Practice-changing crizotinib study in ALK-positive NSCLC

Crizotinib significantly prolonged progression-free survival (PFS) and overall response rate (ORR) compared with standard chemotherapy in patients with advanced, anaplastic lymphoma kinase (ALK)-positive non-small-cell lung cancer (NSCLC), reported a late breaking abstract yesterday. Furthermore, in comparison with chemotherapy, crizotinib was associated with significantly greater improvements in lung cancer symptoms and patient quality of life.

“These results establish crizotinib as the standard of care for patients with advanced previously treated ALK-positive NSCLC,” said study presenter, Dr Alice Shaw from Massachusetts General Hospital Cancer Center, Boston, USA.

Rearrangements of the ALK gene are found in around 5% of all lung cancers. “In NSCLC, ALK is activated by chromosomal rearrangement, leading to constitutive kinase activation and oncogene addiction,” explained Dr Shaw. In previous uncontrolled studies, crizotinib has been shown to induce significant clinical responses in patients with advanced ALK-positive lung cancer.

The investigators hypothesized that crizotinib would have superior efficacy to standard second-line chemotherapy in advanced ALK-positive NSCLC. The current study represents the first head-to-head comparison of crizotinib with standard therapy for this patient group.

In this prospective Phase 3 trial, 347 ALK-positive patients with stage IIIB/IV NSCLC and one prior chemotherapy were randomized 1:1 between February 2010 and February 2012 to crizotinib 500 mg twice daily, 21-day cycle (n=173) or chemotherapy (n=174). Chemotherapy was either programmed 500 mg/m² or docetaxel 75 mg/m² given intravenously on day 1 of every 21-day cycle. Altogether, 105 sites across 21 countries in Europe, North America, South America and Asia-Pacific participated in the trial.

The primary endpoint of progression-free survival (PFS), independent radiologic review was 7.7 months (median) in the crizotinib group versus 3.0 months in the chemotherapy group (HR 0.49; 95% CI 0.37–0.64, p<0.0001). The ORR was 65% in patients randomized to crizotinib versus 20% in those randomized to chemotherapy (p<0.0001).

However, an interim analysis of overall survival (OS) produced no difference between the two groups. “But the interim analysis is immature and not enough events have occurred to draw meaningful conclusions,” explained Dr Shaw.

It was important to note, she added, that significant crossover occurred during the study. “Patients who were randomized to receive chemotherapy and had disease progression were allowed to crossover to receive crizotinib. Hence, the majority of patients in the chemotherapy arm actually did receive crizotinib. This makes determining OS very challenging,” said Dr Shaw.

Commenting on the data, Dr Enriqueita Felip, from Vall d’Hebron University Hospital, Barcelona, Spain, said, “This is the first randomized study in the specific subgroup of lung cancer patients with tumors bearing ALK translocations. After the PROFILE 1007 study...”

Crizotinib also produced greater positive patient reported outcomes for symptoms (oxygen, dyspnea, fatigue, alopecia, and pain) compared with crizotinib (p<0.0001), and quality of life (p<0.0001).

Characterizing the ALK-positive NSCLC population in Europe

Following on from the positive data reported yesterday morning by Dr Alice Shaw on the Phase 3 trial of crizotinib as second-line therapy for patients with anaplastic lymphoma kinase (ALK)-positive non-small-cell lung cancer (NSCLC), findings from the European Thoracic Oncology Platform Lungscape Project, which is evaluating the prevalence of ALK positivity in resected stage I-III lung adenocarcinomas in Europe, were met with great interest.

In yesterday’s Proffered Papers Session on Biomarkers in Lung Cancer, Dr Fiona Blackhall from the Christie Hospital NHS Foundation Trust, Manchester, UK, explained that the prevalence of ALK-positive patients with NSCLC in Europe is unknown. As such, the Lungscape Project is providing a platform for evaluating the expression and clinical significance of ALK in a large cohort of patients with resected NSCLC (www.etop-eu.org).

At the time of her presentation, Dr Blackhall said that 15 European sites are currently participating in the study. These sites have retrospectively identified cases of NSCLC with clinical demographic and outcome data, and available tissue for research according to predefined protocol criteria. Accepted cases on the basis of completeness of clinical data were assessed for ALK expression using immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) was performed on ALK-positive cases and matched ALK-negative controls.

Dr Blackhall advised that 1099 patient cases have been included in the database so far, 69 (6.3%) of which were ALK-positive by IHC. There was a high level of concordance between ALK IHC+ and FISH+ (90.5% sensitivity and 97.7% specificity between ALK IHC+ and ALK FISH+), ALK IHC+ and ALK FISH+ also appear to provide prognostic information in patients with early-stage, resected adenocarcinoma, Dr Blackwell noted.

Dr Blackwell said that these findings represent the first large European dataset evaluating prevalence and outcome of ALK positivity in patients with stage I-III, resected lung adenocarcinoma, using IHC and FISH confirmation.
Diagnosis and management issues in lymphoma

- Lymphoma comprises heterogeneous disease subtypes, which reflect the heterogeneity of lymphoid cells.
- Detection methods in young patients with lymphoma:
  - Radiology
  - Nuclear medicine

- Key learning points from Sunday for all younger oncologists keen to expand their list of publications!
- Don’t miss today’s Young Oncologist track sessions, all of which have been specifically designed to:
  - Provide an overview of the latest research in oncology
  - Facilitate networking and collaboration among young oncologists

Towards integrated management of patients with carcinoma of an uncommon primary site

- The PETACC8 trial, presented yesterday by Dr Julien, was a randomized Phase 3, European intergroup trial to test cetuximab in the adjuvant setting, with disease-free survival (DFS) and secondary endpoints of disease recurrence and overall survival (OS).
- Dr Taieb concluded that “The addition of cetuximab to the FOLFOX4 regimen improves DFS and OS.”

**Key points**

- Combination therapy was associated with increased toxicity compared to FOLFOX4 alone.
- The addition of erlotinib to sorafenib does not prolong overall survival.
- This trial is a significant step forward in personalized medicine.

**Bone metastases: What to use and when**

- Spinal cord compression, pathologic fractures and other skeletal-related events (SREs) feature prominently in patients with metastatic castration-refractory prostate cancer (mCRPC).
- Various agents, including zoledronate and denosumab, appear to delay the development of SREs, and the newer agents, enzalutamide and abiraterone, offer a better standard of care for the prevention of SREs and metastatic bone pain.

**PM0113: A promising new drug for ovarian cancer**

- PM0113 (Adducan) is a small molecule inhibitor of PKC-δ, which is involved in the development of drug resistance in ovarian cancer.
- The phase 2 trial presented at the recent ESMO Congress in Vienna showed promising results.
- At the midline, 20% of patients with ovarian cancer had partial or complete responses to PM0113.

**Addition cetuximab to adjuvant chemotherapy offers no benefit to patients with resected stage IIIC colon cancer**

- As large clinical trials are needed to show significant benefit with any adjuvant therapy for digestive tract cancer, several cooperative groups came together under the name of PETACC (Pan European Trials in Alimentary Tract Cancer) to enable enrollment of a large number of patients.
- This consortium is composed of 46 centers in 14 countries.

**Moonlight Networking**

- Last night was perfect. It was a lot of people, exchanged contact information and started some important friendships.
- “It was great! I received tutoring from ‘older’ young oncologists.”
- “A very feliz evening, amusing, didactic and insightful. Askos for a reprint?”

**Toward cancer care in the 21st century: The future of molecular medicine**

- Dr Gauducheau, Nantes, France, presented the first results of a randomized phase 3 trial investigating the use of CD80 to improve immunological responses in patients with metastatic colorectal cancer.
- The results showed that the combination of CD80 with biological therapy improved survival in patients with metastatic colorectal cancer.

**Phase 3 SEARCH trial data, reported during Sunday’s Presidential Symposium, revealed: **

- The role of nuclear imaging methods such as FDG-fluoro-2-deoxy-D-glucose (FDG) positron emission tomographic (PET) and bone marrow scintigraphy for lymphoma staging was also considered.
- While the sensitivity of FDG PET for the detection of nodal and extranodal metastases and high-risk features for disease progression is well established, PET has an invasive and unpleasant procedure, and in some cases, palpation infiltration may result in false negative results. In this context, PET may be a better choice for patients with lymphoma.
How targeted therapies are shaping the future of oncology

I still remember when I started my training in oncology in 1993 when very few drugs were available for the fight against cancer and the concept of personalized medicine was just a dream. At the end of the day today, today’s ESMO presentations will highlight once more the immense progress we have witnessed in the past few years. It is a complete privilege to be here and learn about the latest developments. In the next few sessions, you can find a little flavor of what you can expect to see in the coming days. I do hope that all of us will share the same feeling!

As we move ever forward towards personalized medicine, biomarkers continue to be required to define critical targets or distinguish diverse components of all cancers. Using biomarkers in such therapeutic strategies has already proven successful for a number of malignancies, including lung and breast cancer. For example, epidermal growth factor receptor (EGFR) has emerged as a critical target for therapeutic development in some forms of cancer, with EGFR mutations driving the unchecked growth and proliferation of malignant cells. However, cancer’s ability to evolve and circumvent the blockade of one key target, such as EGFR, and patients eventually relapse. Therefore, using one single marker may not be the best strategy and other approaches are being sought.

In the last decade, there has been a shift towards a holistic approach to treating patients with cancer with much research dedicated towards personalized medicine. The use of biomarkers has provided a platform of information in terms of tumor biology and resistance to some treatments. However, not all types of cancer have these biomarkers available for use. Actually, very few biomarkers are currently being used to guide treatment decisions. The use of gene expression profiling has helped us to understand the tumor biology of several cancers, particularly breast and metastatic prostate cancer. The use of new techniques (e.g. RNA sequencing, radiolabeled positron emission tomography (PET) scans) will hopefully allow us to identify those patients who are most likely to respond to a given treatment and to spare these patients the toxicity of ineffective therapies. Without any doubt, we are definitely progressing towards a new era of personalized medicine and it is a privilege as young oncologists to be part of this "revolution" in oncology.

Dr Margaret Tempero from the University of California San Francisco (UCSF), California, USA, will provide an update on this important topic in tomorrow’s Special Symposia entitled "From biology to treatment in advanced pancreatic and gastrointestinal cancer", which is taking place at 11:00 – 12:30 in Hall D.

Pancreatic cancer remains a challenge for clinicians in day-to-day practice and the identification of biomarkers to help guide treatment is a real need. These new findings may benefit patients in the future, as some pancreatic cancer is generally diagnosed at a late stage and therapeutic options are limited.

For patients suffering from colorectal cancer, the recent ESMO abstracts clearly show that new therapeutic options are emerging. Today’s special session ‘Optimizing treatment in colorectal cancer’ will take place from 11:00 – 12:30 in Hall D and you can check in the abstracts if you are interested to learn more.

In the last few years, there has been an exciting new insight in colorectal cancer biology with the recognition of molecular-driven approaches, with attention focused on the use of molecular-driven approaches, with attention focused on the use of new targeted therapies that may provide really effective treatment for patients with colorectal cancer.

The special session ‘Optimizing treatment in colorectal cancer’ will take place from 11:00 – 12:30 in Hall D and you can check in the abstracts if you are interested to learn more.
Treatment with bevacizumab beyond progression: A new standard in mCRC?

The addition of bevacizumab to 5-FU-based chemotherapy has been a standard 1st-line treatment option for patients with metastatic colorectal cancer (mCRC) for many years. However, the current strong case is that the use of this agent beyond progression is an important clinical question.

Bevacizumab (Avastin) is a recombinant humanized monoclonal antibody that specifically binds to human vascular endothelial growth factor (VEGF), which is involved in tumor angiogenesis.

Several trials have investigated the use of bevacizumab beyond progression, including the BEYOND trial. This trial showed that bevacizumab beyond progression benefited patients with mCRC who had progressed on prior chemotherapy.

In the BEYOND trial, patients who continued to receive bevacizumab beyond progression had a longer overall survival compared to those who discontinued treatment. This finding has been supported by other trials, such as the BEYOND-2 trial, which also demonstrated improved overall survival in patients who continued on bevacizumab beyond progression.

However, the use of bevacizumab beyond progression is not without challenges. Drug toxicity and the need for infusion scheduling are some of the issues that need to be considered.

In conclusion, the use of bevacizumab beyond progression in patients with mCRC who have progressed on prior chemotherapy shows promise. Further studies are needed to determine the optimal strategy and to improve patient outcomes.

ESMO teamed up with the European Sarcoma Network to present the latest data from the COMPARZ trial. This trial investigated whether longer duration of trastuzumab after adjuvant chemotherapy had to continue, especially to find biomarkers for use in future treatment. The trial had 126 patients with HER2-positive early breast cancer. It was randomized to 2 years versus 1 year of trastuzumab after adjuvant chemotherapy. The primary endpoints were disease-free survival (PFS) benefit in mRCC, the COMPARZ trial investigating whether longer duration of trastuzumab after adjuvant chemotherapy had to continue, especially to find biomarkers for use in future treatment. The trial had 126 patients with HER2-positive early breast cancer. It was randomized to 2 years versus 1 year of trastuzumab after adjuvant chemotherapy. The primary endpoints were disease-free survival (PFS) benefit in mRCC, the COMPARZ trial investigating whether longer duration of trastuzumab after adjuvant chemotherapy had to continue, especially to find biomarkers for use in future treatment. The trial had 126 patients with HER2-positive early breast cancer. It was randomized to 2 years versus 1 year of trastuzumab after adjuvant chemotherapy. The primary endpoints were disease-free survival (PFS) benefit in mRCC, the COMPARZ trial investigating whether longer duration of trastuzumab after adjuvant chemotherapy had to continue, especially to find biomarkers for use in future treatment. The trial had 126 patients with HER2-positive early breast cancer. It was randomized to 2 years versus 1 year of trastuzumab after adjuvant chemotherapy. The primary endpoints were disease-free survival (PFS) benefit in mRCC, the COMPARZ trial investigating whether longer duration of trastuzumab after adjuvant chemotherapy had to continue, especially to find biomarkers for use in future treatment. The trial had 126 patients with HER2-positive early breast cancer. It was randomized to 2 years versus 1 year of trastuzumab after adjuvant chemotherapy. The primary endpoints were disease-free survival (PFS) benefit in mRCC, the COMPARZ trial investigating whether longer duration of trastuzumab after adjuvant chemotherapy had to continue, especially to find biomarkers for use in future treatment. The trial had 126 patients with HER2-positive early breast cancer. It was randomized to 2 years versus 1 year of trastuzumab after adjuvant chemotherapy. The primary endpoints were disease-free survival (PFS) benefit in mRCC, the COMPARZ
Defining standards of care in renal cell carcinoma

Today’s Pressed Papers session on renal cancer (10:15 – 10:35) will include headline results from several high profile Phase 3 trials as well as recently randomized Phase 2 presentations. Proffered papers not to be missed are:

LISAT-PR Dr Oriol Ribas from the Ohio: Designating CancerSubtype, this oral presentation on results from the Phase 3 INICHT trial of temozolomide (TMZ) plus bevacizumab (BEV) versus TMZ alone in advanced renal cancer patients. TMZ plus BEV are considered highly active treatments for the comparison of these 2 regimens will be presented.

LISAT-PR Dr Thomas Huber from the Baplo Samsun Cancer Center, Dallas, USA, will present results from the Phase 2 PRIME trial of temsirolimus (TOR) as second-line treatment versus placebo in patients with metastatic renal cell carcinoma (mRCC). Key efficacy and safety endpoints for this study will be presented, together with overall survival data.

TECO Dr Alan Rassou from H.C. Crocker Hospital El, Andrew Berenson, Ph.D, will present results from the Phase 2 TELOCO-2 study, a Phase 3 trial comparing the combination therapy with everolimus (EVE) + BEV or interferon alpha + BEV in patients with mRCC. Efficacy data from this study, including PFS and overall survival (OS) will be presented and compared to placebo.

Session Info: Pressed Paper Session, Renal Cancer
Day/Time: Monday, October 12, 2012
Room: Hall D

ESMO members are invited to visit us in the exclusive ESMO Congress Lounge, located in green level/01

Emerging diagnostic and therapeutic targets in cancerous tissues: from science to clinical practice

Friday 11:00 – 11:45

Biotherapy based treatment in head and neck squamous cell carcinomas

16:00 – 17:30

Relax!

Targeting the cancer microenvironment

With clinical research placing so much emphasis on the genetics of cancer, predictive biomarkers, and the identification of molecular targets in tumor cells, it is no surprise that these factors also have ‘tumor’.

Dr Gegev Petridis, also from the University of Ioannina, described the genetic mutations and cell signaling pathways that are frequently required in solid tumors. His talk focused on defining the impact of these mutations on the 4th most common cause of cancer death. It does, however, remain to be seen how these mutations may be relevant in the future. However, the scientific community is currently searching for these mutations in order to determine the importance of these tumors.

Dr Pentheroudakis, the chair of the session, described the main mechanisms of therapeutic strategies. The aim is to understand the mechanisms of tumor progression in order to target them. New therapeutic strategies have led to new drugs and technologies.

Dr Pavlidis also gave an overview on a framework for optimizing the therapeutic management of patients with advanced clinical pathologic CUP patients.

LISAT-PR Dr Brian van’t Veer from the University of Amsterdam, the Netherlands, reported on a novel therapeutic approach to the treatment of metastatic breast cancer. Dr van’t Veer is the lead of the TAILORx study, which aims to determine the effectiveness of new breast cancer treatments.

LISAT-PR Dr John Kirkwood from the Royal Marsden, London, UK, reported on the prognostic value of plasma DNA in predicting the outcome in patients with metastatic colorectal cancer (mCRC).

LISAT-PR Dr Daniele Parmigiani from the Hospital of the University of Pavia, Italy, presented the results of the GONO study, which investigated the impact of the addition of cetuximab to chemotherapy in patients with advanced colorectal cancer.

LISAT-PR Dr Josep Tabernero from the Hospital del Mar, Spain, discussed the results of the SWOG S0495 trial, which evaluated the efficacy and safety of the combination of chemotherapy and targeted therapy in patients with advanced renal cell carcinoma.

Dr Pentheroudakis’s talk was followed by the discussion from his colleague, Professor Pentheroudakis, on the impact of the therapeutic management of patients with advanced clinical pathologic CUP patients.

A vailable for iphone, iPad and Android

ESMO Designated Centers - 27 centers accredited for the period 2013-15

ESMO Designated Centers - 27 centers accredited for the period 2012-2014

ESMO 2012 emphasizes palliative care

The European Society for Medical Oncology (ESMO) has awarded its ESMO Designated Center of Integrated Oncology and Palliative Care to 27 accredited oncology centers.

The deadline for the award of the ESMO Designated Center of Integrated Oncology and Palliative Care is 10th October 2013.

ESMO’s work in palliative care is essential for patients and healthcare professionals in the European Union. ESMO is the largest European organization in the field of medical oncology, and its work in palliative care is both globally and regionally the most important.

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Opportunity to find out more about European Fellowships

The ESMO Fellowship Program, which has been running for over 20 years, aims to create a cadre of young oncologists with clinical competence and professional levels of clinical competence and professional excellence, and improve quality of patient care.

The idea behind yesterday's session was for case studies to be presented by leading experts in their fields, and the audience to provide feedback on how they would interpret guidelines.

Dr Berta Sousa from the Champalimaud Cancer Centre, Lisbon, Portugal, presented the case of a 42 year old pre-menopausal patient with breast cancer. From the interactive key pads, she found that 65% of the audience would not undertake brain imaging screening of a symptomatic patient. Furthermore, the most popular treatment of choice was capecitabine + oxaliplatin, which was favored by 29% of patients.

Dr Wei-Xiang Qi from Shanghai, China, will present a systemic review and meta-analysis of 23 randomized phase 2 and phase 3 trials as well as several meta-analyses. Presentations not to be missed are:

- Dr Chao Ping from Shenzhen, China, will present a systematic review and meta-analysis of randomized controlled trials that compared taxanes-based regimens with anthracyclines-based regimens in patients with metastatic breast cancer.
- Dr Alessandra Geretti from Geneva, Italy, will present data evaluating the effect of body mass index on progression in 403 women with metastatic breast cancer. All patients received first line chemotherapy and were managed with or without bevacizumab. Results showing how the audience used the CPGs

Breast cancer, locally advanced and metastatic

Today’s Poster Discussion session on breast cancer (12:45 – 13:45, Hall B) will include headline results from randomized phase 2 and phase 3 trials as well as several meta-analyses. Presentations not to be missed are:

- Dr Enrico Forma from Genova, Italy, will present a treatment response interim analysis comparing palbociclib and trastuzumab chemotherapy in first-line HER2-positive and HER2-negative basal-like breast cancer.
- Dr Alexey Verey from Geneve, Switzerland, will present results showing that the use of bevacizumab results in higher quality of life scores in patients with metastatic breast cancer.
- Dr Chao Ping from Shenzhen, China, will present a systematic review and meta-analysis of randomized controlled trials that compared taxanes-based regimens with anthracyclines-based regimens in patients with metastatic breast cancer.

Don’t miss the ESMO Booth, which is located in the main exhibitions hall.
Play provokes pause for thought on cancer screening

An updated version of a play by a leading oncologist exploring how unnecessary screening results in the diagnosis of ‘pseudo-cancers’ was staged to great acclaim yesterday. The satirical drama was performed by a cast of eminent oncologists.

First performed in 2002 at the 3rd European Breast Cancer Conference in Barcelona, the play “2084” envisages the hero of Orwell’s novel as a medical oncologist in the year 2084. The drama showed how Winston Smith’s attempt to carry out clinical research led him into confrontations with the authorities and ended with him being hauled before the Ministry of Truth and Health accused of the ultimate crime of “not being politically correct.”

“My initial motivation for writing this play was the creeping bureaucracy of the EU that was making life for those of us involved in clinical research on cancer therapy, almost impossible,” explained Professor Baum.

For ESMO 2012 Professor Baum has updated the play with a new third Act addressing the problems of over-diagnosis. Although the play may be ‘tongue in cheek’, it makes an extremely serious point that there’s a downside to screening. “For every life saved 10 healthy women will, as a consequence, become cancer patients and will be treated unnecessarily. These women will have either a part of their breast or a whole breast removed, and they will often receive radiotherapy and sometimes chemotherapy,” said Professor Baum.

In yesterday’s performance ESMO President Professor Martine Piccart took the role of Martine Kwik-Fix, the senior data manager at Republican Marsden Hospital. The cast list, which reads like a Who’s Who of European oncology, also featured Kamal Saini (Brussels), Mario Dicato (Luxembourg), John Crown (Dublin), Angela Di Leo (Pistoia, Italy), Elisabeth de Vries (Groningen, Netherlands), Michael Grant (Vienna), Nadia Harbeck (Munich), Cristina Sessa (Bellinzona, Switzerland) and David Cameron (Edinburgh).

The new version ended on the surprisingly upbeat note of Winston and Martine singing a song of freedom from the tyranny of the ‘cancer bean counters’ to the tune of ‘La Marseillaise’. Here, the audience could not resist expressing their enthusiasm by joining in.

“Thanks to the director Jonathan Fox, the performance exceeded my greatest expectations and the audience were wonderfully appreciative,” said Professor Baum afterwards.

Commenting on the play, Professor Jean-Pierre Armand, from the Gustave Roussy Institute, Villejuif, France, said, “What really amazed me was that such a professional production was achieved by actors who were all key opinion leaders in oncology more used to giving high level scientific presentations. But I shouldn’t have been so surprised, as for this they need to be born actors.”

It was especially impressive, he added, that they had succeeded in staging such a professional production with just 3 rehearsals.

Professor Armand added that, “he would take it upon himself to ensure that the play was widely disseminated to hospitals throughout Europe.”