



CongressDaily

■ **Saturday** □ Sunday □ Monday

Saturday 9 October, 2010

OPENING CEREMONY HIGHLIGHTS

The 35th ESMO Congress was officially opened by President Professor David J. Kerr who delivered his Presidential Address declaring that this year will be “a congress of records”. “The meeting will have over 14,000 attendees from 115 different countries and nearly 130 different sessions with the latest updates in oncology and state-of-the-art science and technology. The original research presented at the ESMO Congress will demonstrate how innovative drug and diagnostic technologies and applications are expanding and redefining oncology practice. We are confident that the new studies presented at the Congress will be of great importance to the international oncology community” said David.

the world’s largest information provider to create the site, which gives cancer specialists access to the most complete resources in oncology today”.

Local Committee Chairs Umberto Veronesi and Roberto Labianca thanked all Committee members and welcomed the Congress to Italy. They were followed by Hon. Roberto Formigoni, President of the Lombardy region, who also welcomed delegates to the meeting.

“The meeting will have over 14,000 attendees from 115 different countries and nearly 130 different sessions...”

David announced the arrival of OncologyPRO (Oncology Professional Resources Online), a unique scientific portal for ESMO members that provides instant easy access to the highest quality scientific knowledge in one location. Delegates can preview OncologyPRO at the Congress before its launch next year. David commented “ESMO is proud to announce an exclusive deal with Thomson Reuters,

The ESMO Scientific Chair, Professor Rolf Stahel, provided the scientific address. Rolf was very excited about this year’s scientific program and the quality of data to be presented. “Researchers are bringing their best work for presentation at the ESMO Congress. There was a 67% increase in abstract submission this year and 57% of submitted abstracts

were accepted. As for Late Breaking Abstracts, submission was up by 200%. This means we have been able to select top quality material, bringing you the very latest scientific developments in cancer research”. Rolf commented that new findings from major trials, which will be presented at the Presidential Symposium on Monday, 11 October, may be practice changing. He also highlighted sessions on personalized medicine, genetic research and political issues such as the disparity remaining in cancer diagnosis, treatment and rehabilitation across Europe.

Alberto Costa received the ESMO Award for his dedication to oncology research and his contributions to scientific communication and educational development. In keeping with ESMO tradition several important figures in oncology were honored with the Flower of Hope.

The Opening Ceremony closed with a wonderful performance showcasing the Best of Italian Opera featuring original La Scala costumes from Zeffirelli’s La Traviata.



Prof David Kerr and Prof Rolf Stahel



HELPFUL CONGRESS INFO

DELEGATE BAG VOUCHERS

ABSTRACT BOOK USB MEMORY STICK

The 35th ESMO Congress abstract USB is distributed on-site at the Pfizer exhibition stand (the voucher is included in your delegate’s bag). A limited number of abstract books will be available also in paper format and will be distributed in the e-poster area on a first come, first served basis.

EDUCATIONAL BOOK CD-ROM

The Educational Book CD-ROM is distributed on-site at the Merck Serono exhibition stand (the voucher is included in your delegate’s bag).

POSTER CD-ROM

The electronic posters CD-ROM is distributed on-site at the Amgen exhibition stand (the voucher is included in your delegate’s bag).

CONTINUED ON **PAGE 02**

MEET, CHAT, EMAIL, RELAX AT ESMO

Visit the exclusive ESMO Members’ Lounge located on level MIC 0 for a relaxing environment where you can get away from the crowd.

Are you an ESMO member? Then visit the exclusive ESMO Members’ Lounge located on level MIC 0 for a relaxing environment where you can get away from the crowd, chat with other members of our community, and access your email in between

sessions. 2010 members can pick up their day entry vouchers to the lounge from the Membership Services Center in the Registration Hall. We’ll be demonstrating products, such as OncologyPRO and ESMO E-Learning tools, in the lounge at set times and

core members of ESMO will also be popping in to say “Hello”. Our staff will also be keen to find out more about your membership experience while also being available to cater to all your membership needs.

CONTINUED ON **PAGE 02**

Today’s Top Picks!

Proffered Paper Session

Chest Tumors I

11:00-12:30
Silver Hall

Special Symposium

ESMO/ESTRO/ESSO
Joint Symposium

11:00-12:30
Red Hall

8th ESMO Patient Seminar

Cancer: We all care and share
Understanding new methods
and new treatments of cancer

15:00-18:40
Red Hall

Special Session

Chronic Disease Alliance: A time
to work across specialties

16:00-17:30
Green Halls 1 + 2

CONTINUED FROM PAGE 01

ESMO BOOTHS

Don't miss the 3 ESMO booths

Membership Services Center for fast track member services

Society Piazza booth for all educational products and services, Fellowship Program and a sneak peek at OncologyPRO

ESMO Experience booth for all ESMO meetings and OncologyPRO

FOR 2010 ESMO MEMBERS

New! 2010 ESMO members are invited to visit us in the exclusive Members Lounge, located in MIC level 0

FOR ALL CONGRESS DELEGATES

Webcast: The entire Congress program will be webcast and available online 48 hours after session takes place

2010 ESMO Highlights: pick up your free copy at the Lilly booth located in the exhibition hall 3

Daily news: pick up your copy at the Congress center or in the breakfast area of selected hotels

SmartPhone: download the SmartPhone application for access to the updated Program Book, Congress Daily Broadcasts and the Late-breaking abstracts

Daily edition of Congress eNews: Saturday, Sunday and Monday!

Twitter: follow us on Twitter! <http://twitter.com/myesmo>

Facebook: find us on Facebook <http://www.facebook.com/esmo.org>

Congress Daily Broadcasts: comments and analysis on specific presentations from key opinion leaders

Internet kiosks: situated in the Registration area and are accessible throughout the Congress

WiFi Free Internet: Wi-Fi access is available throughout the Congress venue, Password: **ESMO2010**

CONTINUED FROM PAGE 01

Not already an ESMO Member? "ESMO membership can help you to achieve your professional career goals and provide optimal treatment to your patients" highlights Dr. Razvan Popescu, Chair of the ESMO Membership Committee, "by providing access to training and resources on the latest treatments and technological developments in oncology".

"ESMO membership can help you to achieve your professional career goals and provide optimal treatment to your patients..."

Sign up for a free ESMO trial membership (valid until June 2011) while you're at the Congress and join our growing European community of medical oncologists. This exclusive on-site opportunity offers the best way for you to get to know ESMO



and will let you see for yourself the real value of joining us. Benefits include online access to Annals of Oncology, networking opportunities, E-Learning, online practice tools and the opportunity to preview OncologyPRO, the new educational portal for oncologists. During the trial period you can upgrade your membership at any time to access the full range of membership benefits! Visit the new Membership Services Center, located in the Registration Hall to begin your ESMO experience today!

Sign up for a free ESMO trial membership while you're at the Congress and join our growing European community of medical oncologists.

The ESMO Experience booth located in the exhibition area (Booth 127), will be demonstrating our E-Learning tools - your chance to access some

The ESMO Experience Booth, located in the exhibition area (Booth 127), will be demonstrating our E-Learning tools.



of our current learning modules from the comfort of your home or practice. Our booth will also feature information about the Society from membership through to our premier range of scientific and educational meetings, individual products and other services. We look forward to welcoming our current members and prospective new members.

HOW IMPORTANT IS GOOD CLINICAL TRIAL DESIGN?

Methodology is absolutely fundamental to good clinical trial design. With this in mind ESMO provides high-level tutorial programs for young oncologists. These programs include lectures at ESMO events/meetings, and supporting clinical trials workshops to inspire young oncologists from different disciplines across the globe to become the next generation of active researchers.

It is important that young oncologists learn the basics of designing clinical trials, are able to independently run projects and interpret results in the correct way. The Young Oncologists Masterclass, that took place yesterday, was designed to address such needs for selected groups of fellows.

The last decade has brought us many papers on biomarkers; however biomarkers are studied mostly in retrospective series giving contentious results. Young oncologists should recognize that inadequate statistical

design of trials incorporating biomarkers represents a significant barrier and prevents patients benefitting from the full potential of recent scientific advances. During the Masterclass, Marc Buyse addressed key issues in biomarker analysis including the statistical bridge between discovery of biomarker data and clinical response data. He spoke about innovative statistical methods based on traditional biostatistics and PK/PD modeling methods, the results of which can be used as surrogate endpoints.

The second issue, also to be discussed in the AIOM/ESMO Joint Symposium (Sunday), is the role of biobanking. In order to have fast results in early clinical trials we need to test novel biomarkers on stored tissue, therefore we need access to well documented quality tissue. It often happens that biological information at the time of analysis is not available due to bad conservation of tissues,



or inappropriate timing. Due to the intervariability of patients and their tumors, standardization is needed. During the Masterclass, Maria Grazia Daidone discussed which material should be collected, and when and how to collect them.

At the end of the session, Pinuccia Valagussa, talked about the role of interim analysis. This is another crucial point in clinical research, because

when studies are closed with interim analyses, the power of the study decreases and results will not be robust. There are few reasons to close a study early that are incontrovertible, such as an excess of toxicity, or a change in the standard of care.

However, most are questionable such as the apparent higher efficacy of the experimental arm. There is a particular role of the independent data safety and monitoring committee in taking such decisions without losing crucial information and good quality of data.

By the end of the Masterclass, young oncologists should have learned some of the principles of good clinical trial design, facilitating the selection and prospective development of clinico-genomic data enriched by biomarker validation. If these data are generated and then implemented, they will lead to more meaningful treatment of cancer patients.

8th ESMO Patient Seminar

Saturday, 9 - Sunday, 10 October

Red Hall

REHABILITATION IS MAIN FOCUS OF ESMO PATIENT SEMINAR

Rehabilitation will be the leading theme of this year's ESMO Patient Seminar as it takes on a more important role in the complex and comprehensive management of cancer patients. Coordinated by the ESMO Cancer Patient Working Group and supported by a local Patient Seminar Task Force, this two-day event will provide patients, their families and caregivers the opportunity to interact with international and local oncologists and learn more about the most recent developments and options in cancer treatment. A 'lay' leading theme aims to support and improve the relationship between oncologists and patients. "Our aim is to educate patients and help them, and their relatives, understand their

disease and the different therapies available" comments Professor Lorenz Jost, Chair of the ESMO Cancer Patient Working Group. "The seminar also allows patient-doctor dialogue where cancer care providers receive input from patients and advocacy groups, enabling doctors to better serve their needs", adds Lorenz.

Rehabilitation optimizes therapeutic operations, and can improve the quality of life for patients and facilitate curing. As rehabilitation involves doctors and nurses, patients and their families, advocacy groups and policy makers, representatives from all these groups will participate and share their experiences and expertise

with attendees. "Just as oncologists are working towards the recognition of medical oncology as an independent specialty, patient advocacy groups are working to achieve optimal standards of rehabilitation locally, and share and implement these best practices on a European level" highlights Professor Francesco De Lorenzo, 8th ESMO Patient Seminar Chair. "Living with cancer should not be a stigma but a reminder to celebrate living and return to normal life" adds Francesco.

The Patient Seminar opens on Saturday afternoon, 9 October, with welcome speeches and keynote lectures, followed by a full day of sessions on Sunday, 10 October



THE IMPORTANCE OF EFFECTIVE COMMUNICATION

Professor Jan Vermorken will be offering you advice and tips on how to conduct effective public speaking and slide presentations. Jan will cover the importance of considering your audience, the benefits of keeping your slides simple, use of tables and figures, delivery of your presentation and common mistakes that we can all avoid. This session will help you to deliver confident and effective presentations - and most importantly, get the correct messages across to your audience.

This breakfast session will take place on Sunday, 10 October, 08:00-08.45 in Turquoise Hall 2.

NEWLY
APPROVED
IN EUROPE

POWERFUL PROTECTION AGAINST FRACTURES

Strengthening outcomes for patients receiving ADT*

Prolia® – the first and only RANK Ligand inhibitor for the treatment of bone loss¹

prolia[®]
denosumab
PRECISE PROTECTION.

*ADT = androgen-deprivation therapy.

Reference: 1. Prolia®(denosumab), Summary of Product Characteristics, 2010.

Prolia® (denosumab) Brief Prescribing Information

Please refer to the SmPC (Summary of Product Characteristics) before prescribing Prolia®.

Pharmaceutical Form: 1 ml solution for injection presented in pre-filled syringe containing 60 mg of denosumab. Contains sorbitol [E420]. **Indications:** Treatment of osteoporosis in postmenopausal women at increased risk of fractures. Prolia® significantly reduces the risk of vertebral, non-vertebral and hip fractures. Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. **Dosage and Administration:** Single subcutaneous injection of Prolia® 60 mg is given once every 6 months. No dose adjustment for renal impaired patients. Patients must be supplemented with calcium and vitamin D. Prolia® is not recommended in paediatric patients (age < 18). **Contraindications:** Hypocalcaemia. Hypersensitivity to the active substance or any of the excipients. **Special warnings and precautions for use:** Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. Patients with severe renal impairment or receiving dialysis are at greater risk of hypocalcaemia. Clinical monitoring of calcium levels is recommended for patients predisposed to hypocalcaemia. Patients receiving Prolia® may

develop skin infections (predominantly cellulitis) leading to hospitalisation and should contact a healthcare professional immediately if they develop signs or symptoms of cellulitis. Osteonecrosis of the jaw (ONJ) has been reported with denosumab and with bisphosphonates. ONJ has been reported rarely with Prolia® 60 mg every 6 months. A dental examination should be considered prior to treatment with Prolia® in patients with concomitant risk factors (refer to SmPC). While on treatment, these patients should avoid invasive dental procedures if possible. Good oral hygiene practices should be maintained during treatment with Prolia®. The needle cover of the syringe contains dry natural rubber (latex derivative), which may cause allergic reactions. Patients with rare hereditary problems of fructose intolerance should not use Prolia®. **Interactions:** No interaction studies have been performed. The potential for pharmacodynamic interactions with hormone replacement therapy (HRT) is considered to be low. **Pregnancy and lactation:** Prolia® is not recommended for use in pregnant women. A risk/benefit decision should be made in patients who are breast feeding. It is unknown whether Prolia® is excreted in human milk. No data are available on the effect of Prolia® on human fertility.

Undesirable effects: Adverse reactions reported in placebo-controlled clinical studies in women with postmenopausal osteoporosis and breast or prostate cancer patients receiving hormone ablation: Common (> 1/100, < 1/10) Urinary tract infection, Upper respiratory tract infection, Sciatica, Cataracts, Constipation, Rash, Pain in extremity; Uncommon (> 1/1,000, < 1/100) Diverticulitis, Cellulitis, Ear infection, Eczema; Very Rare (< 1/10,000) Hypocalcaemia. In the osteoporosis clinical program ONJ has been reported rarely with Prolia®. Please consult the SmPC for a full description of side effects. **Pharmaceutical Precautions:** Do not mix with other medicinal products. Store in a refrigerator (2°C–8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light. Do not shake excessively. Prolia® may be stored at room temperature (up to 25°C) for up to 30 days in the original container. Once removed from the refrigerator use within these 30 days. **Marketing authorisation holder:** Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda, The Netherlands. Further information is available from the SmPC. Date of PI preparation: May 2010. Adverse events should be reported. **Legal Category:** Medicinal product subject to medical prescription. **Marketing authorisation number:** EU/1/10/618/003.

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Prolia® (denosumab) is not yet authorised in Italy.
Submitted to AIFA on 17th September 2010.

AMGEN[®]



Daily Editorial

Gordon McVie, Editor-in-Chief, ESMO Congress Daily (gordon.mcvie@ieo.it)

WELCOME TO THE 35TH ESMO MEETING IN MILAN



Prof Umberto Veronesi, 35th ESMO Congress, Local Committee Honorary Chair and Prof Gordon McVie



Prof David Kerr

Welcome to Milan, home of ABVD and adjuvant CMF, not to mention, AC Milan, Inter Milan, La Scala and Fashion Week. The two abbreviations are typical of the jargon special to medical oncology - for those not familiar with these acronyms ABVD is an internationally-applied cocktail of cytotoxic drugs used in first line to treat Hodgkin's lymphoma, while CMF describes the first combination of drugs shown to prolong survival of women at risk of relapse after local treatment of their 'early' breast cancer. Both regimens were born here at the National Cancer Institute (INT), the brainchild of Gianni Bonadonna, with Umberto Veronesi as the 'grandfather' (then Scientific Director at INT, now at the European Institute of Oncology). Each day you can read about the 'Home Teams' here, in the Daily News - those organizations doing top-class translational oncology here in Milan.

It's therefore highly appropriate that ESMO honors Milan in 2010 at what, according to President David Kerr, will be the biggest and the best ESMO

Conference ever held. I've known David since his youth and he doesn't use flowery language nor empty boasts. Indeed he and I were born a kilometer apart in central Glasgow, Scotland, though some years apart, and we share an epigenetic love of calling spades spades! We've worked together too, and our first European Commission Grant in the early 1980s was on drug-loaded albumin microspheres for intraarterial infusion of liver metastases. Thirty years later the idea has at last made it into clinical practice.

David is the Rhodes Professor in Clinical Pharmacology and Cancer Therapeutics at Oxford University, England, and is renowned as an innovator and a team builder. His group in Oxford work on biomarkers in colorectal cancers. They have data and biobanked tissues from over 10,000 patients (included in clinical trials), managed by Rachel Midgley, and this has yielded a number of important Nature Genetics papers with Ian Tomlinson on novel cancer susceptibility. So when David says

that the academic level of this Congress is top class, with record numbers of Late Breaking Abstracts and outstanding translational science papers, you have to believe that this will be a great event.

It is particularly pleasing to welcome medical oncologists and scientists from Japan, China, India and Africa to Milan. While President over the next couple of years, David is keen to see ESMO membership hit the 10,000 mark and the organization becoming the provider of choice for educational and service support for the medical oncology community. But he has another particular ambition - namely to help developing countries benefit from ESMO, and from its members' talents. He has been instrumental in setting up Indox and recently Afrox to help colleagues in India and Africa meet the challenges of cancer care in India and Sub-Saharan Africa. Scotland is famed for its missionary zeal and David has the leadership skills and experience to take ESMO to these dizzy heights. With your support it will be easy!

MEET THE HOME TEAM

Silvia Marsoni is director of the South Europe New Drug Office (SENDO) based in Milan. Her career started as a clinician and pharmacologist in the Mario Negri Institute, another internationally acclaimed academic center based here in Milan. Many years at the NCI in Bethesda prepared Silvia for the daunting task of running SENDO, best described as an Academic Clinical Research Organisation. She brings novel molecules from Academia and Pharma to early clinical trial, with carefully tailored preclinical pharmacology, innovative protocol design and GCP standard clinical data and analytical execution. The founding partners in this not-for-profit company are INT, IEO, Mario Negri and IOSI (in Bellinzona). Several other top Italian centers carry out the phase I and II studies, many of which are presented at this ESMO Congress.

Several centers have biobanks, but don't necessarily store a blood sample from every patient. So as new targets arrive, and also new drugs to fit them, enormous amounts of time are wasted in identifying patients who fit entry criteria for phase I and II studies, which could have been saved with previous storage of relevant biomaterials. Silvia commends the practice in The Netherlands which

has led the way in "population-based" tissue banking.

Silvia feels that the attraction for doing translational research in the Milan region is critical mass and all the requisite skills in those institutes above, plus IFOM and two large academic hospitals, beginning to execute hypothesis-driven clinical trials. One is San Raffaele which has an in-house drug discovery programme and the other is Humanitas which houses one of Europe's leading clinical immunologists, Alberto Mantovani. Not surprisingly novel immune-targeted protocols are being developed by his group and that led by Maria Rescigno at IEO.

While optimistic about the development of effective novel molecules by SENDO, Silvia cautions that Italy, which has always had a reputation for bureaucracy, is now slowed up by a multitude of ethical committees, acting independently of each other and doing so very slowly. She pleads for "fast-track" procedures to accelerate the approval of the trials of the new generation of drugs and vaccines.

Currently SENDO is running 14 trials - four phase I clinical studies, six phase Ib combination studies and four phase II studies.



Silvia Marsoni, Director of the South Europe New Drug Office (SENDO)

Early Clinical Trials currently open at SENDO

Phase of Study		Drug	New Drug Type	Sponsor
1	FIM - ST	ST 1968 (Dx3 schedule)	Camptothecin analog	SigmaTau
2	FIM - ST	EOS 3810	FGFR1 TKI	EOS
3	FIM - Transplanted pts	CR-3294	Antimucositis	ROTTHAPHARM
4	FIM - Prostate cancer	LMF44-02	New formulation leuproline	MEDIOLANUM
1	IB in ST	AZD2281/DOXIL	PARP inhibitor	SENDO-Tech
2	IB in ST	SATRAPLATIN/NAVELBIN	Platinum analog	SAKK-SENDO
3	IB in OC	TRAJECTIDIN/DDP	Minor groove alkylator	PHARMAMAR
4	IB in ST	RAD/SORAFENIB	mTOR inhibitor/MTKI	SENDO-Tech
5	IB in ST	BI 6727/BIBF 1120	VEGFR TKI/FGFR TKI	BOEHRINGER
6	IB in ST	LBH589/Carbo/PTX	HDAC inhibitor	SAKK-SENDO
1	II in H&N	ST 1968 (intermittent schedule)	Camptothecin analog	SigmaTau
2	II in NHL-MCL	OFATUMUMAB + Bendamustine	anti CD20	INT-GITL
3	II in NHL-Marginal	OFATUMUMAB + Bendamustine	anti CD20	SENDO Foundation
4	II H&N	PANITUMUMAB	anti EGFR	SAKK-SENDO

FIM=first in man study; MCL=mantle cell lymphomas; OC=ovarian cancer; ST=solid tumors

ESMO HIGHLIGHTS 2010 NOW AVAILABLE

As an important educational resource for oncologists, ESMO Highlights is now an annual service following positive feedback from our members. In addition, ESMO Highlights 2010 has been expanded to cover a wider range of tumor types - nine cancer specialties are now included in our current edition along with over 400 carefully prepared PowerPoint slides. "ESMO Highlights serves as both a resume of the most important studies and a superb presentation resource", comments Professor Michael H. Cullen, ESMO Highlights Working Group Chair, "and we

hope that our members and the wider multidisciplinary oncology community, who were unable to attend sessions or meetings of importance to their practice, will benefit from this service".

Prepared by the ESMO Highlights Working Group and an ever-growing panel of distinguished invited experts, ESMO Highlights acts to identify the most important research and clinical findings during the preceding year. Pick up your copy of the ESMO Highlights 2010 from the Lilly booth situated in Hall 3.

Pick up your copy of the ESMO Highlights 2010 from the Lilly booth in Hall 3.



ESMO FOUNDATION BENEFIT CONCERT

One of the greatest tenors of all time, José Carreras, will make his return to La Scala after an absence of 14 years to raise funds for the fight against cancer.

The ESMO Foundation Benefit Concert will be held at the world-renowned opera house, the Teatro alla Scala on Sunday night at 20:00. Maestro Carreras will be joined on stage by Sabina Puertolas and the Scala Philharmonic Orchestra.

"Cancer has taught me to listen to others..."

After developing leukemia in 1987, José spent 11 months in hospital and required a bone marrow transplant. Of his experience he says that "People who survive cancer change, I've become more ready to listen to others, more able to talk to people and communicate. Cancer has taught me to listen to others. The message I want to transmit to others who are fighting against cancer is to hold on to those you love and your friends because even the smallest glimmer of hope can help you to fight with more determination. Cancer leaves deep wounds but you

can win. My illness has changed me. Sick people must continue to hope". His experience led José to set up the International Leukemia Foundation that bears his name to fight against leukemia and encourage progress in scientific research.

The tenor says of his return to La Scala "It's an extraordinary opportunity for an artist, and this is also an extraordinary opportunity for local companies to become part of this great event and

offer concrete support to the noble cause of the fight against cancer".

"My illness has changed me. Sick people must continue to hope."

Tickets can be purchased from the Concert Desk in the registration area.



ESMO Milan 2010 Industry Satellite Symposium

RANK Ligand Inhibition for Bone Health in Cancer Patients – Targeted Toward a New Standard of Care

17.30–19.30, Sunday 10 October 2010

Silver Room, Hall 4

Milano Convention Centre
Milan, Italy

Programme

Meeting chair: Rob Coleman (UK)

The central role of the RANK Ligand pathway in cancer treatment induced bone loss
Bertrand Tombal (Belgium)

RANK Ligand inhibition – improving care in men with advanced prostate cancer
Karim Fizazi (France)

Challenging the current standard for prevention of bone complications in the advanced cancer setting
Allan Lipton (USA)

Working towards prevention of bone metastases with innovative adjuvant therapies
Rob Coleman (UK)

Refreshments will be provided prior to the symposium

10/10/2010 17.30–19.30 © 2010 Amgen Inc. All rights reserved. NP-AMG-480-2010.

Submitted to AIFA on September 17th 2010



AMGEN
Oncology

Educational session

Diagnostic and management issues in metastatic breast cancer

Saturday, 9 October 09:00-10:30

Gold Hall



Fabrice Andre, Institute Gustave Roussy, France

METASTATIC BREAST CANCER STILL PROVING DIFFICULT TO DIAGNOSE

Diagnosis of metastatic lesions is becoming an important issue in the management of breast cancer. This is related to the finding that some suspected metastatic lesions are actually not metastasis from breast cancer. In addition, some studies have recently reported some discrepancy in the expression of key therapeutic targets (ER, HER2) between primary

and metastasis. Treatment for metastatic lesions will also be covered in this session. In the last few years, new drugs have provided a major impact on metastatic disease, and it is now considered a chronic disease in a significant proportion of cases. In addition, the development of new agents will probably lead to further progress in the next few years.

TODAY'S EDUCATIONAL SESSIONS

Saturday, 9 October

Diagnostic and management issues in metastatic breast cancer This session covers the role of the pathologist in choice of optimal treatment, along with treatment for triple-negative and HER2-overexpressing breast cancer. 09:00-10:30 Gold Hall Missed it? Session repeated later today: 14:15-15:45 Violet Hall	New therapeutic options in urological cancer This session covers new hormonal agents in the treatment of advanced prostate cancer, new agents for bladder cancer and selection of targeted therapy in renal cancer. 09:00-10:30 Violet Hall Missed it? Session repeated later today: 16:00-17:30 Silver Hall	How much do we know about cancer cells? This session covers the epithelial-mesenchymal transition (EMT) phenomenon, cancer stem cells and circulating cancer cells. 09:00-10:30 Pink Hall Missed it? Session repeated later today: 16:00-17:30 Pink Hall	Advances in neuroendocrine tumors This session covers lung and gastrointestinal neuroendocrine and Merkel tumors. 09:00-10:30 Blue Hall Missed it? Session repeated later today: 14:15-15:45 Pink Hall
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Treatment of PT1N0 breast cancer This session covers use of multigene predictors to assess risk of relapse, benefits and adverse effects of endocrine therapy, and use of chemotherapy with or without trastuzumab. 11:00-12:30 Gold Hall Missed it? Session repeated later today: 16:00-17:30 Violet Hall	Advances in the treatment of advanced colorectal cancer This session covers the role of the molecular pathologist in optimal treatment decision, optimal use of chemotherapy in advanced colorectal cancer and the integration of molecular targeted agents in the continuum of care. 11:00-12:30 Violet Hall Missed it? Session repeated later today: 16:00-17:30 Gold Hall	Prevention and treatment of side effects of systemic treatment This session covers anemia, cardiotoxicity and bone loss 11:00-12:30 Pink Hall Missed it? Session repeated tomorrow: 10:45-12:15 Green Halls 1+2
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Updates in B-cell malignancies This session covers multiple myeloma, follicular lymphoma and chronic lymphocytic leukemia (CLL). 11:00-12:30 Blue Hall Missed it? Session repeated tomorrow: 09:00-10:30 Blue Hall	Early-stage NSCLC: Challenges in staging and adjuvant treatment This session will cover evidence-based staging, role of adjuvant chemotherapy and use of markers to select patients for adjuvant therapies. 14:15-15:45 Gold Hall Missed it? Session repeated tomorrow: 09:00-10:30 Silver Hall	Challenging issues in ovarian cancer This session will cover use of proteomic profiling to guide therapy selection, addition of new drugs to standard therapy in first-line treatment of ovarian cancer, and optimal treatment for relapsing ovarian cancer. 14:15-15:45 Silver Hall Missed it? Session repeated tomorrow: 10:45-12:15 Silver Hall
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JOINT SYMPOSIA

Saturday, 9 October

 European Society for Medical Oncology	ESMO/CSCO Joint Symposium Personalized medicine: Do ethnic differences matter? This joint symposium will cover pharmacogenomics and SNP in diverse ethnicity, hepatocellular carcinoma, personalized management of lung cancer with focus on EGFR mutation and beyond, and colorectal cancer. 09:00-10:30 Red Hall
 Chinese Society of Clinical Oncology	
 European Society for Medical Oncology	ESMO/ESTRO/ESSO Joint Symposium Surgery, radiotherapy and ablation of metastatic disease and chemotherapy for localized disease: Changing roles in multidisciplinary management of colorectal cancer This joint symposium will cover image guided therapy of metastases from colorectal cancer, question whether a tumor is curable if it's resectable, radiotherapy from palliation to cure and prophylaxis, and locoregional delivery of chemotherapy for metastatic CRC. 11:00-12:30 Red Hall
 The European Society of Radiotherapy & Oncology	
 The European Society of Senology	
 European Society for Medical Oncology	ESMO/JSMO Joint Symposium Biomarkers and selected therapeutics in lung and gastrointestinal cancer This joint symposium will cover recent progress in JSMO and society activities, new evidence in EGFR-TKI for EGFR mutated NSCLC, updated results in anti-HER2 and angiogenesis inhibitors for gastric cancer, predictive biomarkers in the treatment of advanced colorectal cancer and the immediate future of customized treatment in lung cancer. 14:00-15:30 Blue Hall
 Japanese Society of Medical Oncology	

Sunday, 10 October

 European Society for Medical Oncology	ESMO/AIOM Joint Symposium Young medical oncologists facing daily difficulties in clinical practice This joint symposium will cover how to present bad news to the patient, risk of burn out in young oncologists, how to present a completed research project as an oral presentation, and how to present data from a project in a manuscript. 13:45-15:15 Violet Hall
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Monday, 11 October

 European Society for Medical Oncology	ESMO/ASCO Joint Symposium The future of antiangiogenesis therapy This joint symposium will cover the biology of antiangiogenic therapy in the adjuvant setting, preclinical biology as it relates to adjuvant therapy, an analysis of currently available adjuvant colorectal data, and possible antiangiogenic effect of COX-2 inhibition in the adjuvant setting for colorectal cancer. 10:45-12:15 Violet Hall
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Tuesday, 12 October

 European Society for Medical Oncology	ESMO DCTF/UICC/WHO Joint Symposium Meeting the challenge of managing cervical cancer in the developing world This joint symposium will cover optimal screening of cervical cancer in developing countries, current knowledge from practical experience of HPV vaccination, daily costs of treating cervical cancer, and a Health Minister's response to managing cervical cancer in low-income countries. 11:15-12:45 Silver Hall
 global cancer control	

Presidential Symposium

Monday, 11 October 15:00-17:30

Gold Hall



Dr. Johann de Bono, Institute of Cancer Research and Royal Marsden Hospital, UK

PROGRESS IN PROSTATE?

Eagerly awaited results from a phase III study in patients with metastatic castration-resistant prostate cancer (mCRPC) treated with abiraterone will be presented at this year's Presidential Symposium. Abiraterone is designed to treat these tumors by inhibiting the production of androgen in the testes, the adrenal glands and prostate cancer tumors themselves. The study included 1195 patients from 13 countries whose mCPRC had previously been treated with one of two chemotherapeutic agents that included docetaxel. Full results will be presented by Dr. Johann de Bono from The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust in London.



Metastatic prostate cancer: radionuclide bone scan

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PREVIEWING AT ESMO

ONCOLOGYPRO

Educational Portal for Oncologists

"We can't spend time reading all the articles and studies that get published."

"It's necessary to select the information that is important to read"

Preview OncologyPRO while you're at this year's ESMO meeting. OncologyPRO, which stands for Oncology Professional Resources Online, is a unique scientific resource for ESMO members giving you instant access to the highest quality scientific knowledge in one easy-to-access place. OncologyPRO puts full-search access to more than 140 oncology journals, including ESMO and public journals, at your fingertips. View clinical guidelines, congress webcasts, abstracts and posters, patient education and even information on clinical trials, biomarkers, monographs and emerging drugs.

The development of this unique resource was inspired by your comments from the global ESMO Survey.

OncologyPRO has therefore been designed to meet your expectations, as part of the multi-disciplinary oncology community.

Whether you're a medical oncologist, radiotherapist, surgical oncologist, or hematologist, OncologyPRO can be personalized to meet your own needs. Even though OncologyPRO won't launch until next year, we're giving you the chance to preview it daily at the Piazza Booth in the Society Piazza, so come along to see what all the fuss it about!

OncologyPRO gives you instant access to the highest quality scientific knowledge in one easy-to-access place.



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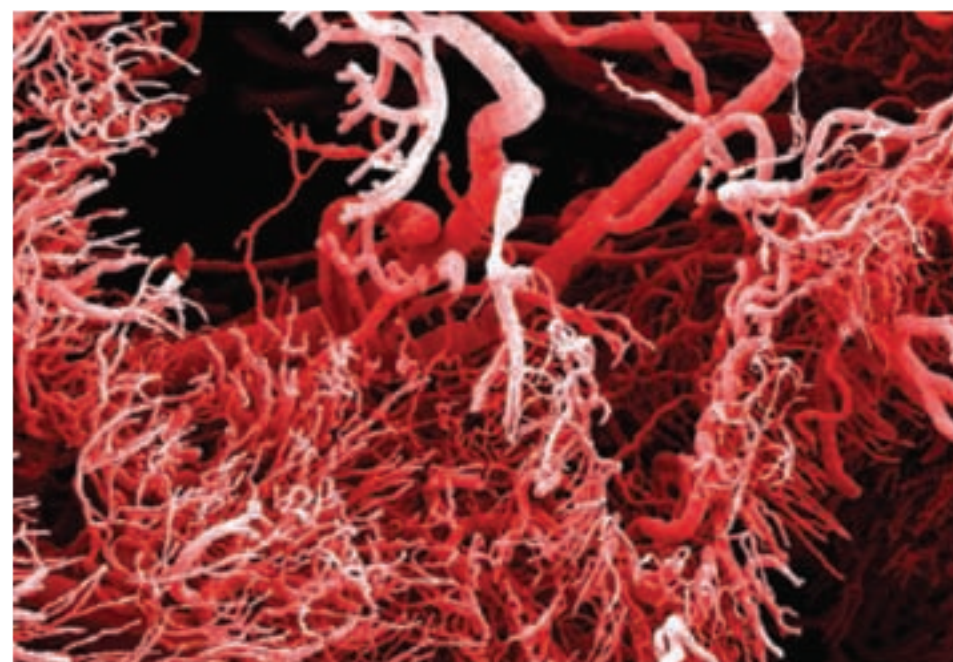
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IMAGE OF THE DAY - ANGIOGENESIS

Not an exquisite coral but the oxygen supply of a fast-growing cancer



Angiogenesis is the creation of new blood vessels from pre-existing vessels

Special Session
 Saturday, 9 October 16:00-17:30

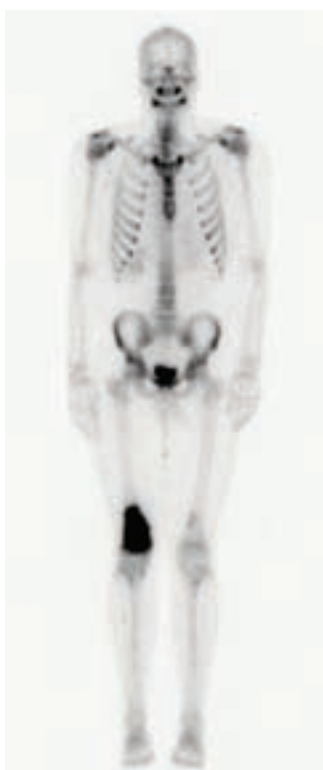
Chronic Disease Alliance: A time to work across specialities
 Green Halls 1 + 2



Hear Europe's leading epidemiologist, Sir Richard Peto talk on all cause mortality - cancer, diabetes and vascular disease - sharing the platform with ESMO President David Kerr.

ESMO DRIVES EUROPEAN ACTION AGAINST RARE CANCERS

Around 20% of all cancers are considered rare, affecting more than 2.5 million people in Europe. Patients with rare cancers are faced with specific challenges, including late or incorrect diagnosis, difficulties finding clinical expertise and gaining access to appropriate treatments, limited numbers of clinical trials, and lack of interest in developing new therapies due to limitations in the market. The European Action Against Rare Cancers (EAARC), a multi-stakeholder initiative led by ESMO, is fully committed to putting rare cancers firmly on the European policy agenda. To learn more about this initiative, visit the ESMO exhibition booth or go to www.rarecancers.eu.



Osteosarcoma of femur

ESMO Examination

Saturday, 9 October 17:30 - 19:30

Blue Hall

ESMO EXAM TODAY

This afternoon 141 young medical oncologists will put their skills to the test during the ESMO Exam. "I took the exam in 2004 and then I immediately joined the Examination Working Group" comments Dr. Giulio Metro, "and I encourage all Full and Junior members to take the Exam because it gives you the opportunity to become a certified ESMO member through the recognition of core curriculum European oncologists."



*Dr. Giulio Metro, Italy
ESMO Examination Working
Group member*

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You can go directly to ESMO mobile Web site: <http://m.esmo.org/milan2010>

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2. The Late-breaking abstracts
3. Congress Daily Broadcasts

LET'S THINK

BOEHRINGER INGELHEIM IS COMMITTED TO ONCOLOGY AND ADVANCED RESEARCH IN THE AREAS OF:

- ANGIOGENESIS INHIBITION
- SIGNAL TRANSDUCTION INHIBITION
- CELL-CYCLE KINASE INHIBITION



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ONCO124 DATE OF PREPARATION: JUNE 2010

LET'S WORK
ONCOLOGY FROM BOEHRINGER INGELHEIM

Boehringer
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BIOMARKERS IN FOCUS: EGFR, KRAS AND BEYOND

Epidermal growth factor receptor (EGFR) gene mutations have been associated with favorable response to EGFR tyrosine kinase inhibitors (TKIs). In contrast, KRAS mutations have been shown to predict poor response to such therapy. The PIK3/Akt signaling pathway is critical for cancer cell growth and survival and the PIK3CA gene has been reported to have somatic mutations that would have a different clinical impact in non small-cell lung cancer (NSCLC) patients treated with TKIs.

and no additional biomarkers were identified in the studied population.

PIK3CA, EGFR and KRAS mutations were analyzed in archival tissue specimens by Vienna Ludovini and colleagues (see 1570).

Treatment crossover in oncology randomized trials remains a significant problem for proper interpretation of survival results.

a statistically significant predictor of OS.

No established therapy exists for NSCLC patients who fail chemotherapy and erlotinib or gefitinib. The efficacy of afatinib (BIBW 2992) an irreversible EGFR and HER2 TKI

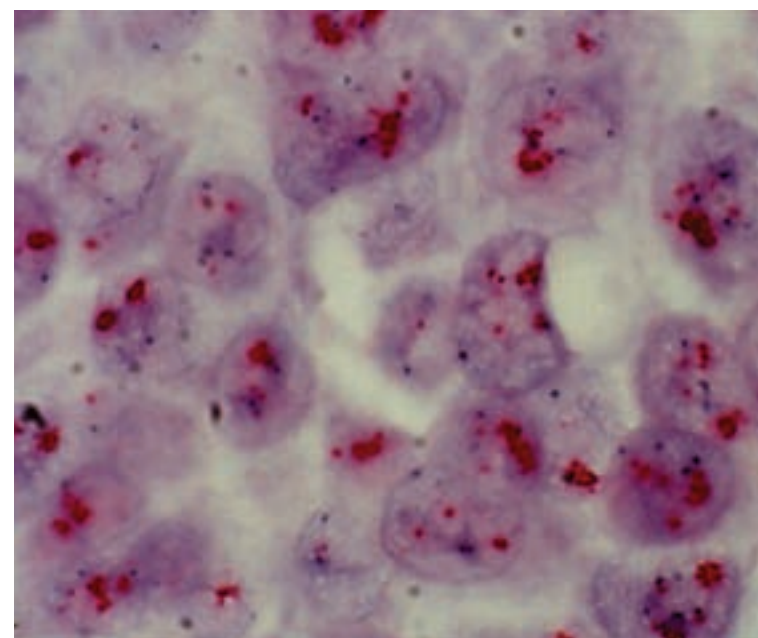
with preclinical activity against the resistance mutation EGFR T790M was assessed in this setting (see LBA1).

On behalf of the OPTIMAL investigators, Yi-Long Wu will present the first biomarker analyses from a randomized, phase III, open-label, first-line study of erlotinib versus carboplatin plus gemcitabine in Chinese patients with advanced NSCLC with EGFR activating mutations (see LBA14). The authors analyzed KRAS, EGFR T790M, HER2, BRAF, PIK3CA, PTEN and c-MET status but treatment outcomes did not differ significantly by EGFR activating mutation type

PIK3CA mutation did not correlate with response but correlated with shorter median time-to-progression (TTP) and poor overall survival (OS). EGFR mutation correlated with favorable response and KRAS mutation with progressive disease and shorter median TTP. The multivariate Cox model indicated that, when adjusted for histology and performance status, PIK3CA mutation remained

...KRAS and PIK3CA mutations might turn out to be indicators of resistance.

The addition of afatinib to best supportive care did not improve OS but markedly improved progression-free survival (PFS) and resulted in a higher overall response rate and disease control rate. When interpreting drug activity in this phase



When to FISH for HER2? (Image courtesy of Prof G. Viale, Milan)

III study, it should be noted that it was conducted in heavily pretreated patients. Treatment crossover in oncology randomized trials remains a significant problem for proper interpretation of survival results. Mature OS was not statistically significantly different for gefitinib vs carboplatin/paclitaxel overall or in EGFR biomarker positive/negative populations in this landmark IPASS study, possibly because of the high percentage of patients who crossed over and received the alternative study treatment (see LBA2).

...dual inhibitors are on the horizon...

KRAS mutation occurs frequently in NSCLC, mainly in tumors of adenocarcinoma histology. As the prognostic and predictive roles of this mutation remain unclear, due to the small sample size of most studies, LACE investigators undertook a pooled analysis of KRAS mutation status in 1751 patients who participated in four randomized trials of adjuvant platinum-based chemotherapy or observation (see 1560). Overall, there was a non-significant trend for poorer OS in patients with KRAS mutation.

The open-label phase II study conducted by Tony Mok evaluated efficacy and safety of first-line PF299804 in a patient population with advanced NSCLC, molecularly selected or enriched for EGFR mutation (see LBA 18). Preliminary data suggest PF299804 shows encouraging efficacy as first-line therapy, as reflected by PFS rates.

Met expression is associated with worse prognosis in NSCLC, and Met activation has been implicated in resistance to EGFR inhibition in EGFR-mutated NSCLC. Presuming that dual inhibition of Met/EGFR may result in promising activity in NSCLC, a group of USA researchers conducted a global randomized, double-blind phase II study comparing MetMab plus erlotinib

to placebo plus erlotinib in second/third line NSCLC (see LBA 15). A total of 128 patients were randomized; baseline characteristics were well-balanced, including Met+, KRAS mutation and EGFR mutation. Both a PFS benefit and an OS benefit were observed in the patients treated with MetMab plus erlotinib.

How can one summarize all of these studies? We are at least one step forward to further individualization of lung cancer treatment; crossover remains a significant problem in study evaluation; dual inhibitors are on the horizon; and KRAS and PIK3CA mutation might turn out to be indicators of resistance.

Data from LBA14 and LBA15 will be presented at the Proffered Paper session on Chest tumors I which will take place on Saturday, 9 October 2010 at 11.00-12.30 in the Silver Hall.

Data from 1560 and 1570 will be presented at the Proffered Paper session on Biomarkers which will take place on Monday, 11 October 2010 at 09.00-10.30 in the Red Hall.

Data from LBA1 and LBA2 will be presented at the Presidential Symposium which will take place on Monday, 11 October 2010 at 15.00-17.30 in the Gold Hall.

Data from LBA18 will be presented at the Proffered Paper session on Chest tumors II which will take place on Monday, 11 October 2010 at 13.15-14.30 in the Gold Hall.

In partnership:



COMMUNITY ONCOLOGY

Dr. Robert Eckert is a committed ESMO member with a difference - he is a "community medical oncologist". When asked what that is, Robert replies that he is a doctor working in a non-teaching hospital, outside a comprehensive cancer center. While full of praise for ESMO, he would like to see the society become more appealing to his kind of oncologist, as the leadership is predominantly academic and may not be aware of the problems facing a colleague working in a district general hospital. So, with ESMO's support, he set out to discover what other community oncologists in his region of Germany thought. Robert's paper (see 1093PD) describes

a survey of 500 doctors like him. He got a good response - 164 responders - and, interestingly, less than half (81) were ESMO members. Robert is urging others who are already members to support the work of the Community Oncology Committee which he chairs, and to advance a new agenda for ESMO, new content for the ESMO website tailored to his group's needs, and a different kind of educational content at ESMO conferences to supplement the existing excellent modules. He would like to be contacted by keen community oncologists and asks them to write to him at robert.eckert@onko-esslingen.de.



QUOTES OF THE DAY

How do you evaluate the Congress Educational and Scientific program?

"I think it is highly relevant and impactful. I especially appreciate presentation of pivotal trial data that changes treatment paradigms"

What do you think about the ESMO Members dedicated services and initiatives?

"It is the best place for communicating with other members"

"Very quiet, very relaxing and good hospitality. Facilities excellent"

"I love the lounge - very nice! I wish ASCO would do this"



FACES IN THE CROWD



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... Presentation of prospective phase 3 studies of Vectibix® combination therapy as 1st- and 2nd-line treatment* for mCRC patients with wild-type *KRAS*¹

2008

April.

..... Landmark Vectibix® data establish *KRAS* as a biomarker that improves patient selection in mCRC²

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December.

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Vectibix® is indicated as monotherapy for the treatment of patients with EGFR-expressing, metastatic colorectal carcinoma with nonmutated (wild-type) *KRAS* after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.
*Under Regulatory Authority Assessment

References: 1. Joint 15th Congress of the European Cancer Organization and 34th Congress of the European Society for Medical Oncologists. Colorectal cancer highlights from the 2009 joint ECCO/ESMO multidisciplinary congress. *Clin Adv Hematol Oncol.* 2009;7:631-632. 2. Amado RG, Wolf M, Peeters M, et al. Wild-type *KRAS* is required for panitumumab efficacy in patients with metastatic colorectal cancer. *J Clin Oncol.* 2008;26:1626-1634. 3. Weiner LM. Fully human therapeutic monoclonal antibodies. *J Immunother.* 2006;29:1-9.

AIFA submission date: 17 September 2010.