NCT01652469.

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# 5001 Oral Abstract Session

Background: STAMPEDE is a randomised controlled trial using a novel multi-arm multi-stage design. It recruits men (pts) with high-risk locally advanced or metastatic prostate cancer (PCa) starting long-term hormone therapy (HT) for the first time. The trial initially assessed adding 1 or 2 of 3 treatment approaches to standard of care (SOC). We report primary survival results for 3 research comparisons that recruited through all their intermediate analyses: docetaxel (D), zoledronic acid (ZA) and the combination (D+ZA).

Methods: SOC was hormone therapy for ≥ 3 yrs; Radiotherapy (RT) was encouraged for N0M0 pts up to Nov-2011, then mandated; RT was optional for N+M0 pts. Stratified randomisation allocated pts 2:1:1:1 to SOC (control), SOC+D, SOC+ZA or SOC+D+ZA. 4 mg ZA was given for six 3-weekly cycles then 4-weekly until 2 yrs. D was given as 75 mg/m² for six 3-weekly cycles with prednisolone.
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Background: Patients (pts) with biochemical recurrence after radical prostatectomy may benefit from dose intensified salvage radiotherapy (RT) of the prostate bed. We performed a randomized phase III trial assessing dose intensification. In this first report we report acute toxicity and early quality of life (QoL).

Methods: Pts with biochemical recurrence but without evidence of macroscopic disease were enrolled in this randomized phase III trial. Pts were randomly assigned to either 64 Gy (32 daily fractions) or 70 Gy (35 daily fractions). Three-dimensional conformal RT (3D-CRT) or intensity-modulated RT (IMRT, or equivalent rotational techniques) were accepted techniques. The primary endpoint was freedom from biochemical recurrence. Secondary endpoints included acute toxicity according to the CTCAE v4.0 and QoL using the EORTC QLQ-C30 and PR25.

Results: From Oct-2005 to Mar-2013, 2,962 pts were randomised to the 4 arms. The groups were balanced with median age 65 yrs; 61% metastatic, 14% N/XM0, 22% NOM0; 93% diagnosed within 6 months of randomisation; median PSA 65 ng/ml. Median follow-up was 42 months. Grade 3-5 toxicity was reported for 31% SOC, 50% SOC+D, 32% SOC+ZA and 52% SOC+D+ZA. There were 405 deaths on the control arm (84% from PCa). The hazard ratio was 0.76 (95% CI 0.63, 0.91; p = 0.003) for SOC+D vs. SOC; 0.93 (95% CI 0.79, 1.11; p = 0.437) for SOC+ZA vs. SOC; and 0.81 (95% CI 0.68, 0.97; p = 0.020) for SOC+D+ZA vs. SOC. Median survival was increased by 10 months from 67 months on SOC to 77 months on SOC+D. Results in M0 and M1 disease will be shown.

Conclusions: Survival data from STAMPEDE show a clinically and statistically significant improvement in survival from adding docetaxel but not from adding zoledronic acid in men starting long-term hormone therapy for the first time. Clinical trial information: NCT00268476.

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