

Today's Top Picks!

Poster Discussion

Gastrointestinal tumors,
non-colorectal

13:00 – 14:00

HALL C

Proffered Paper Session

Breast cancer, metastatic

13:55 – 15:55

HALL A

Proffered Paper Session

Renal cancer

14:00 – 15:50

HALL D

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MONDAY 1 OCTOBER 2012

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 250 mg twice daily, 21 day cycle (n=173) or chemotherapy (n=174). Chemotherapy was either pemetrexed 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).

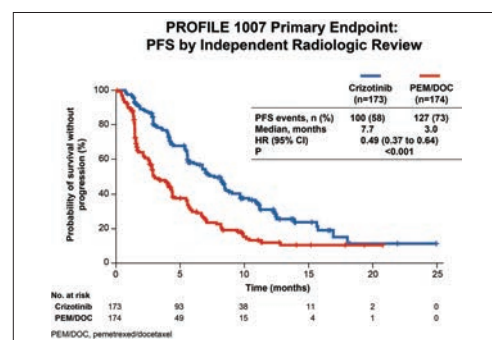
However, an interim analysis of overall survival (OS) produced no difference between the two groups. "But the interim analysis is immature and not enough events have occurred to draw meaningful conclusions," explained Dr Shaw.

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 Enriqueta 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



Alice Shaw, Boston, MA, USA



Progression-free survival by independent radiologic review in the PROFILE 1007 study

worldwide implementation of targeted therapy in lung cancer patients defined by another molecular alteration, EGFR mutation, this is the second group of lung cancer patients to clearly benefit from a therapy directly targeting a molecular alteration. The results of this study represent a significant step towards individualized therapy in lung cancer patients."

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



Discussant: Jean-Charles Soria, Villejuif, France

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 Blackwell 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 3+ 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.

Education Sessions: Key learning points from Sunday

Diagnosis and management issues in lymphoma

- Lymphomas comprise heterogeneous disease subtypes, which reflect the heterogeneity of lymphoid tissues in the human body. Advance research methods, such as next generation sequencing technologies, are unraveling a complex landscape of molecular alterations. These findings are refining sub-classification and helping to identify new biomarkers and drug targets

- A new addition to the therapeutic armamentaria are agents, known as immunotoxins, which use monoclonal antibodies to deliver radiotherapy or toxins directly to the tumor cell. Examples include: brentuximab vedotin, an anti-CD30 antibody conjugated to a antitubulin; and inotuzumab ozogamicin, a cytotoxic agent linked to an anti-CD22 antibody, which has shown a promising response rate in refractory indolent B-cell non-Hodgkin lymphoma

- The role of nuclear imaging methods such as 8F-fluoro-2-deoxy-D-glucose (FDG) positron emission tomography (PET) and bone marrow examination for lymphoma staging was also considered. While the sensitivity of FDG-PET allows for the detection of nodal and extranodal tumor manifestations and might change clinical patient management, its routine use is compromised by relatively high radiation exposure and high costs. On the other hand, bone marrow biopsy reliably detects bone marrow infiltration but is an invasive and an unpleasant procedure, and in some cases, patchy infiltration may result in false negative results. So it was concluded that FDG-PET bone marrow biopsy is complementary, and one should not replace the other

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

- It is important to note that cancer of unknown primary (CUP) represents 3% of patients with cancer. The prognosis for patients with CUP is poor. As a group, the median survival is approximately 3 to 4 months with less than 25% and 10% of patients alive at 1 and 5 years, respectively

- Although the majority of diseases are relatively refractory to systemic treatments, certain clinical presentations of CUP carry a much better prognosis. In each instance, distinct clinical and pathologic details should be considered for appropriate and potentially curative management

- Molecular studies have shown that CUP is a heterogeneous group of tumors with active angiogenesis and common expression of oncoproteins, such as c-myc, ras, HER2, Bcl2. The major intracellular AKT and MAPK axes are frequently activated and carry adverse prognostic significance

Updates in supportive and palliative care

- The prevalence of depression among cancer patients is estimated to be approximately 38% for major depression, and 57% for depression spectrum syndromes, such as demoralization syndrome. Risk factors for depression in cancer patients include young age, low socioeconomic status, and tumor location, with the highest rates of depression seen in patients with lung, pancreatic and head and neck cancer. There is scientific evidence indicating that biological mechanisms related to the cancer itself or its treatments, such as production of pro-inflammatory cytokines, contribute to the development of depression syndrome in cancer patients. Depression leads to increased length of stay in hospital, reduced adherence to treatment, and increase risk of suicide. The optimal treatment of depression should be a combination of control or elimination of potential organic causes, psychotherapy, pharmacotherapy and working with the patient's family and staff members

- Pain is a serious issue in oncology and affects 33% of patients after curative treatment, 59% of patients on anticancer treatment, and 64% of patients with metastatic, advanced, or terminal disease. According to the recently released ESMO recommendations, the intensity of pain and treatment outcomes should be regularly assessed by the treating physicians using validated assessment tools. The treatment of cancer pain should rely, not only on drug treatment, but also on non-pharmacological interventions such as intraspinal interventions or celiac plexus blockade. The formulation of specific recommendations is at the moment complicated by the lack of randomized controlled trials and further well-designed studies are needed to improve cancer pain management

Phase 3 SEARCH trial data, reported during Sunday's Presidential Symposium, reveal:

- The addition of erlotinib to sorafenib does not prolong overall survival or time to progression compared with sorafenib alone
- Combination therapy was associated with increased toxicity
- Further subgroup analyses are required
- Sorafenib remains the standard of care for advanced HCC

Adding cetuximab to adjuvant chemotherapy offers no benefit to patients with resected stage III colon cancer

Findings from the primary analysis of the randomized Phase 3, European intergroup PETACC8 trial, presented yesterday by Dr Julien Taieb of the Georges Pompidou European Hospital, Paris, France, showed that the addition of cetuximab to standard adjuvant FOLFOX4 chemotherapy regimen offers no benefit to patients with resected stage III, KRAS wild-type (wt) colon cancer.

The rationale for this adjuvant study was based on previous finding that adding cetuximab to FOLFOX was beneficial in patients with metastatic KRAS wt colon cancer. However, PETACC8 is the second trial to test cetuximab in the adjuvant setting, with findings from the US N0147 trial (cetuximab + mFOLFOX6) also failing to show any benefit.

As large clinical trials are needed to show significant benefits with any adjuvant therapy for digestive tract cancers, several cooperative groups came together under the name of PETACC (Pan-European Trials in Alimentary Tract Cancer) to enable enrolment of a large number of patients. This consortium is composed of over a dozen European national and international co-operative groups. This major pan-European collaboration was launched to investigate whether cetuximab in combination with oxaliplatin-based chemotherapy (FOLFOX4) would reduce disease recurrence and prolong survival in fully resected stage III colon cancer after surgery. Scientists from the Fédération Francophone de Cancérologie Digestive (FFCD) led this intergroup trial in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC) and national groups involved in the PETACC structure. In this PETACC8 trial, 1602 patients with KRAS wt, stage III, fully resected colon cancer were randomized 28–56 days following resection to 12 biweekly cycles of oxaliplatin 85 mg/m² on day 1, with leucovorin 200 mg/m² and 5-FU 400 mg/m² bolus IV followed by 5-FU 600 mg/m² over 22 hours IV on days 1–2 (FOLFOX4), without (arm A) or with (arm B) weekly cetuximab 250 mg/m² (loading dose 400 mg/m²). The primary endpoint was disease free survival (DFS), and secondary endpoints included overall survival, treatment compliance, safety and biological studies for evaluation of markers predictive for relapse and/or treatment efficacy.

At the time of this interim analysis, the median follow-up was approximately 3.3 years. No difference was seen between the arms for DFS (HR 1.047; 95% CI: 0.853–1.286; p=0.6562) or overall survival (OS; HR 1.092; 95% CI: 0.813–1.466; p=0.5583) in KRAS wt patients (n=1602) or for DFS (HR 0.985; 95% CI: 0.755–1.284; p=0.9117) or OS (HR 0.981; 95% CI: 0.669–1.438; p=0.9236) in KRAS/BRAF wt patients (n=984).

Worse DFS was seen with cetuximab in patients aged >70 years (n=149, HR 1.97; 95% CI: 0.99–3.93; p=0.051), in females (n=666; HR 1.45; 95% CI: 1.03–2.02; p=0.031) and patients with right-sided colon cancer (n=570; HR 1.40; 95% CI: 1.01–1.94; p=0.043). Conversely, a trend towards a better outcome was seen in patients with poor prognosis tumors (i.e. those with high grade tumors [HR 0.76; 95% CI: 0.49–1.16], T4 disease [HR 0.71; 95% CI: 0.50–1.02], or perforation/obstruction [HR 0.79; 95% CI: 0.53–1.18]) and was significant in patients with pT4N2 at diagnosis (n=146; HR 0.555; 95% CI: 0.348–0.885; p=0.0122).

Dr Taieb concluded that "The addition of cetuximab to FOLFOX4 offered no DFS or OS benefit to patients with resected, stage III, KRAS wt or KRAS and BRAF wt colon cancer." He reasoned that "cetuximab may have a different form of activity in micrometastatic disease compared with that observed in stage IV disease" as a possible explanation for why cetuximab did not provide any additional benefit in this setting.

A step forward in personalized medicine in breast cancer

Two studies in yesterday's proffered papers session explored use of DNA microarrays and surgery in breast cancer.

Professor Jean-Yves Pierga from the Institute Curie, Paris, France, presented the first results of the REMAGUS04 trial using DNA arrays to select treatment.

"There is a need to determine robust and high throughput biotechnologies for biomarker determination for clinical use. DNA arrays allow quantifying gene expression at the whole genome level and could improve prediction of the benefit from specific immunotherapy," said Professor Pierga.

The Diagonal Linear Discriminant Analysis-30 (DLDA30) probe has been developed to predict resistance to neoadjuvant chemotherapies with a better sensitivity than standard parameters.

The phase 3 REMAGUS04 trial set out to evaluate whether the expression of of DLD30 and with TOP2A could improve neoadjuvant chemotherapy efficacy.

In the study after under going biopsy, 142 patients with adenocarcinoma of the breast who were not eligible for breast conserving surgery were randomized to a standard treatment arm or a 'genomic-driven' arm where they received treatments according to their DLD30/TOP2A expression.

Results show that the pathological complete response (pCR) was 35% in the standard arm versus 38% in the genomic arm. The results also showed that a DLD30 positive score was associated with an increased likelihood of pCR, which occurred in 36% of DLD30 positive patients versus 3% of DLD30 negative patients.

"This is the first prospective trial showing that whole genome array is feasible in the context of daily practice within 15 days," said Professor Pierga. "Gene expression arrays could be a solution in the future to propose an all-in one assay for personalized medicine."

Dr Carmen Criscitiello, from the European School of Oncology, Milan, Italy, followed up with a thoughtful and patient-centric analysis of the NeoALTTO trial, looking to investigate the different factors affecting choice of surgery in patients enrolled in the NeoALTTO trial.

In the NeoALTTO trial, patients with HER2 positive breast cancer were randomized to either trastuzumab, lapatinib or their combination concomitantly with paclitaxel prior to surgery.

Results showed that the pCR was 24.7% in patients receiving lapatinib plus paclitaxel versus 29.5% for patients receiving trastuzumab plus paclitaxel versus 51.3% for patients receiving all three drug. "But despite the combination producing nearly double the pCR, breast conservation was similar in each arm," said Dr Criscitiello. Breast conservation was achieved in 42.9% of patients in the lapatinib plus paclitaxel arm, 38.9% of patients in the trastuzumab plus paclitaxel arm and 41.3% in the lapatinib, trastuzumab and paclitaxel arm.

The factors found to be independently associated with the type of planned surgery at diagnosis were geographic region (with surgery occurring less frequently in developed countries) and tumor size.

"These results call for a clear consensus on the role of breast cancer surgery in patients responding to neoadjuvant therapies. This will translate the progress in neoadjuvant therapies into improved breast conservation rates," said Dr Criscitiello.

PM01183: A promising new drug for ovarian cancer

In platinum resistant/ refractory ovarian cancer PM01183 (lurbicetectedin) produced an overall response rate of 27%, reported the results of a phase 2 trial presented in the proffered papers session for gynecological cancers yesterday.

At first relapse, 30% of patients with ovarian cancer have platinum resistant/ refractory disease, though almost all recurrent ovarian cancer patients ultimately develop platinum resistance.

PM01183 is a new synthetic entity belonging to the tetrahydroisoquinoline family, which binds to the DNA minor groove inducing DNA breaks and transcription blockage.

Dr Dominique Berton-Rigaud from the Center René Gauducheau, Nantes, France, presented the first stage of a randomized phase 2 for PM01183.

Moonlight Networking

Last night over 100 young oncologists connected at the Moonlight Networking event on the "Motto am Fluß". To say the least, participants were very enthusiastic about the evening noting that it was a fantastic opportunity to meet people from other countries in a relaxed environment. Christoph Zelinski, CCC, Vienna kicked off the evening saying, "You are the future of Oncology and of ESMO!"

This exclusive networking event was supported by the OeGHÖ, the Comprehensive Cancer Center (CCC) Vienna and the ESMO YOC.



"Last night was perfect. I met a lot of people, exchanged contact information and started some important friendships."

Milan Petrova, Military Medical Academy, Bulgaria

"It was great! I received tutoring from 'older' young oncologists."

Anna Berghoff, Medical University, Vienna, Austria

"A very felicitous evening, amusing, delicious and loquacious! Asks for a reprise!"

Catharina Dressler, CCC, Vienna, Austria

Bone treatments: What to use and when

Spinal cord compression, pathological fracture and other skeletal-related events (SREs) feature prominently in patients with metastatic castration-resistant prostate cancer (mCRPC). The bisphosphonate, zoledronate, is widely, though not universally, regarded as a standard treatment to reduce the risk of SREs in these patients. However, new drugs are emerging suggesting that we may soon be able to offer a better standard of care for the prevention of SREs and metastatic bone pain.

During yesterday's Special Symposium on the medical treatment of advanced prostate cancer, Dr Chris Parker, Consultant Clinical Oncologist at the Royal Marsden Hospital NHS Foundation Trust, Sutton, UK, reviewed data for the various existing and emerging bone treatments for prostate cancer and provided his expert opinion regarding how we can best use these agents to improve overall survival (OS) and quality of life (QoL) and to delay SREs and bone metastases.

Dr Parker began his presentation by commenting on the lack of survival benefit observed with older bone-targeted agents such as zoledronate and clodronate, and the lack of difference in OS observed between zoledronate and denosumab, an inhibitor of receptor activator of nuclear factor kappa-B (RANK) ligand.

Various agents, including zoledronate and denosumab, appear to delay the development of SREs, and the newer agents, enzalutamide and abiraterone, also provide benefit in this setting. However, data from earlier this year showed that the bone-targeted alpha-emitter radium-223 is the first agent to improve OS (median OS of 14.9 months versus 11.3 months; HR 0.695; 95% CI: 0.581–0.832, p=0.0007), delay SREs (HR 0.64; 95% CI: 0.52–0.78, p<0.001) and improve QoL (FACT-P total score: 27 versus 18, p< 0.05) versus placebo in patients with mCRPC, suggesting that it may be a suitable option for both non-chemotherapy and post-chemotherapy patients with mCRPC.

For the first stage, the trial enrolled 22 patients with platinum-resistant or refractory ovarian cancer, who had received no more than 2 prior chemotherapy lines for metastatic disease.

Results of the first stage showed that 6 patients responded to PM01183 (2 according to Rustin criteria and 4 according to RECIST), giving an overall response rate of 27% (95%CI: 11%–50%) including one radiological complete response. At the first evaluation, only six patients (27%) had progressed. Drug-related toxicity was tolerable, with

the most common adverse events being anemia (90%), neutropenia (grade 1 16%, grade 2 19%, grade 3 18%, and grade 4 18%) and fatigue (55%).

In the second stage of the trial, which began in April 2012, 60 patients with platinum resistant or refractory ovarian cancer are being randomized 1:1 to receive either PM01183 or topotecan.

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Estrogen receptor-positive breast cancer and endocrine therapy

The special session 'Optimizing treatment in luminal breast cancer' held yesterday, addressed the question of which estrogen-positive breast cancer patients require chemotherapy.

Greater attention is now being placed on neoadjuvant therapies in breast cancer, such as letrozole, anastrozole and tamoxifen, to improve outcomes in high-risk patients. But, asked Professor Matthew Ellis from Washington University, St Louis, School of Medicine, MO, USA, what if the patient's tumor is resistant to endocrine therapy?

Professor Ellis reported on a multivariable analysis suggesting that tumors with a ki67 levels above 10% should be considered as endocrine resistant. Another study, said Professor Ellis, has addressed the question of whether neoadjuvant fulvestrant might be superior to anastrozole in decreasing

the proportion of endocrine-resistant tumors. The Preoperative Endocrine Prognostic Index, said Professor Ellis, may offer an alternative approach for making chemotherapy decisions in Stage 2 and 3 breast cancer.

"An increase in the pathological complete response rate for estrogen positive breast cancer from that seen with endocrine therapy alone would represent a highly significant finding," said Professor Ellis. Ki67 analysis, he added, is currently in the process of standardization, and molecular signatures for proliferation monitoring are also under development.



José Baselga, Past President (ESMO)
Massachusetts General Hospital



James Ingle
Mayo Clinic, Minnesota, USA

OncologyPRO demo
at the ESMO booth

Daily Editorial

How targeted therapies are shaping the future of oncology

I still remember when I started my training in oncology in 1998 when very few drugs were available for the fight against cancer, and the concept of personalised medicine was just a small light at the end of the tunnel. 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 be part of this evolution in oncology. In the next few sentences, you can find a little flavour of what you can expect to see in the coming days. I do hope that all of you do 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 various forms of cancer, with EGFR mutations driving the unchecked growth and proliferation of many tumors. However, cancers inevitably evolve to 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.

This year, there has been some exciting news in lung cancer looking for targeted agents, biomarkers and correlation with outcomes will be presented. Those finding will corroborate the importance of properly selecting patients before deciding on the best therapeutic approach. Indeed, it is clear that clinical trials should no longer be conducted in unselected patient populations.

We are also fortunate enough to have new data on the duration of adjuvant trastuzumab in HER2 positive early breast cancer patients. It is worth noting that although one year of trastuzumab therapy has been providing survival benefit to patients with early breast cancer and HER2 overexpression for over 7 years, the optimal duration of trastuzumab is still debated. However, data being presented at today's Presidential Symposium II (16:00 – 17:45, Hall A) will hopefully confirm the optimal treatment duration of trastuzumab. Findings from the Protocol of Herceptin Adjuvant with Reduced Exposure (PHARE) trial comparing 6 to 12 months of trastuzumab in adjuvant early breast cancer (LBA5_PR) and from the Herceptin Adjuvant (HERA) trial of 2 years versus 1 year of trastuzumab after adjuvant chemotherapy in women with HER2-positive early breast cancer (8 years of median follow up) (LBA6_PR) will be presented. I do think that these awaited data are extremely important for clinicians and patients and these two presentations should not be missed!



Evandro de Azambuja
Institut Jules Bordet, Brussels, Belgium

Importantly as well, don't miss the colorectal cancer, Controversy session taking place today at 12.30 – 13.30 in Hall E and join in with the debate entitled: 'How soon will colorectal cancer patient management be driven by molecular factors?' This session will include presentations by leading experts in the field both for and against a move towards a molecular-driven approach, with attendees asked to provide their 'vote' for the winning argument – it certainly promises to be an informative and highly interactive session and I strongly recommend that you come along and participate!

Again, another matter of treatment duration will be presented at the Proffered Papers session, Gastrointestinal tumors - colorectal, which is taking place today at 8.45 – 10.45 in Hall A. In this session, data from a randomized Phase 3 study evaluating the continuation of bevacizumab beyond progression in metastatic colorectal cancer patients who received this treatment as part of first-line treatment will be presented (LBA17). Until recently, no predictive factors existed in pancreatic cancer and the prognosis for these patients has remained particularly bleak. However, emerging data now suggest that molecular targeting in this setting may be feasible.

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

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, since pancreatic cancer is generally diagnosed at a very late stage and therapeutic options are limited.

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 plethora of information in terms of tumor biology and sensitivity/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 diseases, particularly breast cancer and, most recently, the use of new techniques (e.g. RNA sequencing, radiolabeled positron emission tomography (PET) computed tomography (CT) scans, etc.) will hopefully allow us to identify those patients who are most likely to respond to a given treatment and to spare those unlikely to respond to unnecessary toxicities. Without any doubt, we are definitely progressing towards personalized medicine and it is such a privilege as young oncologist to be part of this "revolution" in oncology!

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And what better way to advance the practice of medical oncology across the world than by helping to expand our community and becoming an ESMO Ambassador.

Becoming an ESMO member is important because it provides oncologists with immediate access to the information they need: educational and scientific resources, clinical practice tools and treatment guidelines, says Dr Razvan Popescu, National Representatives and Membership Committee Chair, from Hirslanden Medical Center, Aarau, Switzerland.

You can tell your friends about the value of ESMO membership, which includes access to OncologyPRO, Annals of Oncology and numerous other benefits. Don't forget that ESMO members receive special attention onsite in Vienna at the Main ESMO Booth, Membership Services Center, and Membership Lounge in the Society Village.

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ESMO-ASCO Joint symposium: Genomics in breast cancer: Opening new doors		
11:00 – 12:30	Hall D	
ESMO DCTF-AOR TIC-SLA COM-UICC-WHO Joint Symposium: Independent and publicly funded research: a new global model		
11:00 – 12:30	Hall G	
ESMO-JSMO Joint symposium: Recent advances in the treatment of GI tract and liver cancer in the EU and Japan		
14:00 – 15:30	Hall F1	
ESMO-ESP Joint Symposium: Molecular diagnostics for personalized cancer treatment		
14:15 – 15:45	Hall C	

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PRESIDENTIAL SYMPOSIUM II

MONDAY 1 OCTOBER 16:00 – 17:45 HALL A

ESMO is again proud to highlight the very best late-breaking abstracts that will be presented at the second upcoming Presidential Symposium. These late-breaking abstracts are of significant importance since they contain information about important studies with cutting-edge data that could change current clinical practice.

LBA5_PR Professor Xavier Pivot from Besancon, France, will present final data from the 'Protocol for Herceptin® as Adjuvant therapy with Reduced Exposure' (PHARE) study comparing 6 to 12 months of trastuzumab in patients with HER2-positive early breast cancer. As the optimal duration of trastuzumab therapy remains an area of debate, the aim of this study was to provide further insights into the clinical benefits of shorter and longer treatment exposure times. Both primary and secondary endpoint data will be presented, including disease free survival, overall survival and cardiac toxicity.

LBA6_PR Professor Richard Gelber from Boston, USA, will present 8-year follow-up data from the international, multicenter HERceptin® Adjuvant (HERA) trial comparing 2 years versus 1 year of trastuzumab after adjuvant chemotherapy in women with HER2-positive early breast cancer. HERA is currently the only randomized trial investigating whether longer duration of trastuzumab can further improve efficacy. Data from a landmark efficacy analysis comparing the outcome of patients randomized to either 2 years or 1 year of trastuzumab who were disease-free at 1 year after randomization will be presented, together with updated efficacy data for the primary and secondary study endpoints.

LBA7 Professor Winette van der Graff from Nijmegen, The Netherlands, will present final data from a randomized Phase 3 survival study (EORTC 62012) of single agent doxorubicin versus doxorubicin plus ifosfamide as first-line chemotherapy for patients with advanced or metastatic soft tissue sarcoma. This study was initiated to address concerns from previous studies that suboptimal doses of ifosfamide had been used in combination with doxorubicin for the treatment of soft tissue sarcomas. Data for the primary endpoint, overall survival, as well as other study endpoints, will be presented.

LBA8_PR Professor Robert Motzer from the Memorial Sloan-Kettering Cancer Center, New York, USA, will present final data from the COMPARZ trial, a randomized, open-label, Phase 3 trial of pazopanib versus sunitinib for the first-line treatment of patients with metastatic renal cell carcinoma (mRCC). As both pazopanib and sunitinib have previously shown a progression-free survival (PFS) benefit in mRCC, the COMPARZ study was designed to provide a direct comparison of efficacy, safety and tolerability of these drugs. Data for the primary endpoint, PFS, as well as secondary endpoints, including overall survival, response rate and quality of life, will be presented.

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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, although the use of this agent beyond progression is an area of ongoing debate. However, emerging data suggest that this question may soon be answered.

Don't miss today's Proffered Papers session on gastrointestinal tumors, colorectal, where Dr Gianluca Masi from Pisa, Italy, will present data from a randomized Phase 3 trial, conducted by the Gruppo Oncologico Nord Ovest (GONO), which evaluated the continuation of bevacizumab beyond progression in patients with mCRC who had received bevacizumab as part of their 1st-line therapy (LBA17).

Session Info: Proffered Papers session, Gastrointestinal tumors, colorectal
Day/Date: Monday, October 1, 2012
Session Time: 8:45 – 10:45
Room: Hall A

Targeting the cancer micro- environment

With clinical research placing so much emphasis on the genetics of cancer, predictive biomarkers and the identification of molecular targets in tumor cells, it's all too easy to forget that cancer cells also have 'context'.

Dr Giuseppe Curigliano from the European Institute of Oncology, Milan, Italy, made the strong case for more research to be performed into cancer microenvironments. Cancer cells interact with normal host stromal cells (e.g. endothelial cells, fibroblasts, various immune cells) with a complex extracellular matrix secreted by both the normal and neoplastic cells embedded in it.

Infiltrating immune cells can furthermore sustain proliferative signaling through the release of itogenic growth mediators. Furthermore, tumor associated macrophages may increase the metastatic potential through CSF1R signaling.

It makes sense, Dr Curigliano agreed, to 'turn on' normal immune cells around a tumor and induce an antitumor immune response. But cancers typically escape immune surveillance by exploiting various natural mechanisms for tolerance. Cytotoxic therapies can be used to induce mammary epithelial cells to produce macrophage recruitment factors, including colony stimulating factor 1 (CSF1) and interleukin, which together enhance CSF1 receptor (CSF1R) dependent macrophage infiltration.

Recent studies have also shown that blockade of macrophage recruitment with CSF1R-signalling antagonists, in combination with paclitaxel, could improve survival in mouse models of breast cancer, and furthermore reductions in pulmonary lung metastases have also been found.

Successes and failures: Do targeted therapies live up to their promise?

ESMO teamed up with the European Association for Cancer Research (EACR) yesterday for a joint symposium to explore recent progress in the development of targeted therapies in oncology. The session provided a brief snapshot of just a few novel results in this exciting landscape.

Dr Pier Paolo Pandolfi of Harvard Medical School, Boston, USA, was certainly full of promise with his new concept of 'pro-senescence therapy'. He discussed how a "deconstruction" of the molecular genetics human cancer led him to explore ways to trigger or potentiate ageing, especially in cancer stem cells.

Sherene Loi from the Institut Jules Bordet, Brussels, Belgium, highlighted the high incidence of molecular aberrations associated with the phosphatidylinositol-3 kinase (PI3K) pathway in cancer. She presented the current status of various agents targeting this pathway (and potential resistance pathways) that are in Phase 1/2 development, and discussed who may stand to benefit from treatment with these novel agents based on our current understanding of the genetic and molecular profile of different types of cancer.

Professor Michal Neeman from the Weizmann Institute of Science, Rehovot, Israel, gave a presentation exploring the role of angiogenesis in cancer. He commented that the development of antiangiogenic therapy has become an especially popular field following the seminal work of Judah Folkman, and that the tight association between tumor progression and induction of angiogenesis is now widely recognized. However, he noted that targeting angiogenesis in cancer therapy has been relatively disappointing, and summarized the latest understanding about the role of hypoxia, vascular endothelial growth factor (VEGF) and the remodeling of the extracellular matrix in angiogenesis and tumor progression. He also emphasized that research should now focus more on the mechanisms by which tumors appear to escape antiangiogenic therapy.

Dr David Miles from the Mount Vernon Cancer Center, Northwood, UK, also looked at the lessons researchers have learned from the 'failure' of antiangiogenic therapies to deliver on their initial promises. In indications such as renal cell cancer, where alterations in VEGF are regarded as the principle oncogenic driver, VEGF inhibition has led to clinically meaningful improvements in progression-free and overall survival, he notes, but in other malignancies the efficacy VEGF inhibition has been more modest. The lack of success of anti-angiogenic agents in the adjuvant setting is unsurprising too, given that micro-metastatic disease is unlikely to be VEGF-dependent. Echoing his fellow panelists, Dr Miles said that the legacy of Folkman would live on; anti-angiogenesis research had to continue, especially to find biomarkers for tumors most susceptible to this approach.

New weapons in the fight against cancer

The increase in our knowledge and understanding of molecular pathways is leading to the identification of novel and appealing targets in oncology. As such, new drug 'weapons' to target these are currently under evaluation and there has been an increase in the assessment of these novel agents at an early stage of clinical development. With molecular evidence accumulating at an exponential rate, there will be a surge in the development of targeted cancer preventions and interventions over the next decade. Promising results from clinical trials identify a spectrum of targeted cancer therapies across a broad range of tumor types. These include both small molecule inhibitors of key receptors and enzyme binding sites, as well as intravenously delivered monoclonal antibodies that block a specific binding interaction between ligands and their receptors. However, some studies presented at this year's ESMO Congress have provided a first glance at some new drugs that may improve cancer treatment in the coming years even further.

Yesterday, data presented during a prostate cancer poster discussion session from a proof-of-concept study demonstrated that a novel androgen receptor (AR) antagonist called ODM-201 reduced levels of prostate-specific antigen (PSA) in patients with progressive castration-resistant prostate cancer. In this dose-escalation trial, 87% of patients who received ODM-201 (n=15) experienced a PSA decrease at 12 weeks. "These early results are very promising," said study author Dr Christophe Massard from Institute Gustave Roussy, Villejuif, France, adding that "ODM-201 might be a new hormonal treatment option, and its efficacy and safety profile seems to be very promising in prostate cancer patients". Unlike other AR antagonists, nonclinical data indicate that ODM-201 has minimal or no brain entrance and lacks the partial agonist activity seen with bicalutamide. "The results need to be confirmed in bigger patient population of course" noted Dr Massard.

Data presented at Saturday's Developmental Therapeutics session also provided an insight into future cancer treatments for non-small-cell lung cancer (NSCLC). Professor Enriqueta Felip from the Vall d'Hebron University Hospital, Barcelona, Spain, presented data from a Phase 2 trial indicating activity for the HSP90 inhibitor, AUY922, in patients with ALK-rearranged (ALK-positive) or EGFR-mutated advanced NSCLC. HSP90 is a chaperone of client proteins relevant in NSCLC pathogenesis, including both ALK and EGFR. ALK positivity occurs in 5-7% of patients with NSCLC, and EGFR mutation occurs in around 10-17% of cases. In this study, 121 patients with previously treated NSCLC received AUY922 (70 mg/m²) as a once-weekly, 1-hour infusion and were stratified by molecular status – ALK-positive, EGFR-mutant, KRAS-mutant or EGFR/KRAS/ALK wild-type. AUY922 was associated with an acceptable safety profile and clinical activity was demonstrated in both ALK-positive and EGFR-mutant patients, with partial responses in 7/22 (32%) patients and 7/35 (20%) patients, respectively. Of particular note, Professor Felip highlighted that in EGFR-mutated patients who had progressed just after receiving EGFR tyrosine kinase inhibitor (TKI) therapy, the median PFS rate at 18 weeks was 45% versus 21% in patients who had not received a TKI as their immediate pre-AUY922 therapy. "These data support the further development of AUY922 in NSCLC," Professor Felip commented, "Expansion of the EGFR-mutated stratum is ongoing and further studies are planned to confirm these efficacy signals" she added.

VIP treatment at the Membership Lounge

Following this, Dr Scott Gettinger from Yale University School of Medicine, New Haven, USA, presented initial data from a first-in-human dose-finding study of the ALK/EGFR inhibitor, AP26113, in patients with advanced malignancies. AP26113 is a novel, synthetic, orally-active TKI that is thought to inhibit mutant activated forms of ALK-positive and EGFR, as well as TKI-resistant forms including L1196M (ALK) and T790M (EGFR). However, AP26113 does not inhibit native EGFR. This dose-finding study is ongoing with 34 patients currently enrolled, 29 of whom have NSCLC. The most common adverse events were nausea, fatigue and diarrhea, although these were mostly Grade 1/2. Preliminary efficacy data indicate activity with the 60 mg dose in ALK-positive patients both naïve and resistant to crizotinib and responses to the 120 mg dose in EGFR-mut patients. Dr Gettinger highlighted that the Phase 2 expansion study will include 4 cohorts of patients: those with ALK-positive NSCLC who are naïve or resistant to prior ALK-targeted therapy, patients with EGFR-mutant NSCLC who are resistant to EGFR-targeted therapy and patients with other cancers with abnormalities in ALK or other AP26113 targets.

The next presentation was given by Dr Alice Shaw, from the Harvard Medical School, Boston, USA, who presented a first-in-human Phase 1 study of LDK378, a novel, potent small molecule ALK inhibitor that has demonstrated tumor regressions in ALK-positive NSCLC xenograft models. The primary objective of the study was to determine the maximum tolerated dose (MTD) and safety profile in adult patients with advanced malignancies harboring a genetic alteration in ALK who have either progressed on ALK inhibitor therapy or who were previously untreated. Dr Shaw explained that "daily oral LDK378 appears to be well tolerated and the MTD was 750 mg/day". She also highlighted that "a high level of activity was seen in patients who had progressed following crizotinib therapy at doses of 400 mg or greater".

Following this, Dr Makoto Nishio from the Thoracic Oncology Center, Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan, presented data to support the potential of CH5424802 as a new therapeutic opportunity for patients with ALK-positive NSCLC. Dr Nishio explained that the Phase 1 part of this Phase 1/2 trial had shown that CH5424802, an oral ALK inhibitor, was also well tolerated and had demonstrated promising efficacy in previously treated patients with ALK-positive NSCLC. In the Phase 2 portion of the trial, 46 patients with ALK-positive NSCLC, advanced or metastatic disease and no prior ALK inhibitor therapy were treated with CH5424802 at 300 mg bid until progressive disease or intolerable toxicity. Overall, 3 people experienced a complete response and a further 36 experienced a partial response. Moreover, 40 patients are still receiving study treatment. Dr Nishio advised that treatment with CH5424802 was well tolerated and treatment-related adverse events leading to discontinuation were observed in only 3 patients. "CH5424802 is a new potent ALK inhibitor for NSCLC", Dr Nishio concluded.

Last year, the US Food and Drug Administration (FDA) approved the ALK tyrosine kinase inhibitor, crizotinib, for the treatment of patients with advanced NSCLC with translocations of the ALK gene as determined by an FDA-approved companion genetic test. This was the first new FDA-approved drug for advanced NSCLC for a number of years, and there was much enthusiasm about the approval among patients and practitioners. Following on from this targeted therapy, we are entering an exciting time as it seems that we have only scratched the surface of personalized therapy. However, as we move ever forward towards molecularly-defined therapies, it will be critical to work out the interplay of molecular testing (who to test, which test to use, and when to test), particularly for those agents that are effective but only in small, specific groups of patients.

Image of the day



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How to hunt for a primary tumor site

An educational session yesterday explored a range of options that clinicians could adopt to manage cancer patients where the primary tumor site is unknown.

Moderators, Professor Nicholas Pavlidis from the University of Ioannina, Greece, and Professor Ahmad Awada from Institut Jules Bordet, Brussels, Belgium, reminded the audience that cancers of unknown primary origin (CUP) represent the 7th to 8th most frequent type of cancer and the 4th most common cause of cancer death. They also stressed that there is no set of rules to follow in these difficult cases and so an integrated approach would be needed in order to gather a wide range of data and information to piece together an optimal management plan.

Dr Karin Oien from the University of Glasgow, UK, provided information on the diagnostic approaches available to the clinician, starting from basic immunohistochemistry (IHC) and working-up to full molecular profiling. She suggested that molecular profiling could contribute towards the diagnosis of poorly differentiated and/or metastatic tumors, especially where morphology and IHC are equivocal or conflicting, in cases where diagnosis includes multiple possible differentials or when tissue or time is limited. However, she warned that profiling results should be evaluated in the context of pathological and clinical findings and that molecular profiling is not currently recommended by ESMO's Clinical Practice Guidelines.



Dr George Pentheroudakis, also from the University of Ioannina, described the genetic mutations and cell signaling pathways that are frequently reported in CUP. "CUP is a heterogeneous group of tumors," he advised, "expression of the oncoproteins, c-myc, ras, human epidermal growth factor receptor 2 (HER2) and Bcl2 are common, but overexpression is rare", he added.

Dr Pentheroudakis' talk was followed by insights from his colleague, Professor Pavlidis, on a framework for optimizing the therapeutic management of patients with distinct clinical pathological CUP subsets.



Karin A. Oien, Glasgow, UK

Defining standards of care in renal cell carcinoma

Today's Proffered Papers session on renal cancer (14:00 – 15:50, Hall D) will include headline results from several high profile Phase 3 trials as well as randomized Phase 2 trials. Presentations not to be missed are noted below.

LBA21_PR Dr Brian Rini from the Clinic Taussig Cancer Institute, USA, will present results from the Phase 3b INTROACT trial of temsirolimus (TEM) plus bevacizumab (BEV) versus interferon (INF) plus BEV in patients with metastatic renal cell carcinoma (mRCC). Key efficacy and safety data for the comparison of these 2 regimens will be presented.

LBA22_PR Dr Thomas Hutson from the Baylor Sammons Cancer Center, Dallas, USA, will present results from the global INTORSECT trial designed to evaluate TEM versus sorafenib (SOR) as second-line therapy in patients with mRCC. Data for the primary endpoint of progression-free survival (PFS) will be presented, together with key secondary endpoint data.

7830 Dr Alain Ravaud from C.H.U. Bordeaux Hospital St. Andre' Bordeaux, France, will present data from the Phase 2 RECORD-2 study, a Phase 2 trial comparing first-line therapy with everolimus (EVE) + BEV or interferon alfa (IFNα) + BEV in patients with mRCC. Efficacy data from this study, including PFS and response rate (RR) will be presented as well as key safety data.

Session Info: Proffered Paper Session, Renal Cancer

Day/Date: Monday, October 1, 2012,

Session Time: 14:00 – 15:50

Room: Hall D

SPECIAL SYMPOSIA		MONDAY 1 OCTOBER
From biology to treatment in advanced pancreatic and gastroesophageal cancer		
11:00 – 12:30	Hall B	
Key topics in supportive care		
16:00 – 17:30	Hall F1	
A paradigm shift in early drug development: Individualizing to more patient benefit		
11:00 – 12:30	Hall C	
Melanoma therapy: From frustration to enthusiasm		
09:15 – 10:45	Hall C	
Latest innovations in NSCLC management		
09:00 – 10:30	Hall D	
Emerging diagnostic and therapeutic targets in gynecological cancers: From science to clinical practice		
09:15 – 10:45	Hall B	
Biologically based treatment in head and neck squamous cell carcinoma		
16:00 – 17:30	Hall F2	

RELAX!

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

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's all too easy to forget that cancer cells also have 'context'.

Dr Giuseppe Curigliano from the European Institute of Oncology, Milan, Italy, made the strong case for more research to be performed into cancer microenvironments. Cancer cells interact with normal host stromal cells (e.g. endothelial cells, fibroblasts, various immune cells) with a complex extracellular matrix secreted by both the normal and neoplastic cells embedded in it.

Infiltrating immune cells can furthermore sustain proliferative signaling through the release of mitogenic growth mediators. Furthermore, tumor associated macrophages may increase the metastatic potential through colony stimulating factor 1 receptor (CSF1 R) signaling.

It makes sense, Dr Curigliano agreed, to 'turn on' normal immune cells around a tumor and induce an antitumor immune response. But cancers typically escape immune surveillance by exploiting various natural mechanisms for tolerance. Cytotoxic therapies can be used to induce mammary epithelial cells to produce macrophage recruitment factors, including colony stimulating factor 1 (CSF1) and interleukin, which together enhance CSF1R dependent macrophage infiltration.

Recent studies have also shown that blockade of macrophage recruitment with CSF1R-signalling antagonists, in combination with paclitaxel, could improve survival in mouse models of breast cancer, and furthermore reductions in lung metastases have also been found.

ESMO members are invited to attend the annual General Assembly to be held on the 1 October 2012, 18:15-19:45, during the ESMO 2012 Congress in Vienna, Hall N-0, Level 01 Green.

ESMO Foundation Benefit Concert

The ESMO Foundation Benefit Concert featuring the work of Mozart, was staged at the world famous Golden Hall 'The Wiener Musikverein' last night to great acclaim.

The program featured bass-baritone José van Dam, together with his students from La Chapelle Musicale Reine Elizabeth, and the Wiener Kammerorchester (Vienna Chamber Orchestra). Strong support was provided by Kinga Borowska (Mezzo, Soprano), Olga Kindler (Soprano), Harriet Langle (violinist) and Gijs Van der Linden (tenor).

Introducing the concert, ESMO and Congress President Professor Martine Piccart, from Jules Bordet Institute, Brussels, Belgium, who is well known for her love of music, thanked the audience for their tremendous support.

Funds collected from the concert, she explained, would be donated to the ESMO Foundation. The Foundation aims to promote the quality of cancer care across Europe, to help doctors and patients cope with rapidly growing technologies that lead to personalized medicine and to encourage research which remains the key to progress for this deadly disease.

Professor Piccart said she was particularly proud to be able to welcome José van Dam, the most famous opera singer of her native country, Belgium. "In addition to his impressive career and his multiple awards recognizing his unique talent, José Van Dam regularly gives musical performances to support cancer research in Belgium," she said.

ESMO 2012 emphasizes palliative care

The European Society for Medical Oncology (ESMO) has awarded its ESMO Designated Center of Integrated Oncology and Palliative Care accreditation to 16 new oncology centers.

The awardees this year include 13 based in Europe, one in Egypt, one in Singapore and one in India. "This demonstrates the truly international scope of ESMO's work. It shows how ESMO wants to help humanity, not just European oncology patients," said Professor Raphael Catane, from the Institute of Oncology, Sheba Medical Center, Israel, who is one of the founding members of the ESMO Palliative Care Working Group.

First set up in 2003, this ambitious project aims to improve the infrastructure for the provision of palliative care globally. The initiative came partly in response to the World Health Organization (WHO) report 'Cancer pain relief and palliative care'. The report, published in 1990, called for the integration of efforts directed at maintaining the patient's quality of life in all stages of cancer treatment. It emphasized that factors causing patient distress exist from the time of diagnosis and that supportive interventions are needed concurrently with efforts to control the underlying cancer.

"In addition to making efforts to prolong the life of oncology patients, ESMO felt we needed to ensure that quality of life was good. We've made considerable efforts to change the mindset of doctors and patients that taking care of symptoms need not diminish efforts to prolong life. From the outset of diagnosis we wanted to integrate palliative care into the practice of medical oncology," said Professor Catane.

But new research now suggests that palliative care may also contribute to improvements in survival. A landmark study published in the NEJM in 2010 by Dr Jennifer Temel, from the Massachusetts General Hospital, Boston, USA, showed that patients with metastatic non-small cell lung cancer randomized to palliative care early after diagnosis not only had better quality of life and less depressive symptoms, but also survived longer than those receiving standard oncologic care alone.

The accreditation, judged anonymously by ESMO Palliative Care Working Group members, assesses centers according to 13 rigorous criteria. These criteria include close integration of oncology and palliative care services for all cancer patients; centers being committed to a philosophy of continuity of care and non abandonment; high levels of home care; support for family members; routine physical and psychological assessments; expert medical and nursing care in evaluation of pain relief; availability of emergency care; provision of respite care; in-patient end of life care; basic or clinical research related to quality of life; physician education around integration of oncology and palliative care.

Any oncology department or cancer centre can apply, with ESMO emphasizing that size is not important, what matters most is the quality and extent of integration of services.

The criteria have come to be regarded as a "roadmap" for how to build palliative care services. Unsuccessful applicants are invited to further develop their programs and reapply. "What's really valuable is that we give feedback which works as a teaching tool, showing centers how they can improve," says Professor Catane.

Receiving the certification allows centers to use the title 'ESMO Designated Center of Integrated Oncology and Palliative Care' and also be eligible to receive fellows in palliative medicine, supported by ESMO fellowships. For successful applicants, however, there is no room for complacency, since accreditation needs to be renewed every 3 years. Of the current 127 (including the 16 new centers) accredited centers, 50 have been reaccredited once (27 this year) and 21 twice (8 this year). "With personnel, policy and financial aspects changing all the time, we want to ensure that integration of palliative care continues," said Professor Catane.

Dr Matti Aapro, from the Clinique de Genollier, Switzerland, a member of the ESMO Supportive and Palliative Care Faculty, adds. "The program is laid out in a very 'user-friendly' manner which allows many centers to continue to improve their skills while already recognized as a 'designated center'." Undoubtedly, the much sought after accolade has contributed to increasing the profile of palliative care within oncology units across the world. "ESMO's initiative has certainly raised a lot of interest, as demonstrated by the growing list of centers that adhere to this program. It's one of many ways to encourage the development of truly multidisciplinary cancer centers which look at the patient's needs in all aspects of cancer treatment," said Dr Aapro.

"While further penetration of ESMO's palliative care policy is still needed, the work of the ESMO Palliative Care Working Group has undoubtedly enhanced the lives of thousands of cancer patients in Europe and beyond," said Professor Catane.

CONGRATULATIONS TO THE DC'S AND FELLOWS WHO RECEIVED SPECIAL RECOGNITION

ESMO Designated Centers - 8 centers accrediting for the 2nd time in 2012 for the period 2013-15

ESMO DESIGNATED CENTERS	COUNTRY
KTb Klinik für Tumorbiologie, Freiburg	Germany
SMBD Jewish General Hospital, Montreal	Canada
Cancer Center Beaumont Hospital, Dublin	Ireland
Alaw Unit, Bangor, North Wales	United Kingdom
The Complex Oncology Center (COC), Prague	Czech Republic
Medical Oncology University Hospital of Parma, Parma	Italy
Ospedali Riuniti di Bergamo, Oncologia Medica, Bergamo	Italy
Istituto Dermatologico dell'Immacolata, Divisione di Oncologia e Oncologia dermatologica, Rome	Italy

Designated Centers accredited 2012

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Medical Oncology University Hospital of Parma, Parma	Italy
Ospedali Riuniti di Bergamo, Oncologia Medica, Bergamo	Italy
Istituto Dermatologico dell'Immacolata, Divisione di Oncologia e Oncologia dermatologica, Rome	Italy
Campus Bio Medico, Rome	Italy
Cancer Center, Ospedale San Pietro Fatenbenefratelli, Rome	Italy
Centre Léon Bérard, Lyon	France
Consorci Sanitari de Terrassa, Barcelona	Spain
El-Gabbari Specialized Oncology and Palliative Care Center, Alexandria	Egypt
Istituto Oncologico Veneto - I.R.C.C.S., Medical Oncology 1, Padova	Italy
Oncologia Medica Policlinico Universitario Tor Vergata (Roma) & San Raffaele Hospices (Rocca di Papa - Montecompatri), Rocca di Papa	Italy
Oncology Center GZA Sint Augustinus, Wilrijk	Belgium
Radboud University Nijmegen Medical Center, Nijmegen	The Netherlands
Raffles Cancer Center	Singapore
Saroj Gupta Cancer Centre & Research Institute (SGCC&RI), Kolkata	India
St. George's Hospital NHS Trust, London	United Kingdom
Struttura Complessa di Oncologia, Macroattività di Cure Palliative, Fondazione I.R.C.C.S. Policlinico San Matteo, Pavia	Italy
Tumor Zentrum, Hirslanden Medical Center, Aarau	Switzerland
U.O.C. Oncologia Medica, Azienda Ospedaliera Sant' Andrea, Sapienza Università Di Roma, Rome	Italy
UOC Oncologia & Breast Unit - OSP. "A.Perrino", Brindisi	Italy

ESMO Designated Centers - 27 centers accredited for the period 2009 and re-accrediting for the 1st time in 2012 for the period 2013-15

ESMO DESIGNATED CENTERS	COUNTRY
A.O. Fatebenefratelli e Oftalmico, Divisione di Oncologia Medica e Chemioterapia	Milan, Italy
Baskent Üniversitesi Tıp Fakültesi, Tıbbi Onkoloji Bilim Dalı, Adana Uygulama ve Araştırma Merkezi	Adana, Turkey
Clinica Universidad de Navarra	Pamplona, Spain
Davidoff Cancer Center, Rabin Medical Center	Petach Tikvah, Israel
Department of Clinical Oncology, Queen Mary Hospital	Pokfulam, Hong Kong
Department of Oncology, 1st Oncology Clinic, Metropolitan Hospital	Athens, Greece
Department of Radiotherapy, Oncology and Palliative Care Unit, Sarawak General Hospital	Sarawak, Malaysia
European Institute of Oncology	Milan, Italy
Hôpital Institut Curie	Paris, France
Hospital Arnau de Vilanova de Valencia	Valencia, Spain
Hospital Vall d'Hebron	Barcelona, Spain
Institute of Oncology Ljubljana	Ljubljana, Slovenia
Instituto de Tratamiento Integral del Cáncer (ITIC), Hospital Clinica Benidorm	Benidorm, Spain
Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (I.R.S.T.)	Meldola, Italy
Klinik für Innere Medizin, Hämatologie/Internistische Onkologie und Palliativmedizin	Bielefeld, Germany
London Regional Cancer Program	London, Ontario, Canada
Medical Oncology Department, Ospedale Sacro Cuore – Don Calabria	Negrar, Verona, Italy
Medizinische Klinik 5 Allg. Innere Medizin - Onkologie - Hämatologie - Stammzelltransplantation - Palliativmedizin, Klinikum Nürnberg	Nürnberg, Germany
National Koranyi Institute of TB and Pulmonology	Budapest, Hungary
Oncologia Varini & Calderoni	Sorengo, Switzerland
Servicio de Oncología y Cuidados Paliativos, Hospital B. Housay	Vicente López, Argentina
Southern Adelaide Health Services	Adelaide, Australia
The Harry R. Horvitz Center for Palliative Medicine	Cleveland, Ohio, USA
The Royal Marsden NHS Foundation Trust	London, United Kingdom
Tumorzentrum Ludwig Heilmeyer - Comprehensive Cancer Center Freiburg.	Freiburg, Germany
Westmead Cancer Care Centre	Westmead, NSW, Australia

Opportunity to find out more about European Fellowships

Come along to a Special session this afternoon to find out more about the ESMO Fellowship Programs and other European educational opportunities for young medical oncologists.

The ESMO Fellowship Program, which has been running for over 20 years, aims to create a cadre of young oncologists with clear perspectives on research. The program funds short term educational visits for just a few days, clinical programs from six weeks to one year, and translational research programs for up to two years. The idea is to guide and challenge fellows early in their academic careers with the goal of advancing science, raising levels of clinical competence and professional excellence, and improving quality of patient care.

To be eligible, applicants must be under 40, current ESMO members, and have a minimum, of one or two years experience in medical oncology, radiation oncology or surgical oncology.

In the packed program, which is run jointly by ESMO, SEOM, HESMO, AIOM and AERIO, Professor Jean-Charles Soria, from the Institut Gustave Roussy, Villejuif, France, will look at the broad concept of educational fellowships. Practical tips

on where you can find out the information you need will be given by Dr Giannis Mountzios from the Metropolitan Hospital Athens, Greece.

Professor Federico Cappuzzo, from Ospedali Riuniti, Livorno, Italy, will provide more details on funding opportunities in Europe and the ESMO fellowship program, while Ramon Salazar from the Institut Català d'Oncologia, Barcelona, Spain, will give advice on how to write a successful grant application. Professor Josep Tabernero, Chair the ESMO Fellowship and Award Committee, from Vall d'Hebron University Hospital, Barcelona, Spain, will look at future directions for the fellowship program.

The session will close with the Fellowship Awards ceremony where successful participants over the past year will receive certificates of recognition.

Session info: Special Session Fellowships in Europe: Educational opportunities for European Young Medical Oncologists. An ESMO/ SEOM/ HESMO/ AIOM/ AERIO Young Oncologists session.
Day/Date: Monday, October 1, 2012
Session Time: 14:15pm – 15:45pm
Room: Hall N-O

ABSTRACT BOOK USB

The ESMO 2012 abstract USB is distributed onsite at the Novartis Oncology exhibition stand no. X125 (the voucher is included in your delegate's bag)



Don't miss the ESMO Booth, which is located in the main exhibitions hall

Guidelines in action

Yesterday, the latest ESMO Clinical Practice Guidelines (CPGs) were presented in an innovative interactive session, demonstrating how guidelines are actually being interpreted by oncologists in 'real life' clinical situations.

The ESMO CPGs have been based on the findings of evidence-based medicine and provide a clear set of recommendations to help clinical decision making and improve the quality of healthcare and outcomes for patients. They are not designed to replace extensive guidelines or review articles; but rather they describe common standards of care. The overall aim is to improve quality of health care and outcomes for patients, and 'provide the right care at the right time for the right person in the right way'.

The latest set of ESMO CPGs included updates in breast cancer, gynecologic tumors, gastrointestinal tumors, lung cancer, urogenital tumors, hematologic malignancies, head and neck tumors, sarcomas and melanomas, neuroendocrine tumors and supportive 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 Center, Lisbon, Portugal, presented the case of a 42 year old pre-menopausal patient with positive ductal breast cancer. From the interactive key pads, she found that 63% of the audience would not undertake brain imaging screening of a symptomatic patient. Furthermore, the most popular treatment of choice was capecitabin + lapatinib, which was favored by 29% of patients.

Dr José Pérez Fidalgo from Hospital Clínico Universitario, Valencia, Spain, presented the case of a 76 year old woman with the rare complication of chemotherapy, extravasation. On their keypads, 52% of respondents felt that it was crucial to inform patients about the risks of extravasation and the symptoms that they need to be aware of to detect it. Furthermore, 76% of the audience did not feel that atrial fibrillation was a risk factor for this complication.

Dr Andrea Marrari from the Instituto Nazionale Tumori, Milan, Italy presented the case of a 31 year old male patient with a sarcoma, who was experiencing abdominal discomfort and nausea, with palpable masses in the abdomen and left leg. Chemotherapy with anthracycline and isosfarnide and concomitant radiation therapy was the treatment of choice for 36% of the audience.

An endometrial cancer case presentation of a 70 year old woman who sought medical attention after a three month history of vague pelvic discomfort and vaginal bleeding was provided by Dr Maria Cristina Marini from the Oncology Institute of Southern Switzerland. In addition to surgery, 37% of participants said that they would treat patients with external radiotherapy plus brachytherapy, and 23% with external radiotherapy.

Dr Wienie Buihuisen from The Netherlands Cancer Institute, Amsterdam, presented the case of 56 year old male mesothelioma patient with hypertension and shortness of breath. The diagnosis of mesothelioma, said 67% of respondents, could best be made on histology during thoracoscopy, and 66% felt that palliative radiotherapy aimed at pain relief should be considered in cases of painful chest wall infiltration.

Results showing how the audience used the CPGs

24% of the audience had consulted ESMO CPGs more than 10 times in the past year, and 29% less than 10 times

57% of the audience had never attended an ESMO CPG session before at the ESMO Congress

The preferred access to ESMO CPGs was ESMO.org in 72% of cases, Annals of Oncology in 25% and OncologyPro in 3%

87% of the audience felt that ESMO Clinical practice guidelines were a helpful source of advice

87% felt that CPGs were good educational tools.

89% felt that ESMO CPGs were intended to improve quality of care

70% did not feel that CPGs were too impractical and rigid to apply to individual patients

53% of participants practiced in Europe, 14% in the Middle East, 11% Asia Pacific and 9% South America, 6% Africa, 3% Central America and Caribbean and 3% North America

76% of the audience were medical oncologists

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 noted below.

322PD Dr Emilio Bria from Verona, Italy, will present a treatment-interaction analysis balancing pathological complete responses and cardiotoxicity of single-dual-HER2 inhibition and neoadjuvant chemotherapy backbone in operable/locally advanced breast cancer patients

323PD Dr Sibylle Iobli from Neu-Isenburg, Germany, will present data from a bi-national, multicenter, randomized, phase 3 trial evaluating the addition of bevacizumab to endocrine therapy as first-line treatment for advanced breast cancer

325PD Dr Chau Ng from Surry, UK, will present data from a phase 1/2 trial of abiraterone acetate in estrogen receptor or androgen receptor positive patients with metastatic breast cancer

LBA14 Dr Christopher Heery from Bethesda, USA, will presents late-breaking data from a phase 2 randomized trial of docetaxel alone or in combination with therapeutic cancer vaccine, CEA-, MUC-1-TRICOM

324PD Dr Mario Campone from Herblain, France, will present a phase 3, double blind, randomized, controlled study evaluating the efficacy and safety of everolimus in postmenopausal women with advanced breast cancer (BOLERO-2). The effect of visceral metastases and prior endocrine therapy will be evaluated

326PD Dr Wei-Xiang Qi from Shanghai, China, will present a systemic review and meta-analysis of randomized controlled trials that compare paclitaxel-based with docetaxel-based regimens in patients with metastatic breast cancer

27PD Dr Alexandra Gennari from Genoa, Italy, will present data evaluating the effect of body mass index on prognosis in 489 women with metastatic breast cancer. All patients received first line chemotherapy regimens including anthracyclines and taxanes, either in sequence or combination

328PD Catherine Beauchemin from Montreal, Canada, will present data on progression-free survival as a surrogate for overall survival in women with metastatic breast cancer

Session Info: Breast cancer, locally advances metastatic

Day/Date: Monday, October 1, 2012,

Session Time: 12:45 – 13:45

Room: Hall B



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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), Angelo Di Leo (Prato, Italy), Elisabeth de Vries (Groningen, Netherlands), Michael Gnant (Vienna), Nadia Harbeck (Munich), Cristiana 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.”



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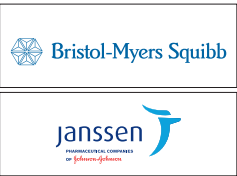
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