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Title: Histology as a potential clinical predictor of outcome in advanced non-small cell lung cancer (NSCLC) treated with vinorelbine and mitomycin (VM) combination chemotherapy

Dr. Thomas 10260 Wibmer thomas.wibmer@uniklinik-ulm.de MD [1], Dr. Thierry 10261 Berghmans thierry.berghmans@bordet.be MD [2], Dr. Cornelia 10262 Kropf cornelia.kropf@uniklinik-ulm.de MD [1], Prof. Jean-Jacques 10263 Lafitte jjlafitte@chru-lille.fr MD [3], Dr. Kathrin M. 10264 Stoiber kathrin.stoiber@uniklinik-ulm.de MD [1], Mrs. Marianne 10270 Paesmans paesmans.marianne@bordet.be [4], Mr. Stefan 10275 Ruediger stefan.ruediger@uniklinik-ulm.de [1], Prof. Arnaud 10285 Scherpereel a-scherpereel@chru-lille.fr MD [3], Mrs. Ioanna 10287 Blanta ioanna.blanta@uniklinik-ulm.de [1], Prof. Wolfgang 10290 Rottbauer wofgang.rottbauer@uniklinik-ulm.de MD [1], Prof. Jean-Paul 10295 Sculier sculier@bordet.be MD [2] and Dr. Christian 10297 Schumann christian.schumann@uniklinik-ulm.de MD [1]. [1] Department of Internal Medicine II, University of Ulm Medical Center, Ulm, Germany ; [2] Department of Intensive Care Unit and Thoracic Oncology, Université libre de Bruxelles, Brussels, Belgium ; [3] Department of Pneumology, CHU de Lille, Lille, France and [4] Data Center, Institut Jules Bordet, Université libre de Bruxelles, Brussels, Belgium .

Body: Introduction: Histology has emerged has an important clinical predictive factor in patients with advanced NSCLC treated with chemotherapy. Aims: To analyze combined patient level-data from 2 phase II trials on efficacy and safety of VM in advanced or metastatic NSCLC, in order to determine if histology and other patient and disease characteristics including gender, smoking history and TTF-1 immunohistochemistry (IHC) might be potential clinical predictors of outcome. Methods: Response rates, unadjusted survival times and Cox covariate adjusted hazerd ratio estimates (HR) were calculated for each subgroup in each individual trial and in the pooled data set. Results: A total of 175 patients were included in this retrospective analysis. Adjusted HRs for both overall survival (OS) and progression free survival (PFS) consistently favored non-adenocarcinoma (non-AC) histology subgroups, achieving statistical significance for OS in the pooled data (n=175; HR 0.677; 95% CI 0.488-0.938; p=0.019) and within one of those two trials (n=65; HR 0.561; 95% CI 0.318-0.988; p=0.045). TTF-1 negative IHC was associated with non-significant favorable OS compared to TTF1 positive subgroup in the cox-adjusted analysis (n=33; HR 1.232; 95% CI 0.555-2.730; p=0.608) and showed a significantly higher response rate (25% vs. 0 %; p=0.040). Gender and smoking history were not strongly related to outcome. Conclusions: These results suggest that non-AC histology and TTF-1 negative IHC may be considered as potential predictors of favorable clinical outcome in the treatment with VM. This approach warrants further investiagtion in a phase III study.