400 mg bid) or sorafenib alone. The primary endpoint was overall survival (OS; Kaplan-Meier analysis) in the intention-to-treat population.

Results: In the ITT palliative treatment cohort, 216 patients were randomised to SIRT + sorafenib and 208 to sorafenib alone. Median OS was 12.1 months (95% confidence interval [CI], 10.6–14.6) in the SIRT + sorafenib arm, and 11.5 months (95% CI, 9.8–13.9) in the sorafenib arm (hazard ratio [HR], 1.067; 95% CI, 0.82–1.25; p = 0.951). In the per protocol group, median OS was 14.1 months (95% CI, 10.95–16.40) in the SIRT + sorafenib arm (n = 114), and 11.1 months (95% CI, 9.7–13.9) in the sorafenib arm (n = 174; HR, 0.86; 95% CI, 0.67–1.11; p = 0.25). Subgroup analyses of the per-protocol population suggested a survival benefit for patients receiving SIRT + sorafenib ≤65y (HR, 0.65; 95% CI 0.43, 1.00, p = 0.05); non-cirrhotics (HR, 0.46; 95% CI 0.25, 0.86, p = 0.02); and non-alcoholic etiology (HR, 0.63; 95% CI 0.45, 0.89, p = 0.012). Adverse events (AEs) of Common Terminology Criteria for AE Grade ≥3 were reported in 115/159 (72.3%) patients in the SIRT + sorafenib arm and 135/197 (68.5%) patients in the sorafenib arm, respectively.

Conclusion: The addition of SIRT to sorafenib did not result in a significant improvement in overall survival compared to sorafenib alone. Subgroup analyses led to hypothesis generating results for patient groups with potential clinical benefit.

O – 029 The impact of combining Selective Internal Radiation Therapy (SIRT) with sorafenib on overall survival in patients with advanced hepatocellular carcinoma: The SORAMIC trial palliative cohort

J Ricke[1,2], B Sangro[3], H Amthauer[4], I Bargellini[5], P Bartenstein[6], E De Toni[6], A Gasbarrini[7], HJ Klumpen[8], M Peck[9], P Popovic[10], O Rosmorduc[11], E Schott[12], C Verslype[13], P Malfertheiner[1,2]

[1]Ludwig-Maximilians University Munich, Munich, Germany, [2]University Hospital Magdeburg, Magdeburg, Germany, [3]Clinica Universidad de Navarra, Pamplona, Spain, [4]Charite University Hospital Berlin, Berlin, Germany, [5]University of Pisa, Pisa, Italy, [6]Ludwig-Maximilians University Munich, Munich, Germany, [7]Catholic University of Rome, Rome, Italy, [8]Academic Medical Center, Amsterdam, Netherlands, [9]Klinikum Klagenfurt am Wörthersee, Klagenfurt, Austria, [10]Ljubljana University Medical Centre, Ljubljana, Slovenia, [11]University Hospital St. Antoine, Paris, France, [12]Charite University Hospital, Berlin, Germany, [13]University Hospital Gasthuisberg, Leuven, Belgium

Introduction: SORAMIC is an RCT comprising diagnostic, local ablation and palliative studies. Based on the result of the diagnostic study patients were assigned to either the local ablation or palliative cohort. The palliative cohort (reported here) was designed to determine the efficacy and safety of combining SIRT (Selective Internal Radiation Therapy) with sorafenib in patients with advanced HCC.

Methods: In the palliative treatment cohort, patients not eligible for TACE were randomised 11:10 to either SIRT with Y-90 resin microspheres plus sorafenib (target dose