**3006** POSTER DISCUSSION

**Time to Deterioration (TTD) in Patient-reported Outcomes in Phase 3 AXis Trial of Axitinib Vs Sorafenib as Second-line Therapy for Metastatic Renal Cell Carcinoma (mRCC)**

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**Background:** In an international, randomized, phase 3 trial of axitinib vs sorafenib as second-line therapy for mRCC, axitinib demonstrated greater median progression-free survival (PFS) compared to sorafenib (6.7 vs 4.7 mo; HR = 0.665, $P < 0.0001$). For patients who had received a prior cytokine regimen, median PFS was significantly higher in those treated with axitinib vs sorafenib (12.1 vs 6.5 mo; HR = 0.464, $P < 0.0001$); comparable values for those with prior sunitinib therapy were 4.8 vs 3.4 mo (HR = 0.741, $P < 0.0107$). Patient-reported kidney-specific symptom and functional outcome assessments were secondary endpoints.
**Patients and Methods:** 723 patients were randomized to receive axitinib 5 mg BID or sorafenib 400 mg BID. The Functional Assessment of Cancer Therapy–Kidney Cancer Symptom Index [FKSI-15] and the disease-related symptoms subscale [FKSI-DRS] were administered on Cycle 1 Day 1 before dosing, every 4 weeks while on study, at end of study treatment/withdrawal, and 28 days after final dose. A priori statistical methods included an analysis of TTD using survival analysis methods; reported $P$ values are 1-sided. TTD was defined as a composite endpoint of death/progression/worsening in FKSI, whichever occurred first. Clinically important changes in FKSI-15 and FKSI-DRS were predefined as decreases of $\geqslant$5 and $\geqslant$3 points, respectively. TDD was also examined by prior therapy with either cytokines or sunitinib.
**Results:** The composite TTD endpoint showed a 16−17% risk reduction for axitinib vs sorafenib (FKSI-15: HR = 0.83, $P = 0.0141$; FKSI-DRS: HR = 0.84, $P = 0.0203$). For patients with prior sunitinib therapy, there were no significant differences between treatments for the composite TTD endpoint ($P > 0.025$), but there was a 23−25% risk reduction in TTD based on FKSI scores alone ($P = 0.023$ for FKSI-15 and $P = 0.038$ for FKSI-DRS). For the prior cytokine therapy subgroup, the composite TTD endpoint demonstrated a 35−39% risk reduction for axitinib vs sorafenib (FKSI-15: HR = 0.61, $P = 0.0004$; FKSI-DRS: HR = 0.65, $P = 0.0024$).
**Conclusions:** Axitinib had superior PFS compared to sorafenib in second-line advanced RCC patients in a phase 3 trial. This PFS benefit with axitinib corresponded with a delay in worsening of the composite TTD endpoint compared with sorafenib in the overall and prior cytokine-treated subgroup. In the prior sunitinib-treated subgroup, axitinib was associated with delays in worsening of quality of life, but not for the composite TDD endpoint.

**3007** POSTER DISCUSSION

**The Effect of Guideline Consistent Antiemetic Prophylaxis on Chemotherapy-Induced Nausea and Vomiting (CINV) in the Overall, Acute, and Delayed Phases: the Pan European Emesis Registry (PEER)**

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**Background:** No prospective studies have assessed the effect of guideline consistent antiemetic prophylaxis (GCP) on patient outcomes in the era of modern antiemetic prophylaxis.
**Objectives:** The primary endpoint was to compare the proportion of patients with Complete Response (CR: No emesis and no use of rescue therapy) in the overall phase (0–120 hours post-chemotherapy) among patients who receive GCP for highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC) with those receiving guideline inconsistent antiemetic prophylaxis (GIP) during cycle 1. The analysis also compared outcomes during the acute (0−24 hours post chemotherapy administration) and delayed (25–120 hours post chemotherapy administration) periods.
**Methods:** PEER was a prospective, observational study which enrolled adults initiating single-day HEC or MEC at one of 52 centers located in 8 European countries (Austria, Belgium, France, Germany, Italy, Spain, Sweden, The Netherlands, and UK). Daily diaries were completed by patients for 5 days following chemotherapy for up to 3 cycles. The GCP definition was based on the 2006 MASCC guidelines. The proportion with CR was analyzed using multivariate logistic regression including well known CINV prognostic factors in the model.
**Results:** 991 patients comprised the evaluable population for cycle 1. The mean age was 56.7 years and 72.9% were female. Patients were classified as receiving HEC (19.1%), females receiving an anthracycline plus cyclophosphamide regimen (Female AC, 46.7%), or MEC (34.2%). The percentage receiving GCP in the overall phase was 29.0% (11.1% HEC, 28.7% Female AC, and 39.2% MEC) and 54.5% (43.4% HEC, 32.2% Female AC, and 91.2% MEC) in the acute phase. For the overall phase, CR was observed in 59.9% and 50.7% for the GCP and GICP groups, respectively ($p = 0.008$). The adjusted odds ratio for CR was 1.43 (95% CI: 1.04, 1.97; $p = 0.027$) for GCP compared to GIP. In the final multivariate model, statistically significant factors associated with CR in the final model included: GCP, MEC, use of primary antiemetics beyond recommended by guideline, no under-dosing of primary antiemetics, no history of nausea or vomiting, less anxiety in the 24 hours prior to chemotherapy, and less nausea in the 24 hours prior to chemotherapy. For the acute phase, CR was observed in 78.9% and 63.4% of the GCP-acute phase and GIP-acute phase patients ($p = 0.02$), respectively, with an adjusted odds ratio of 1.71 (95% CI: 1.19, 2.47; $p = 0.004$). CR in the delayed phase was 67.6% and 59.7% of GCP-overall patients and GICP-overall phase patients ($p < 0.001$), respectively, with an adjusted odds ratio of 1.48 (95% CI: 1.06, 2.05; $p = 0.021$).
**Conclusions:** Guideline consistent antiemetic prophylaxis reduces the incidence of CINV in the overall, acute, and delayed phases following highly and moderately emetogenic chemotherapy.

**3008** POSTER DISCUSSION

**CCAT: a UK Initiative to Address the Consequences of Cancer Treatment Through Research, Influence and Practice Development**

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**Background:** People who have been treated for cancer may be left with ongoing long-term physical, social or psychological issues. These problems can have a serious impact on people's lives, but frequently are not recognised or addressed. As the incidence of cancer rises and treatments become more successful, so the number of cancer survivors will increase. The number of people living into old age with the long term impact of cancer treatment is rising rapidly and there is a need to find effective, sustainable ways to better meet these patients' needs.
**Methods:** The Consequences of Cancer Treatment Collaborative (CCaT) has been set up by the UK charity Macmillan Cancer Support as part of a UK health services initiative to address the growing issue of cancer survivorship (the National Cancer Survivorship Initiative). CCaT is a collaborative of 12 senior nurses and allied health professionals with expertise in clinical practice, service development, research and education. By bridging the gap between research and practice, the group aims to improve care for people living with the effects of treatment, through a range of individual and collective projects.
**Results:** A wide range of projects have been set up and these include:

- Assessment of a nurse-led bowel management programme for bothersome symptoms after rectal cancer.
- Retrospective evaluation of the prevalence of long term urinary, sexual and bowel dysfunction in colorectal cancer patients.
- Overseeing the adaptation, implementation and evaluation of the Lance Armstrong Foundation "Cancer Transitions" educational programme for cancer survivors.
- Return to work:
  - Occupational Therapist role
  - Occupational health perspectives
- Development of 10 top tips for cancer survivorship

**Conclusions:** Through their collective voice, CCaT aims to influence services, help bridge the gap between research and practice, and make consequences of treatment a far more visible issue within the UK research and policy agendas.

**3009** POSTER DISCUSSION

**No Increased Incidence of Scalp Skin Metastases After Scalp Cooling in Breast Cancer Patients**

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**Background:** Chemotherapy-induced alopecia is a commonly feared side effect of chemotherapy treatment and can be prevented by scalp cooling. Given the theoretical increased risk of scalp skin metastases, there are some reservations about the use of scalp cooling in patients who are receiving adjuvant chemotherapy.
**Methods:** The incidence of scalp skin metastases in adjuvant treated breast cancer patients *without* scalp cooling was determined from data of the Munich Cancer Registry (MCR) [1] and files of patients who participated in the Dutch N4+-study [2]. Besides, we studied the incidence of scalp skin metastases in all kind of cancer patients *with scalp cooling* in literature [3] and patient files of Dutch scalp cooled patients [4].
**Results:**
1. In the MCR skin metastases occurred in 2.4% of 28,916 patients. Scalp skin metastases occurred in <1% of breast cancer patients.
2. Scalp skin metastases were reported in 0.5% of 885 breast cancer patients with four or more positive lymph nodes (N4+) at diagnosis.
3. In the literature, scalp skin metastases have been reported in 13 scalp cooled patients out of more than 3000 patients in 60 studies. However, follow up time was short in most studies. In a few studies, scalp skin metastases were systematically studied and were reported in <1% of about 1700 patients.
4. Three out of 395 Dutch scalp cooled patients of whom medical records were systematically checked, developed scalp skin metastases during a median follow up of 110 months. In the several Dutch scalp cooling studies from 2006 and onwards (n > 2500) about 70% of the scalp cooled patients received adjuvant chemotherapy and one scalp skin metastasis was reported. Scalp cooling was unlikely to have contributed in these cases.

**Discussion/Conclusion:** The scalp skin is anyhow a rare site of recurrence in breast cancer. No increase in scalp skin metastases has been observed in adjuvant treated scalp cooled patients. It is therefore unlikely that scalp cooling reduces the localized effect of chemotherapy such that the risk of scalp metastases increases. However, it remains a subject of discussion in the adjuvant setting, especially in patients with solid tumours with a less well known incidence of scalp skin metastases without scalp cooling. Scalp cooling is offered in the adjuvant setting in 51 of 59 Dutch scalp cooling hospitals.

## *Poster Presentations* (Mon, 26 Sep, 09:30–12:00) **Symptom Science**

**3010** POSTER

**Feasibility and Acute Toxicity of Single Fraction Half-Body and Wide Pelvic Irradiation With Helical Tomotherapy**

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**Introduction:** Single fraction half-body irradiation has became an old fashioned pallitive treatment for wide spread bone metastatic patients mainly due to GI toxicity. Nowadays, Helical Tomotherapy offers the possibility to delivery homogeneously high dose to the target volume while optimally sparing the organs at risk, specially the bowels.
This work evaluates the feasibility of helical tomotherapy treatment by analyzing dose distributions, delivery quality assurances, precision of set up and the acute toxicity.
**Material and Method:** Nine patients, 3 males and 6 females (mean age 62 yo), previously diagnosed of wide bone metastatic disease, were treated using the accelerator Tomotherapy Hi-Art II. Four patientes received half-body irradiation and 5 patients, enlarged pelvic field encompassing lower lumbar vertebrae and whole pelvis. The dose prescription was 8 Gray (Gy) in a single fraction, except in three patients where the dose was 6.5 Gy because the pelvic region had been previously treated. The plannig parameters were: jaw 5 cm, modulation factor between 1.2 and 2 and pitch 0.1, 0.215 and 0.43.
Clinical management protocol included blood test prior and one month after treatment. Steorids and antiemetics were administred prior and inmediatly post-treatmen.
**Results:** None of ten patients presented gastrointestinal toxicity or other acute side effect. Blood test samples taken prior and one month after treatment have not shown haematological toxicity. Subjective pain relief was noticed within two weeks after treatment by every patient, in a bimodal pattern with a first transient relief 24 hours after the treatment and a more lasting one appearing in the second week post-treatment.
In all patients, 98% of PTV received $\geqslant$ 90% of prescription dose, the homogeneity index $((D_{2\%} - D_{98\%})/D_{50\%})$ ranged from 0.07 to 0.18, while bowel volumen for the prescription dose was less 0.5% with a mean volume of 745 and 1428 $cm^3$ for 3 Gy and 5 Gy, respectively, when applicable. The treatment times varied from 11 to 26 minutes for 32 cm and 53 cm radiation lengths.
The mean positioning corrections were 0.10 mm (SD: 2.45 mm) for lateral direction, −1.38 mm (SD: 5.49 mm) for longitudinal direction, and 5.34 mm (SD: 5.95 mm), for vertical direction. The mean roll correction was 0.13º (SD: 1.16º).
**Conclusions:** The helical tomotherapy allows an easy way to get highly conformed dose distribution and protection of OARs, specially, of large target volume avoiding difficulties due to conventional linac field size limitations.

**3011** POSTER

**18-Month Safety Analysis of Fentanyl Pectin Nasal Spray (FPNS) in Patients With Breakthrough Pain in Cancer (BTPC)**

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**Background:** To assess the long-term safety of FPNS, a new treatment in Europe for BTPc, a 16-week study with an optional extension period (EP) was conducted. This study, identified as NCT00458510, is currently ongoing, but not recruiting participants. This report is the 18-month EP analysis.
**Materials and Methods:** Patients (new or from a previous study) experiencing 1–4 BTPc episodes/day while taking $\geqslant$60 mg/day oral morphine (or equivalent) entered the 16-week, open-label study. Upon completion, patients then had the option to enter the EP. FPNS was used to treat $\leqslant$4 BTPc episodes/day. During the EP, subjects were reviewed every 4 weeks; adverse events (AEs), concomitant medication, and study drug reconciliation data were gathered.
**Results:** Overall, data were available for 171 patients for the 18-month analysis. Of these patients, 34 remained on treatment, 161 have withdrawn, and 7 have completed the trial. Mean duration of treatment was 259.7 days (range 6–1017 days), with approximately 47% of the subjects being exposed to FPNS >180 days when including previous study exposure. Patients were primarily exposed to 400-μg (25.8%) and 800-μg (28.2%) doses; 78% maintained their titrated dose. Most withdrawals were due to death (61/171; 35.7%) or withdrawal of consent (29/171; 17.0%); a minority were due to AEs (10/171; 5.8%) or lack of efficacy (2/171; 1.2%). No treatment-related AE (TRAE) that resulted in death was considered related to FPNS. The overall incidence of AEs was similar across the dose groups and TRAEs were reported in 13 (7.6%) of patients. The only TRAE that was reported for at least 1% of patients was constipation (n = 4, 2.3%) – consistent with the known pharmacology of opioids. Three (1.8%) patients had TRAEs which were nasally related: 1 subject each reported mild postnasal drip, mild nasal dryness, and mild rhinalgia with mild nasal discomfort.
**Conclusions:** FPNS is a highly acceptable treatment option for BTPc in which the majority of individuals maintained their current effective titrated dose and experienced good systemic and local nasal tolerability over an 18-month period.
Sponsored by Archimedes Pharma Ltd.