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Identification of predictive biomarkers of overall survival (OS) in patients (pts) with advanced renal cell carcinoma (RCC) treated with interferon alpha (I) with or without bevacizumab (B): Results from CALGB 90206 (Alliance).

Subcategory:**Kidney Cancer****Category:**

Genitourinary (Nonprostate) Cancer

Meeting:**2013 ASCO Annual Meeting****Session Type and Session Title:**

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Abstracts that were granted an exception in accordance with ASCO's Conflict of Interest Policy are designated with a caret symbol (^).

Abstract Disclosures**Abstract:**

Background: CALGB 90206 was a phase III trial of 732 pts with RCC comparing B+I versus I alone demonstrating no difference in OS. To date, there are no validated predictive biomarkers for B in RCC. For this reason, baseline plasma samples from CALGB 90206 pts were analyzed to identify and test predictive markers for B+I in RCC pts. **Methods:** Baseline EDTA plasma samples from 424 consenting pts were analyzed using an optimized multiplex ELISA platform for 32 candidate factors related to tumor growth, angiogenesis, and inflammation. The data were randomly split into training (n=286) and validation (n=138) sets. The proportional hazards model was used to test for treatment-marker interactions of OS. The estimated coefficients from the training set were used to compute a risk score (RS) for each pt in the validation set. The RS classified pts by risk in the validation set. The model was assessed for its predictive accuracy using area under the curve (AUC). **Results:** A statistically significant 3-way interaction between interleukin-6 (IL-6), hepatocyte growth factor (HGF) and treatment was observed in the training set ($p<0.0001$). The median levels of IL-6 and HGF in the training set were 8.4 pg/ml and 89 pg/ml, respectively. In the validation set, the RS was predictive of OS ($p<0.001$) with the high and low risk groups having a median OS of 10 months and 32 months, respectively. The AUC in the validation set was 0.82 (95% CI=0.77-0.88). The median OS (in months) by median levels of IL-6 and HGF stratified by treatment arm in the validation set is presented in the table with associated 95% CI (NR=not reached). **Conclusions:** IL-6 and HGF are predictive for OS in RCC patients treated with B+I and a RS based on these factors identified patients who benefitted most from B. If independently validated, this novel RS could guide clinical decisions and pt selection in future RCC trials.

Validation set: I Arm (n=67)

	Low HGF (n=36)	High HGF (n=31)
Low IL-6 (n=43)	27 (19-40)	18 (11-NR)
High IL-6 (n=24)	11 (6-NR)	6 (5-25)

Validation set: B+I Arm (n=71)

	Low HGF (n=36)	High HGF (n=35)
Low IL-6 (n=34)	55 (42-NR)	16 (14-NR)
High IL-6 (n=37)	16 (12-NR)	12 (8-32)

Associated Presentation(s):

1. Identification of predictive biomarkers of overall survival (OS) in patients (pts) with advanced renal cell carcinoma (RCC) treated with interferon alpha (I) with or without bevacizumab (B): Results from CALGB 90206 (Alliance).

Meeting: **2013 ASCO Annual Meeting**

Presenter: **Andrew B. Nixon**

Session: **Genitourinary (Nonprostate) Cancer** (Poster Discussion Session)

Other Abstracts in this Sub-Category:

1. **Record-3: Phase II randomized trial comparing sequential first-line everolimus (EVE) and second-line sunitinib (SUN) versus first-line SUN and second-line EVE in patients with metastatic renal cell carcinoma (mRCC).**

Meeting: **2013 ASCO Annual Meeting**

Abstract No: **4504**

First Author: **R. J. Motzer**

2. **Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with metastatic renal cell carcinoma (mRCC).**

Meeting: **2013 ASCO Annual Meeting**

Abstract No: **4505**

First Author: **D. C. Cho**

Category: Genitourinary (Nonprostate) Cancer - **Kidney Cancer**

3. **Phase II efficacy and safety study of nintedanib versus sunitinib in previously untreated renal cell carcinoma (RCC) patients.**

Meeting: **2013 ASCO Annual Meeting**

Abstract No: **4506**

First Author: **T. Eisen**

Category: Genitourinary (Nonprostate) Cancer - **Kidney Cancer**

Abstracts by A. B. Nixon :

1. **A phase I study to assess the safety, tolerability, and PK of ARRY-380, an oral HER2 inhibitor.**

Meeting: **2010 Breast Cancer Symposium**

Abstract No: 262

First Author: S. L. Moulder

Category: Systemic Therapy - **New Systemic Agents - New drugs and targets (includes anti-angiogenics) - HER2 directed**

2. **Phase II trial of the irreversible oral pan-HER inhibitor PF-00299804 (PF) as first-line treatment in recurrent and/or metastatic (RM) squamous cell carcinoma of the head and neck (SCCHN).**

Meeting: **2010 ASCO Annual Meeting**

Abstract No: 5531

First Author: C. Le Tourneau

Category: Head and Neck Cancer - **Head & Neck Cancer**

3. **Prognostic and predictive impact of biologic classification by qRT-PCR with a 50-gene subtype predictor (PAM50) for adjuvant tamoxifen in premenopausal breast cancer: Results from the NCIC CTG MA.12 randomized trial.**

Meeting: **2010 ASCO Annual Meeting**

Abstract No: 508

First Author: S. K. Chia

Category: Breast Cancer - Local-Regional and Adjuvant Therapy - **Adjuvant Therapy**

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Presentations by A. B. Nixon :**1. Co-Chair**

Meeting: **2012 ASCO Annual Meeting**

Session: **Breast Cancer - Triple-Negative/Cytotoxics/Local Therapy**(Oral Abstract Session)

Co-Chair: **Stephen K. L. Chia**

2. Breast Cancer - Local-Regional and Adjuvant Therapy

Meeting: **2010 ASCO Annual Meeting**

Session: **Breast Cancer - Local-Regional and Adjuvant Therapy**(Poster Discussion Session)

Co-Chair: **Stephen K. L. Chia**

3. Prognostic and predictive impact of biologic classification by qRT-PCR with a 50-gene subtype predictor (PAM50) for adjuvant tamoxifen in premenopausal breast cancer: Results from the NCIC CTG MA.12 randomized trial.

Meeting: **2010 ASCO Annual Meeting**

Session: **Breast Cancer - Local-Regional and Adjuvant Therapy**(Oral Abstract Session)

Presenter: **Stephen K. L. Chia**

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Educational Book Manuscripts by A. B. Nixon :**1. “Right Drug for the Right Patient”: Hurdles and the Path Forward in Colorectal Cancer**

Source: **2013 Educational Book**

Category: **Gastrointestinal (Colorectal) Cancer**

2. A Multidisciplinary Approach in Muscle-Invasive Disease: Novel Chemotherapy Combinations and Targets in Chemoradiation

Source: **2013 Educational Book**

Category: **Genitourinary Cancer**

3. Aberrant Epigenetic Regulation: A Central Contributor to Lung Carcinogenesis and a New Therapeutic Target

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