multi-center, observational study on GIST patients treated with Imatinib between the availability on the French Market and the end of the 2008. Centers were randomly selected in national files of oncologists, gastrointestinal surgeons and specialists. The planned follow-up duration was three years. A case report form had to be completed at inclusion and during each follow-up visit. Quality of life was assessed using QLQ-C30 and SF36 questionnaires. RESULTS: Thirty on 51 selected centers enrolled at least one patient and 139 patients were included (as of June 2009). The median age of disease onset was 58 years (range 21–86); 42% were metastatic at diagnosis. Primary tumor sites were: most often stomach (44%), or bowel (34%). At the start of the study, 46% of patients had a tumor size over 5 cm. 68% of patients had surgery of the primary tumor before starting Imatinib. 68% of patients were considered as high risk of relapse according to the Miettinen classification. For 99% of the patients, Imatinib was given at an initial dosage of 400 mg, 1% at 300 mg. Compliance was superior to 90% for 99% of patients. With a median follow-up of 2.1 years, two-years overall survival from first treatment with Imatinib was 83.9% (95%: [74.3%–90.1%]). CONCLUSIONS: EPIGIST is still an ongoing survey. Current results confirm previous published data on survival in GIST treated with Imatinib in an unslected cohort of patients outside of a clinical trial.

A COMPARATIVE EFFECTIVENESS ASSESSMENT OF FIRST-LINE BEVACIZUMAB + INTERFERON ALPHA-2A VS SUNITINIB IN METASTATIC RENAL CELL CARCINOMA

Bonthapally V1, Walzer S1, de Castro Carpeño J 2, Vergnenegre A3, Chouaid C4, Heigener D5, Bischoff HG6, Aultman R7, Siebert U8
1Center of Operative Urology Bremen, Bremen, Germany, 2AiM GmbH Assessment in Medicine, Schopfheim, Germany, 3Institut Gustave Roussy, Villejuif, France, 4University Hospital of Barri Barri, Spain, 5Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, 6PRCCS San Matteo University Hospital Foundation, Pavia, Italy, 7F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland, 8UMIT—University for Health Sciences, Medical Informatics and Technology, Hall T, Austria

OBJECTIVES: Bevacizumab (BEV) + Interferon-alpha-2A (IFN-α) and sunitinib (SUN) have shown significant increase in progression free survival (PFS) compared to IFN-α in first-line metastatic renal cell carcinoma (mRCC) therapy. There is no head-to-head evidence available comparing both regimens, however there is an increasing need to assess and compare the relative efficacy and effectiveness of both therapeutic strategies. METHODS: We applied the widely accepted indirect comparison method (Bucher et al. J Clin Epidemiol 1997) to PFS data of the pivotal phase III trials, that is, the unadjusted investigator-assessed PFS hazard ratios (HR) for BEV-IFN-α vs. IFN-α (0.61) and for SUN vs IFN-α (0.52). To enable valid indirect comparison, the IFN control arms of both trials have been standardised by recalculating the indirect HR and transferring them into direct HR estimates using the cross-trial proportions. In addition, we adjusted for effects of down-dosing and patient compliance based on published evidence. Sensitivity analyses on adjustment components have been performed. RESULTS: The unadjusted indirect efficacy comparison resulted in a statistically non-significant PFS difference of SUN vs BEV-IFN-α (HR: 0.82; 95% CI: 0.64–1.06; p = 0.13). Standardising the IFN arms and simulating realistic scenarios for SUN down-dosing and patient compliance results in similar PFS HRs for BEV-IFN-α (HR: 0.63) and Sunitinib (HR: 0.64) as compared to IFN alone. The adjusted indirect PFS HR of SUN vs BEV + IFN-α was 1.025 (95% CI: 0.81–1.30; p = 0.83). Results were mostly influenced by IFN-α control arm adjustment, followed by patient compliance and down-dosing. CONCLUSIONS: Based on our comparative effectiveness evaluation in first-line mRCC therapy, there is no statistically significant evidence for a difference in efficacy and effectiveness regarding PFS between BEV-IFN-α and SUN. These findings imply that additional treatment decision criteria such as tolerability need to be considered to guide treatment decisions.

AN INDIRECT COMPARISON OF THE EFFICACY OF BEVACIZUMAB PLUS CISPLATIN AND GEMCITABINE (BCG) OR BEVACIZUMAB PLUS VATINIB PLUS CISPLATIN AND GEMCITABINE (VBCG) IN PATIENTS WITH ADVANCED OR RECURRENT NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC)

Walzer S1, de Castro Carpeño J 2, Vergnenegre A3, Chouaid C4, Heigener D5, Bischoff HG6, Aultman R7, Siebert U8
1Center of Operative Urology Bremen, Bremen, Germany, 2AiM GmbH Assessment in Medicine, Schopfheim, Germany, 3Institut Gustave Roussy, Villejuif, France, 4University Hospital of Barri Barri, Spain, 5Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, 6PRCCS San Matteo University Hospital Foundation, Pavia, Italy, 7F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland, 8UMIT—University for Health Sciences, Medical Informatics and Technology, Hall T, Austria

OBJECTIVES: New treatment options are needed for advanced NSCLC offering improved overall progression-free survival (PFS) and overall survival (OS) over standard chemotherapy. Bevacizumab, a humanised monoclonal antibody (MAb) against VEGF, plus chemotherapy increases PFS and OS in advanced NSCLC patients versus chemotherapy alone1. Cetuximab, a MAb targeting EGFR, showed significant OS when combined with chemotherapy.2 This study compared the clinical benefits for NSCLC patients treated with BCG or BCP to CVC using indirect treatment comparison (ITC) methodology. METHODS: In the absence of head-to-head trials, ITC was performed on patients with non-squamous NSCLC comparing the relative benefit of first-line therapies BCG/BCP versus CVC by hazard ratios (HR) adjusted for differences in underlying chemotherapy and populations. Where HRs were not reported, HRs and standard errors were estimated. Based on the ITC a statistical disease model was developed to estimate the adjusted time in PFS in OS. RESULTS: ITC-estimated HRs for the primary endpoints in AVAIL1 and E4599 showed that the adjusted PFS HR for BCG versus CVC was 0.80 resulting in an expected time spent in PFS for BCG of 9.62 versus 7.99 months for CVC. Model-derived data showed BCP treatment in patients with adenocarcinoma histology resulted in adjusted BCP HR of 0.89 versus CVC. Model data also showed that BCP patients experienced on average, 19.55 versus 17.57 months (CVC) of OS. Sensitivity analyses confirmed the robustness of these findings. CONCLUSIONS: Interpretation of ITC findings are limited due to cross-study heterogeneity. However results show that BCG or BCP therapy in patients with advanced non-squamous NSCLC brings a superior benefit in terms of OS and PFS compared to CVC therapy.