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Eric Van Cutsem, MD, PhD
University Hospital Gasthuisberg, Leuven, Belgium

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symposium article

Molecular markers and biological targeted therapies in metastatic colorectal cancer: expert opinion and recommendations derived from the 11th ESMO/World Congress on Gastrointestinal Cancer, Barcelona, 2009 vii

abstracts

Oral presentations viii
Poster discussions vi20
Posters vi31
Author index vi122

O-0004. EFFICACY FINDINGS FROM THE X-ACT TRIAL OF CAPECITABINE VS. 5-FU/LV AS ADJUVANT THERAPY FOR PATIENTS WITH STAGE III COLON CANCER: NO IMPACT OF AGE ON DISEASE-FREE SURVIVAL OR OVERALL SURVIVAL

Twelves C[1], Scheithauer W[2], McKendrick J[3], Nowacki M[4], Seitz J[5], Van Hazel G[6], Wong A[7], Diaz-Rubio E[8], Gilberg F[9], Cassidy J[10]
[1]*University of Leeds, St James' University Hospital, Leeds, UK,* [2]*Vienna University Medical School, Vienna, Austria,* [3]*Box Hill Hospital, Melbourne, Australia,* [4]*Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland,* [5]*Hôpital La Timone, Marseille, France,* [6]*Mount Medical Centre, Perth, Australia,* [7]*Tom Baker Cancer Centre, Calgary, Alberta, Canada,* [8]*Hospital Clínico San Carlos, Madrid, Spain,* [9]*F. Hoffmann-La Roche, Basel, Switzerland,* [10]*Glasgow University, Glasgow, Scotland*

Background: The X-ACT trial demonstrated that the oral fluoropyrimidine capecitabine is at least equivalent to bolus i.v. 5-FU/LV as adjuvant therapy for patients with stage III colon cancer [Twelves et al. *NEJM* 2005]. In a recent analysis of the ACCENT database, investigators concluded that improved efficacy associated with newer adjuvant regimens vs. 5-FU/LV may not be preserved in patients aged ≥70 years [McCleary et al. ASCO 2009]. We therefore examined disease-free survival (DFS) and overall survival (OS) across age groups in the X-ACT trial to determine the efficacy of capecitabine in patients aged ≥70 years.

Methods: 1987 patients with resected stage III disease were randomised to capecitabine (n=1004) or bolus 5-FU/LV (Mayo Clinic regimen; n=983) for 24 weeks. The primary efficacy endpoint was DFS.

Results: After a median follow-up of 6.9 years, capecitabine was at least equivalent to 5-FU/LV in terms of DFS in the intent-to-treat (ITT) population [hazard ratio (HR) 0.88, 95% CI, 0.77–1.01; P<0.001 for upper 95% CI limit vs. predefined non-inferiority margin of 1.20]. A subgroup analysis by age shows that there is a consistent trend across all age groups for greater benefit with capecitabine vs. 5-FU/LV (see Table).

Age (years)	Patients (n)	5-year DFS (%)			5-year OS (%)		
		Cape	5-FU/LV	HR [95% CI]	Cape	5-FU/LV	HR [95% CI]
ITT	**1987**	**59.1**	**54.6**	**0.88 [0.77–1.01]**	**70.9**	**67.8**	**0.86 [0.74–1.01]**
<40	**76**	**56.0**	**49.0**	**0.82 [0.42–1.62]**	**79.1**	**65.6**	**0.65 [0.30–1.44]**
40–69	**1513**	**59.4**	**54.5**	**0.87 [0.75–1.01]**	**70.9**	**68.6**	**0.87 [0.73–1.04]**
≥70	**396**	**58.1**	**55.8**	**0.97 [0.72–1.31]**	**68.8**	**65.0**	**0.91 [0.65–1.26]**

Conclusions: Oral capecitabine is an effective alternative to 5-FU/LV as adjuvant therapy for stage III colon cancer and can be considered for use in all age groups, including patients aged ≥70 years.

O-0005. EFFICACY FINDINGS FROM A RANDOMISED PHASE III TRIAL OF CAPECITABINE + OXALIPLATIN VS. BOLUS 5-FU/LV FOR STAGE III COLON CANCER (NO16968): NO IMPACT OF AGE ON DISEASE-FREE SURVIVAL

Haller D[1], Cassidy J[2], Tabernero J[3], Maroun J[4], De Braud F[5], Price T[6], Van Cutsem E[7], Hill M[8], Gilberg F[9], **Schmoll H**[10]
[1]*University of Pennsylvania, Department of Hematology/Oncology, Philadelphia, Pennsylvania, USA,* [2]*Glasgow University, Glasgow, Scotland,* [3]*Vall d'Hebron University Hospital, Barcelona, Spain,* [4]*Ottawa Regional Cancer Centre, Ottawa, Ontario, Canada,* [5]*Istituto Europeo di Oncologia, Milan, Italy,* [6]*The Queen Elizabeth Hospital, Adelaide, Australia,* [7]*University Hospital Gasthuisberg, Leuven, Belgium,* [8]*Maidstone Hospital, Maidstone, UK,* [9]*F. Hoffmann-La Roche, Basel, Switzerland,* [10]*Martin Luther University, Innere Med. IV, Halle, Germany*

Background: Adjuvant capecitabine is at least equivalent to bolus i.v. 5-FU/LV for disease-free survival (DFS) and overall survival (OS) in stage III colon cancer. NO16968 compared XELOX with bolus i.v. 5-FU/LV (standard regimen at study start) for stage III colon cancer. In a planned safety analysis, XELOX had an acceptable safety profile [Schmoll et al. *JCO* 2007]. In a recent analysis of the ACCENT database, investigators concluded that improved efficacy associated with newer adjuvant regimens vs. 5-FU/LV may not be preserved in patients (pts) ≥70 years [McCleary et al. ASCO 2009]. We examined DFS across age groups in NO16968 to determine XELOX efficacy in pts ≥70 years.

Methods: Pts were randomized to either XELOX (capecitabine 1000mg/m^2 bid d1–14 + oxaliplatin 130mg/m^2 i.v. d1, q3w x8) or bolus i.v. 5-FU/LV regimens: Mayo Clinic (LV 20mg/m^2 + 5-FU 425mg/m^2 d1–5, q4w x6) or Roswell Park (LV 500mg/m^2 + 5-FU 500mg/m^2 d1, w1–6 in 8w cycles x4).

Results: 1886 pts were randomized between Apr 2003 and Oct 2004. 1864 were evaluable in the previously reported safety analysis. After a median follow-up of 57 months, 1886 pts are evaluable for DFS (primary endpoint), which was significantly superior for XELOX (HR=0.80; 95% CI, 0.69–0.93, p=0.0045) (see Table). Analysis of 3-year DFS in pts <70 and ≥70 years showed a similar advantage of XELOX over 5-FU/LV. Additional analyses are currently being conducted and will be presented.

O-0006. DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED PHASE III TRIAL OF AFLIBERCEPT (A) PLUS GEMCITABINE (G) VERSUS PLACEBO (P) PLUS GEMCITABINE (G) IN PATIENTS WITH METASTATIC PANCREATIC CANCER: FINAL RESULTS

Riess H[1], Manges R[2], Karasek P[3], Humblet Y[4], Barono C[5], Santoro A[6], Wojcik-Tomaszewska J[7], Assadourian S[8], Hatteville L[8], Vincent G[8], Philip P[9], Rougier P[10]
[1]*Charité, University Medicine, Berlin, Germany,* [2]*Investigative Clinical Research LLC, Indianapolis, Indiana, USA,* [3]*Masaryk Memorial Cancer Institute, Brno, Czech Republic,* [4]*Saint-Luc University Hospital, Bruxelles, Belgium,* [5]*Medical Oncology Unit, Gemelli Hospital, Roma, Italy,* [6]*Istituto Clinico Humanitas, Milano, Italy,* [7]*Wojewodzkie Centrum Onkologii, Gdansk, Poland,* [8]*Sanofi-aventis, Antony, France,* [9]*Karmanos Cancer Institute, Detroit, Michigan, USA,* [10]*Hôpital Ambroise Paré, Boulogne, France*

Background: Aflibercept, a recombinant fusion protein, is a potent inhibitor of vascular endothelial growth factor (VEGF) that also binds to placental growth factor. The primary objective of this multicenter randomized study (EFC10547) was to determine whether AG prolongs overall survival (OS) compared to PG, in patients (pts) with metastatic pancreatic cancer (MPC).

Methods: Main eligibility criteria were: metastatic disease, no prior therapy for advanced disease, PS 0-2 and no bleeding risk. Pts were stratified on PS (0 vs 1 vs 2), primary pancreas tumor resection (yes/no) and geographical region. This trial had 90% power to detect a median OS improvement from 5.5 to 6.3 months (mo). The trial was stopped according to recommendation of the independent Data Monitoring Committee after first interim analysis (IA) as pre-specified futility criteria was met. Results of final analysis including the period from data cutoff (May 09) for IA to the unblinding of pts (Sep 09) are presented.

Results: Between December 2007 and September 2009, 546 patients were randomized to receive either placebo or aflibercept 4mg/kg administered every 2 weeks (q2w) in combination with weekly intravenous gemcitabine 1000 mg/m^2, 7 weeks on/1 week off, then day 1, 8, 15 q4w. Pts characteristics (275PG/271AG): male (57%/59%), age>65year (35%/41%), PS1-2 (64%/63%), pancreas tumor resection (11%/10%), >1 organ involved (58%/60%). Median duration of follow-up was 7.9mo. As of 11 Sep 09, 284 (142/142) pts have died. Median OS (PG/AG) 7.8/6.5mo (HR 1.16; 95%CI: 0.92, 1.47). Median progression free survival (PFS) (PG/AG) 3.7/3.7mo (HR 1.02; 95%CI: 0.83, 1.25). 541 pts were treated and evaluable for safety. Median infusions P5/G10, A4/G7. Main grade (Gr) 3/4 adverse events (AE) related to VEGF blockade (%pts PG/AG): hypertension 3.0/14.1, venous thromboembolic events 10.0/7.0, proteinuria 1.2/5.3, bleeding 1.5/3.7, arterial thromboembolic events 1.8/2.2, cardiac dysfunction 0.4/1.5. Other Gr 3/4 AE >10%pts (%PG/AG): neutropenia 24.5/30.8, asthenia 10.3/14.8, alkaline phosphates increase 11.1/11.9, thrombocytopenia 6.4/11.2, hyperbilirubinemia 10.5/8.0. 26 fatal AEs: 12 pts in PG arm (main reasons: 4pts unknown cause, 3 pts sepsis), 14 pts in AG arm (3 pts cerebrovascular accident, 3 pts sepsis, 2 pts gastrointestinal hemorrhage).

Conclusions: The addition of A to G did not result in an OS benefit in patients with MPC. The median survival time in PG arm was longer than expected for this disease setting. The safety profile of AG was in accordance with what was expected in this disease setting and with such combination treatment including a VEGF pathway inhibitor.

O-0007. A PHASE III STUDY COMPARING LAROTAXEL TO 5-FU (CONTINUOUS INTRAVENOUS 5-FU OR CAPECITABINE) IN PATIENTS WITH ADVANCED PANCREATIC CANCER (APC) PREVIOUSLY TREATED WITH A GEMCITABINE CONTAINING REGIMEN

Van Cutsem E[1], Macarulla T[2], Van Laethem J[3], Couture F[4], Peeters M[5], Gehn Hoff M[6], Roman L[7], Lequesne L[8], Charpentier E[8], Conroy T[9]
[1]*University Hospital Gasthuisberg, Leuven-cfr, Belgium,* [2]*Hospital Vall d'Hebron, Barcelona, Spain,* [3]*Hôpital Erasme, Bruxelles, Belgium,* [4]*CHUQ Hospital Hotel-Dieu, Quebec, Canada,* [5]*UZ Gent, Gent, Belgium,* [6]*Hospital Sirio Libanes, Sao Paulo, Brazil,* [7]*Leningrad Regional Oncology Center, St-Petersburg, Russia,* [8]*Sanofi-aventis, Antony, France,* [9]*Centre Alexis Vautrin, Nancy, France*

Background: Larotaxel (LARO) is a microtubule interacting agent with reduced recognition to P-glycoprotein that showed preclinical efficacy in tumors resistant to or refractory to docetaxel, another taxane that had shown clinical activity in patients (pts) with APC. The primary objective of this international randomized study was to determine whether LARO prolongs overall survival (OS) compared to 5-FU (5-FU continuous intravenous (CIV) or capecitabine according to the choice of the investigator for whole study duration) in pts with APC.

Methods: Main eligibility criteria were: advanced disease, previous treatment with a gemcitabine-based regimen for advanced disease or in adjuvant setting with disease free interval less than 6 months, performance status (PS) 0-1, no prior locoregional

radiotherapy and adequate biological functions. Pts were stratified on disease stage locally advanced (LA) vs. metastatic (M) and prior adjuvant therapy yes vs. no. A total of 400 pts had to be randomized to detect 30% reduction in hazard ratio (HR) in LARO group with 90% power. Starting dose of LARO was reduced from 90 to 75 mg/m^2 following safety issues (Amendment 2) – patients randomized prior to amendment 2 were excluded from Intent To Treat population.

Results: Between July 2007 and July 2009, 408 patients (204 patients by arm) were randomized to receive either LARO 75 mg/m^2 on day 1 every 3 weeks (q3w) or 5-FU q3w (5-FU 1000 mg/m^2/day CIV over 4 days or capecitabine 2000 mg/m^2/day over 14 days and 1 week rest). In 5-FU arm, 71 pts (34.8%) were treated with 5-FU CIV. Results are presented LARO/5-FU. Pts characteristics were well balanced: male 55.4%/59.3%, age≥65year 40.2%/34.8%, PS 0 37.7%/37.7%, PS 1 60.8%/60.8%, metastatic 93.1%/92.6%, pancreatectomy 36.8%/36.3%, >2 organs involved 50.5%/45.1%. Efficacy results: median OS 4.8/5.1 months (mos) (HR 1.05; 95%CI: 0.842, 1.30, p= 0.69); median progression free survival 2.0/2.0 mos (HR 1.02; 95%CI: 0.83, 1.26). In both arms, pts with PS 0 had a better prognostic compared to pts with PS1: median OS PS0/PS1 in LARO arm was 6.2/4.0 mos; in 5-FU arm was 7.3/3.7 mos. A total of 395 pts were treated and evaluable for safety (198/197). Median (min-max) number of cycles were 2 (1-25) and 2 (1-22). Incidence per pts of clinical adverse events of any NCI grade with ≥10% difference between both arms were diarrhea 47.0%/29.9% (including colitis 2.0%/1.0%, enteritis 1.5%/0%), nausea 39.4%/28.9%, alopecia 35.4%/3.0%, constipation 24.7%/13.7%, sensory neuropathy 19.2%/6.6%, myalgia 13.1%/1.0%, stomatitis/mucositis 15.7%/27.9%, and hand foot syndrome 0.5%/22.3%. Main hematological toxicities were grade 3-4 neutropenia 42.1%/6.3%, and complicated neutropenia (febrile neutropenia and/or neutropenic infection) 15.7%/0.5%.

Conclusions: In patients with APC previously treated with a gemcitabine-based regimen the median survival times were longer than expected and no difference was observed between LARO and 5-FU. The safety profile of LARO was as expected for a taxane in this setting.

O-0008. PHASE III STUDY OF FOLFOX4 VS. DOXORUBICIN IN ASIAN PATIENTS WITH ADVANCED HCC: SUBGROUP ANALYSES ACCORDING TO BASELINE DISEASE STATUS

Qin S[1], Fan J[2], Cheng Y[3], Lim H[4], Kang W[4], Cho J[5], Thongprasert S[6], Bhudhisawasdi V[7], Chao Y[8], Yang T[9], Shen W[9], Sun Y[10]
[1]PLA Cancer Center of Nanjing Bayi Hospital, Nanjing, China, [2]Zhongshan Hospital Fudan University, Shanghai, China, [3]Jilin Provincial Cancer Hospital, Jilin, China, [4]Department of Medicine, Samsung Medical Center, Seoul, Korea, [5]Yonsei University College of Medicine, Gangnam Severance Cancer Hospital, Seoul, Korea, [6]Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand, [7]Department of Surgery, Khon Kaen University, Khon Kaen, Thailand, [8]Cancer Center, Taipei Veterans General Hospital, Taipei, Taiwan, [9]Chang Gung Memorial Hospital, Linkou, Taiwan, [10]Cancer Institute and Hospital, Chinese Academy of Medical Sciences, Beijing, China

Background: In Asia, where hepatitis B is very common, hepatocellular carcinoma (HCC) is the third most common cancer. Locally advanced or metastatic HCC are not eligible for surgery or localized treatments and median survival is only 3 months with supportive care. Although sorafenib prolongs survival in HCC patients, tumour response is seen in <3% of those treated. Systemic chemotherapies are used but there is no evidence of a survival benefit. Oxaliplatin-containing regimens have shown efficacy against advanced HCC in several Phase II trials.

Methods: This open-label, randomized, multicentre Phase III study was conducted in patients from mainland China, Taiwan, Korea and Thailand, who had locally advanced or metastatic HCC and were ineligible for complete resection or local treatment. Patients were randomized 1:1 to receive either FOLFOX4 (oxaliplatin 85mg/m^2 i.v. d1; LV 200mg/m^2 i.v. h0–h2 d1 and d2; 5FU 400mg/m^2 i.v. bolus h2, then 600 mg/m^2 over 22 hours d1 and d2 q2w) or doxorubicin (50 mg/m^2 i.v. q3w). Treatment was continued until disease progression, intolerable toxicity, or eligibility for surgical resection. The primary objective was to determine whether FOLFOX4 improves overall survival (OS) compared with doxorubicin; secondary objectives included time to tumour progression (TTP), response rate (RR) by RECIST 1.0, and safety. Data from subgroup analyses according to disease status at baseline (metastatic vs. localized disease) are presented.

Results: Primary results have been reported elsewhere.[1] The analysis after 266 events (deaths) has shown that in patients with metastatic disease who received FOLFOX4 (N=104) and doxorubicin (N=112), respectively, median OS was 5.7 months (95% CI: 4.8, 7.8) vs. 4.5 months [95% CI: 3.8, 5.5; *P*=0.028; HR: 0.688 (95% CI: 0.498, 0.950)]; median TTP was 2.8 months (95% CI: 2.1, 3.5) vs. 1.7 months [(95% CI: 1.5, 2.1; *P*=0.0059; HR: 0.641 (95% CI: 0.471, 0.874)]. RR was 9.6% vs. 2.7% (*P*=0.0322) and DCR was 49.0% vs. 23.2% (*P*<0.0001). In patients whose tumour was confined to the liver and received FOLFOX4 (N=80) and doxorubicin (N=75), respectively, median OS was 6.8 months (95% CI: 5.3, 7.3) vs. 6.5 months (95% CI: 4.3, 8.2; *P*=0.8482); median TTP was 3.3 months (95% CI: 2.6, 4.1) vs. 2.2 months (95% CI: 1.7, 3.2; *P*=0.0119). RR was 6.3% vs. 2.7% (*P*=0.4440) and DCR was 56.3% vs. 44.0% (*P*=0.1274). Toxicity was consistent with previous experience of FOLFOX4 and doxorubicin.

Conclusions: In this large international Phase III study of systemic chemotherapy in patients with unresectable HCC, a statistically significant survival benefit was seen with FOLFOX4 in those with metastatic disease and FOLFOX4 significantly increased TTP, RR and DCR vs. doxorubicin.

Reference:

1. Qin S, Bai Y, Ye S *et al.* ASCO, Chicago, USA. 4–8 June 2010. Abstract #42222 (submitted).

O-0009. EVIDENCE OF ACTIVITY AND CLINICAL BENEFIT WITH SUNITINIB IN PATIENTS WITH PANCREATIC NEUROENDOCRINE TUMORS (NET)

Raymond E[1], Niccoli P[2], Raoul J[3], Bang Y[4], Borbath I[5], Lombard-Bohas C[6], Valle J[7], Hörsch D[8], Patyna S[9], Lu D[9], Korytowsky B[9], Mundayat R[9], Chao R[9], Vinik A[10]
[1]Service Inter-Hospitalier de Cancerologie et Service de Gastroenteropancréatologie, Hôpital Beaujon, Clichy, France, [2]Assistance Publique, Hôpitaux de Marseille CHU Timone, Institut Paoli-Calmettes and RENATEN network, Marseille, France, [3]Eugène Marquis Centre and European University in Brittany, Rennes, France, [4]Seoul National University Hospital, Seoul, Korea, [5]Cliniques Universitaires Saint-Luc, Brussels, Belgium, [6]Hôpital Edouard Herriot, Hospices Civils de Lyon, France, [7]The Christie NHS Foundation Trust, Manchester, UK, [8]Center for Neuroendocrine Tumors, Bad Berka Central Clinic, Bad Berka, Germany, [9]Pfizer Inc., New York, NY, USA, [10]EVMS Strelitz Diabetes Research Center and Neuroendocrine Unit, Norfolk, VA, USA

Background: In a randomized, double-blind phase III trial, sunitinib was associated with superior progression-free survival (PFS; primary endpoint) over placebo in patients with progressive pancreatic NET (11.4 vs. 5.5 mo, respectively; P=0.0001). We report further assessment of clinical benefit in this trial, including patient reported outcome and exploratory analyses of prognostic factors for PFS.

Methods: Patients with advanced well-differentiated pancreatic NET, and disease progression in the past 12 mo, were randomized 1:1 to receive sunitinib 37.5 mg orally once-daily (n=86) or placebo (n=85), each with best supportive care. Patients completed the 15-domain EORTC Quality-of-Life (QoL) Questionnaire–Core 30 (QLQ-C30) version 3.0, on Day 1, every 4 wks (cycle) thereafter, and at end of treatment/withdrawal. Repeated-measures mixed-effects models were used to assess statistical (2-sided P value; 0.05 level) and clinical (≥10 point minimally important difference) mean between-treatment differences in QLQ-C30 changes from baseline. The influences of baseline characteristics on treatment effect were assessed using a Cox proportional hazards model.

Results: At baseline, all 15 QLQ-C30 domain scores had a ≤7-point mean difference between treatment arms. Post-baseline QLQ-C30 data were available for 73/86 and 71/85 patients in the sunitinib and placebo arms, respectively, through up to 10 cycles (during which each arm had ≥10 patients). Overall, compared with the placebo arm, patients on sunitinib had a clinically and statistically significant worsening of diarrhea (diff.=21.38; P<0.001) and a significant trend toward worsening of insomnia (diff.=7.753, P=0.0372). However, within the QLQ-C30, there were no clinically or statistically significant between-treatment differences in the following domains: cognitive, emotional, physical, role, social functioning nor other symptoms and scales; in addition, there were no significant between-treatment differences in mean change from baseline in the global QoL domain nor most other domains, when compared using a 2-sample T-test. The treatment effect significantly favored sunitinib regardless of age (<65 vs. ≥65 yrs), race (white vs. non-white), gender, ECOG status (0 vs. 1/2), number of metastatic sites (≤2 vs. ≥3), or time from diagnosis to study enrolment (<3 vs. ≥3 yrs). Sunitinib showed benefit over placebo in non-functioning tumors, with a trend for benefit in functioning tumors. The hazard ratio (HR) for PFS favored sunitinib patients, regardless of treatment with or without somatostatin analogs, which were allowed before and/or during the study. Similarly, sunitinib improved PFS relative to placebo regardless of prior chemotherapy use. By multivariate analysis, only time from diagnosis to enrolment (≥3 vs. <3 yr) was a potential independent predictor of PFS (HR 0.603; 95% CI 0.382, 0.952; P=0.0299). The PFS advantage with sunitinib was greater when adjusting for time from diagnosis (HR 0.374; 95% CI 0.234, 0.599; P<0.0001).

Conclusions: Complementing prior reports of efficacy from this trial in which sunitinib demonstrated improved PFS in patients with pancreatic NET, these results indicate that sunitinib maintains global QoL with overall clinical benefit observed across all patient subgroups studied.

O-0010. 90 YTTRIUM-DOTA-OCTREOTATE FOR THE TREATMENT OF ADVANCED NEUROENDOCRINE TUMOURS

Toumpanakis C, Caplin M, Quigley A, Marelli L, Chilkunda D, Khan M, Meyer T, Buscombe J
Royal Free Hospital, Neuroendocrine Tumour Unit, London, UK

Background: Peptide receptor therapy for neuroendocrine tumours (NETs) is a relatively new treatment modality, which was first trialed in 1992 using high dose ^{111}In-octreotide Progress has resulted in the use of beta emitting radionuclides Yttrium^{90} and Lutetium^{177}. The results with Lu^{177} and Y^{90} therapies are very promising especially when one considers that these patients have often failed other therapies. Aim: