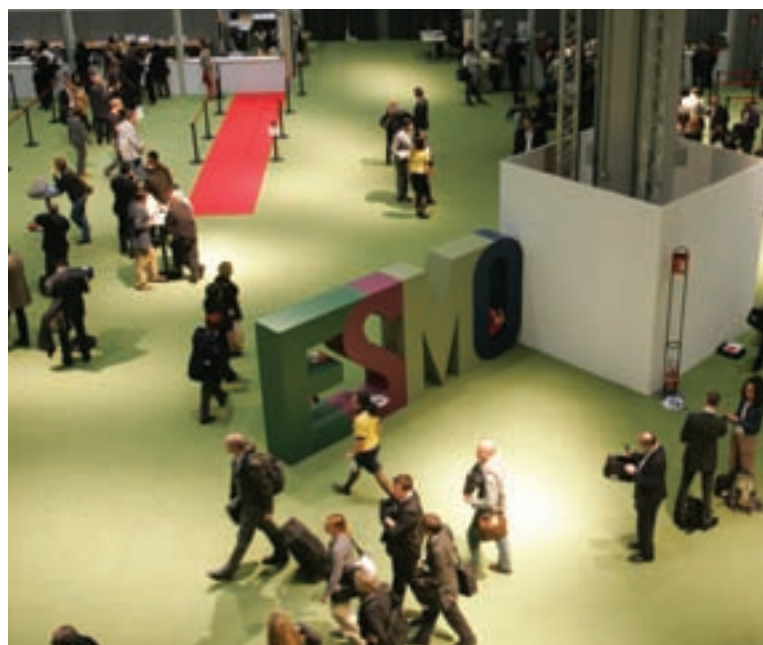




CongressDaily

☐ Saturday ☒ Sunday ☐ Monday

Sunday 10 October, 2010



OUR RECORD-BREAKING CONGRESS!

The 35th ESMO Congress got off to a record-breaking start – just over 15,000 delegates registered on Friday – and we have more speakers, presentations and exhibition space on offer than ever before. Friday's Young Oncologists Masterclass on the importance of conducting well-designed clinical trials was packed to capacity and satellite symposia which took place that afternoon were also well attended. The Educational and Scientific programs have been praised by delegates – the Congress has been described as “wonderful” with relevant sessions that are “well structured” and containing “a good bridge between science and daily practice”.

Over 3,500 delegates attended to hear José Baselga, Fabrice Andre

and Giuseppe Viale speak about diagnostic and management issues in metastatic breast cancer at one of yesterday's educational sessions.

“...a good bridge between science and daily practice.”

Many other sessions have already required the opening of the ‘overflow rooms’ including the multidisciplinary interactive session ‘Locally advanced pancreatic cancer’ and the ESMO/CSCO Joint Symposium ‘Personalized medicine: Do ethnic differences matter?’. Today's sessions will be equally in demand, so get there early!

The new ESMO branding has also been well received, with the new look and feel described as “modern, dynamic, innovative” and “working for the future”.

We look forward to seeing you at all of today's sessions.

Today's sessions will be equally in demand, so get there early!



ESMO Clinical Practice Guidelines

Sunday, 10 October 10:45-12:45

Gold Hall

ESMO CLINICAL PRACTICE GUIDELINES

Professor Nicholas Pavlidis, Chair of the ESMO Guidelines Working Group, presents this year's ESMO Guidelines Interactive Session to provide you with a set of recommendations for the best standards of cancer care in triple-negative breast cancer, GIST and pancreatic cancer. “These topics reflect the current therapeutic dilemma on the management of these tumors as well as the discovery of novel promising compounds” comments Nicholas. “In addition, answers to any debates or controversies can be given through evidence-based guidelines, and the selection and application of novel treatments are more appropriately

implemented through updated guidelines”.

“Answers to any debates or controversies can be given through evidence-based guidelines.”

Our guidelines have been developed and updated for you to support appropriate clinical decision-making, improve the quality of health care and outcomes for patients and achieve high common standards of medical practice in all European countries. Each clinical practice guideline includes information on the incidence

of the malignancy, diagnostic criteria, staging of disease and risk assessment, treatment plans and follow-up. “ESMO guidelines should be important to all our members as they are disease-specific, updated annually and always based on the findings of evidence-based medicine” adds Nicholas.

So, what can you expect from this session? You'll be introduced to the philosophy and practice of how to use the ESMO guidelines, while European experts will bring you the latest evidence-based information. This ESMO Guidelines Interactive Session will also give you the chance

to participate in interactive ‘clinical cases’ through an electronic voting system. “The session will serve as an excellent educational tool, particularly on the topics scheduled to be presented” states Nicholas. Since the first ESMO Guidelines Interactive Session back in 2000, this is the seventh to be organized, with all being previously well received by our members.

Need more information? ESMO Clinical Practice Guidelines are available at www.esmo.org



Prof Nicholas Pavlidis

Today's Top Picks!

Special Session

Communication Skills Training (CST)

09:30-11:00
Yellow Hall 2

ESMO Clinical Practice Guidelines

Breast Cancer
GIST
Pancreatic Cancer

10:45-12:45
Gold Hall

Proffered Paper Session

Melanoma

11:00-12:15
Pink Hall

Proffered Paper Session

Colorectal Cancer

13:30-15:00
Gold Hall

Proffered Paper Session

Breast Cancer, advanced

15:30-17:30
Violet Hall

JOIN OUR COMMUNITY

Many ESMO members have already visited the exclusive ESMO Members' Lounge at this year's Congress. The Lounge is located on level MIC 0 and provides 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. Come and try it out for yourself and see what you're missing!

"An excellent initiative... it's important to have some space from the crowds..."

2010 members can pick up their day entry voucher to the lounge from the Membership Services Center in the Registration Hall.

There's a great deal of excitement around The ESMO Experience

Booth, located in the exhibition area (Booth 127), where many members

"Easy to use and find what you need."

have already tried out our practical E-Learning tools and promising new product OncologyPRO.

Our booth also features 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 seeing you!

Not already an ESMO Member? Join the 522 new members of ESMO who have signed up already. Your free ESMO trial membership is valid until June 2011 - 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 our community. Visit the Membership Services Center located in the Registration Hall to begin your ESMO experience today!

Why don't you try our E-Learning tools at the ESMO Experience Booth?



ONCOLOGY>PRO

Educational Portal for Oncologists

PREVIEWS AT ESMO

Preview OncologyPRO while you're at this year's ESMO Congress. OncologyPRO (Oncology Professional Resources Online), is a unique scientific resource for ESMO members giving you instant easy access to the highest quality scientific knowledge in one location. OncologyPRO can be personalized to meet your own needs and 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, monographs, patient education and even information on clinical trials, biomarkers, and emerging drugs.

OncologyPRO won't launch until next year, but we're giving you the chance to preview it daily at the Piazza Booth in the Society Piazza.

Come along to see how OncologyPRO can work for you!

"It's easy to navigate, has very comprehensive content and has just one login to access all the information."

EDUCATIONAL SESSIONS: KEY LEARNING POINTS FROM SATURDAY

Diagnostic and management issues in metastatic breast cancer

- The pathologist needs to provide a definite diagnosis of metastatic breast carcinoma and accurately assess biological parameters that will have an impact on treatment decision.
- Several targeted therapies are successfully being developed for triple-negative breast cancer and the BRCA pathway appears to be a key determinant.
- Increased availability of novel anti-HER2 agents and a better understanding of the mechanisms of resistance to anti-HER2 agents should further improve outcome in HER2 breast cancer.

New therapeutic opportunities in urological cancer

- Current treatment options for patients with advanced prostate cancer remain limited.
- New therapies under investigation for advanced bladder cancer include novel agents.
- Targeted agent selection in renal cancer remains difficult but should consider disease status, histology, performance status and drug availability.

How much do we know about cancer cells?

- Identification of cancer stem cells will probably have several translational implications for cancer management.
- Circulating tumor cells (CTC) detection and characterization might become a valuable tool to refine prognostication and serve as a real-time tumor biopsy for individually tailored cancer therapy.
- Using CTCs as a prognostic and/or predictive biomarker may lead to improvement in clinical outcome of cancer patients.

Treatment of pT1N0 breast cancer

- Multigene predictors capturing gene-expression profiling or other molecular measurements have great potential for improving breast cancer management when used in conjunction with the usual clinical pathological factors.
- Tailored endocrine treatments should be considered in patients with endocrine-responsive tumors classified as pT1 pN0 with a balance between efficacy and side effects.
- There are no prospective data on trastuzumab use in pT1abNOM0, although preliminary reports strongly suggest that proportional benefits of all adjuvant treatments are independent of T and N status.

Advances in the treatment of advanced colorectal cancer

- Prognostic and predictive biomarkers that reflect molecular and therapeutic complexities of advanced colorectal cancer may improve patient management and therapeutic agent selection.
- Main clinical determinants of treatment choice are resectability, symptoms, bulk of disease, performance status and clinical course.
- Targeted agents have substantially improved and can now be adjusted to the individual patient and his or her tumor type.

Updates in B-cell malignancies

- Patients with asymptomatic multiple myeloma may remain stable for a long time without any therapy. When treatment is needed, new drugs should be included in the first-line strategy.
- Watch and wait remains an option for follicular lymphoma, R-CHOP is not the standard first-line treatment and transplantation should be kept for cases of (aggressive) relapse.
- For fit chronic lymphocytic leukemia patients, FCR offers the best results. Deletion of chromosome 17 is the worst prognostic factor.

Early-stage NSCLC: Challenges in staging and adjuvant treatment

- Staging of NSCLC is a multidisciplinary process involving imaging, endoscopic and surgical techniques.
- Randomized studies of adjuvant chemotherapy in NSCLC indicate a 4–5% improvement in survival at 5 years.
- As the clinical usefulness of patient selection for adjuvant chemotherapy is still under investigation, routine use of biomarkers is not currently recommended in clinical practice.

Challenging issues in ovarian cancer

- Emerging proteomic technology may help to select patients who may be more likely to benefit from certain targeted therapies.
- Primary therapy with carboplatin and paclitaxel remains a well-tolerated standard regimen in ovarian cancer.
- Arbitrary choices about which therapies to use to manage recurrent ovarian cancer will continue to be made unless we identify specific molecular targets for the individual patient.

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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NP-AMG-515-2010
09.2010

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)

HOT (AND NOT SO HOT) NEW DRUGS

ESMO showcases a number of new molecules here in Milan, but don't be surprised that a large number of studies are negative. While the newspapers, and sadly many cancer journals only publish positive trials, negative results can be equally important, particularly if they yield insights into the mechanisms of drug resistance. And of course once a negative study has been publicized it will not usually need to be repeated, thus cutting down duplication of effort and accelerating the process of drug development.

In selecting hot topics it would be unwise to believe your somewhat biased editor, so I talked with a number of other wiser heads who are presenting at the ESMO Congress. Having lived through 30 years of hype and subsequent depression as one disaster after another plagued immunotherapy initiatives, my bias has been overturned by ipilimumab. The drug dominated ASCO recently and mature results will be presented here, and rightly so. For the first time we've seen an impact of an antibody on survival in melanoma. The target of the antibody is not a cancer cell, but CTLA-4 (cytotoxic T lymphocyte-associated antigen 4) on particular T cells whose job it is to inhibit the functions of anticancer T-cell suppressor clones. The implication of this is that it may also turn out to be active in cancers other than melanoma. It is interesting to talk to Lex Eggermont, newly appointed Scientific Director, Institut Gustav Roussy in Paris, and ESMO presenter, who has spent most of his work in translational immunological research and who has led the European development of this exciting antibody. (It's also good to

remember that surgeons like Lex can also be prominent in lab research). He is astonished by the melanoma results and gratified too. He shares the optimism that these results might be seen across other tumor types, but he warns that doctors and patients will need to learn how to detect and manage the side effects of this new class of antibodies. The role of the target T-cell suppressors hit by the antibody is to suppress autoantibody production, so lifting that braking mechanism has led to appearance of autoimmune syndromes, such as thyroiditis and colitis. So treatment of severe diarrhea associated with the drug is not restricted to antidiarrheals but must include prompt administration of steroids.

Another Senior Oncologist to move jobs lately is Hilary Calvert, deservedly rewarded by ESMO here in Milan with the Lifetime Achievement Award. Hilary trained in Medical Oncology and Biochemical Pharmacology at the Institute of Cancer Research (ICR) in London. He was the man behind the clinical development of carboplatin, and later as a Professor in Newcastle, several novel antifolates and the first PARP inhibitors. Now Director of Cancer Drug Development at University College, London, Hilary is probably one of the few clinicians at this meeting who could draw the structure of methotrexate or PARP on a whiteboard. "Yes" he predicts, PARP inhibitors are likely to become significant cancer drugs, particularly in patients whose cancers carry BRCA mutations, not only breast, but others such as prostate. And "Yes" they may be good chemosensitisers (he started working on PARP as it was one of the resistance mechanisms for temozolomide). "Yes"

they also may make a contribution to radiosensitization and certainly should be better than the current anti-hypoxia strategies, he thinks. And chemoprevention agents? Hilary feels this is highly contentious, but among the nine drugs presently in trial, few have serious adverse effects, though it's much too early to detect mutagenic effects. In vitro he says they are "very potent" in engineered cell lines which carry BRCA mutations, so worth pursuing. "Even if there were to prove to be a 1% chance of carcinogenicity after long-term use as chemopreventive molecules, BRCA mutation carriers face up to an 80% life-long risk of cancer", he says, "so if they truly prevent those tumors emerging, that would be a positive net benefit". Other drugs which Hilary predicts will not be so valuable are the kinase inhibitors and he is concerned that resistance pathways are too easy for the cancer cell to learn. Exceptions are, of course, imatinib and gefitinib. But the two areas for optimism in his view are both where translocations have been exploited - braf in melanoma and ALP in non-small cell lung carcinomas. He cites really impressive results in the appropriate subsets, and, as of now, slow appearance of resistance.

The last expert view comes from the same stable (ICR) as Hilary - Johann De Bono. He gives detailed results of the first trial of a new drug in decades for castration-resistant prostate cancer, abiraterone. Note that the term "hormone-resistant" is challenged by the new drug, as it is a hormonal agent in the sense that it targets resistance pathways which allow prostate cancer cells to "escape" androgen or anti-androgen control. Johann works in a



Prof Lex Eggermont; Prof Hilary Calvert; Prof Johann De Bono and Prof Alan Ashworth

prolific phase I trials unit at the Royal Marsden and recently co-authored a note in Nature with the Scientific Director Elect at ICR, Alan Ashworth (presenter on PARP in a plenary session this afternoon here at ESMO and 2009 ESMO Lifetime Achievement Award recipient). They make a strong case for changing the way we develop drugs today, as the classic model was built to evaluate cytotoxic agents, and the clever new breed of molecules is not nearly so toxic, will probably be best in combination, and be measurable by biomarker effect. By the way, I strongly urge you to go to listen to Johann and Alan, and to join the session on biomarkers.

Alan Ashworth will present at the Special Symposium 'Bullseye: PARP' at 13.45-15.15 today in the Pink Hall.

Lex Eggermont is co-chairing Melanoma Proffered Paper Session taking place today at 11.00-12.15 in the Pink Hall.

Johann De Bono will present results from the LBA5 abstract during the Presidential Symposium at 15.00-17.30 tomorrow afternoon in the Gold Hall.

The Special Symposium 'The use of biomarkers to guide treatment in hematological malignancies' will take place at 09.15-10.45 on Tuesday in the Pink Hall.

MEET THE HOME TEAM



Pier Giuseppe Pelicci, Co-Scientific Director of the European Institute of Oncology (IEO)

Pier Giuseppe Pelicci is co-Scientific Director of the European Institute of Oncology (IEO), founded 16 years ago by Umberto Veronesi (Honorary Chair of the ESMO Local Committee). Pier Giuseppe (known as PGP at IEO) is an MD PhD and trained in Hemato-oncology in Perugia and in Cell and Molecular Biology at New York University. PGP's view of translational research is rosy for a number of reasons and he remains a true optimist about Milan's strengths in future contributions to cancer research and care. Of IEO, PGP underlines the fact that it is new, not encumbered by tradition and 'straitjacketed' by the past. His recipe for the best chances of success of translating from bench to bedside is to invest in excellent basic full-time scientists and the best

full-time clinicians - then build bridges between both groups by training MD PhDs who speak the 'language' of the lab and the clinic. PGP's view is that it is a waste of time translating bad basic science, and equally, good science is never going to be proven useful if not rigorously tested in the clinic.

At IEO, PGP has, along with Umberto Veronesi, emphasized investment in infrastructure - including biobanks, biostatistics and 'omics platforms' - while also attracting promising young scientists and clinicians and giving them independence to work in their own way. The biobank at IEO stores frozen tissues and cells, along with xenotransplanted samples. But PGP believes in topdown research priorities too and he cites four, in no order:

- Cancer stem cells, and increasing our understanding of them, will provide insights into the etiology of cancer, uncover suitable cancer-specific targets, and assist in the design of therapeutic strategies for overcoming or preventing resistance. IEO boasts six stem cell lab groups and a large imaging program.
- Epigenomics will, likewise, unlock some of the secrets of the influence of the microenvironment on cancer causation, and PGP points to the existence of new molecules aimed at epigenetic targets which are already in clinical trials.
- Linked to this, but also dependant on efficient tissue banking, must be a comprehensive search for

meaningful biomarkers, whether 'omic', epigenomic or imaging based. PGP believes that dependable markers will accelerate the time taken for new innovative molecules to arrive in the clinic.

- Drug discovery, development and innovative early phase clinical trials are so obviously important that they require no further comment.

PGP's final boast for translational research strengths in Milan is the European School of Molecular Medicine in which over one hundred PhD students are currently enrolled. Four courses will be strengthened next year by a very attractive option for medical oncologists - a PhD in molecular oncology.

JOINT SYMPOSIA

Sunday, 10 October

**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

Monday, 11 October

**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

Tuesday, 12 October

**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, 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

PROFILE OF A YOUNG ONCOLOGIST:
MICHAEL KARAMOUZIS

Michael (Michalis) Karamouzis was born on 31 January 1972 in Patras, a town-port in the west coast of Greece. After graduating in medicine from the University of Patras, he completed his fellowship in Medical Oncology at Saint Savvas Oncologic Hospital, Athens. Michael then became Visiting Assistant Professor in the Division of Hematology-Oncology at the Medical School of the University of Pittsburgh, Philadelphia, USA, where his interests were aerodigestive and breast carcinomas. He returned to Greece and was appointed Assistant Professor in the Department of Biological Chemistry at the Medical School of the University of Athens where he was mainly involved in student education and basic translational research in the field of signal transduction in carcinogenesis, becoming a member of a highly-respected research group. He was also elected Chair of the Greek Young Medical Oncologists Group where he coordinated a group of about 100 members that organized annual educational activities. Michael currently works

as a Medical Oncologist in Leukos Stavros Clinic, Athens.

Through his work as Chair of the Greek Young Medical Oncologists Group, Michael was nominated Chair of the ESMO Young Oncologists Committee (YOC) in 2010.

But what does that mean to him? Well, Michael's main aim for the future of the YOC is for all members to be fully active, propose ideas for future projects, and to improve their education. In addition, he hopes to achieve a broader representation of all European Countries in the YOC and create a global network with other Young Oncologists Groups from the USA, Asia, and South America. The range of Young Oncologists events within ESMO in Milan are highly commended as they provide a great opportunity to learn, and to communicate and exchange ideas with fellow young oncologists.

If you're a Young Oncologist, there are a number of excellent benefits to becoming a member of ESMO, not least by gaining access to, and



Prof Michael Karamouzis

acquiring a presence within, the network of international colleagues in the oncology community. There is also the opportunity to get involved in ESMO committees and programs, particularly tailored to young oncologists, as Michael has done.

For more information, please visit the 'Organizational structure' section of www.esmo.org.

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

Special Symposium The more (we are), the better (we serve)!
ESMO and OECI: towards high-quality cancer care

Sunday, 10 October **10.30-12.00**
Orange Hall 1

IN GOD (GOOD ORGANIZATION AND DELIVERY) OF RESEARCH AND CARE WE TRUST!

Come and join the Special ESMO-OECI Symposium today where you will discover the accreditation-designation programs that will guide you through this world of cancer complexity! Today's lonely oncologist must face the ever accelerating progresses in the field of research, diagnosis and treatment of cancer in order to be able to deliver the optimal integrated approach to the patient. Our individual validated expertise no longer means that the patient will eventually benefit from the best multidisciplinary combination strategy in a timely fashion. This can only be achieved if cancer centers implement a real oncological policy, provide an adequate organizational frame and offer up-to-date technical platforms and the sufficient human resources necessary to help us drive our patients towards survival.

The time has come to establish standards of good oncology practice for our cancer centers!

The time has come to assess our cancer centers and recognize those centers which are striving for quality and improvement!

The time has come to be able to accredit the cancer centers that are working in full respect of their GOD (Good Organisation and Delivery) of research and care!

Professor David Kerr and Dr. Mahasti Saghatian are expecting you at this Special Symposium where they will reveal the Accreditation and Designation Codes to you!



Dr. Mahasti Saghatian

Proffered Paper session Breast cancer, advanced

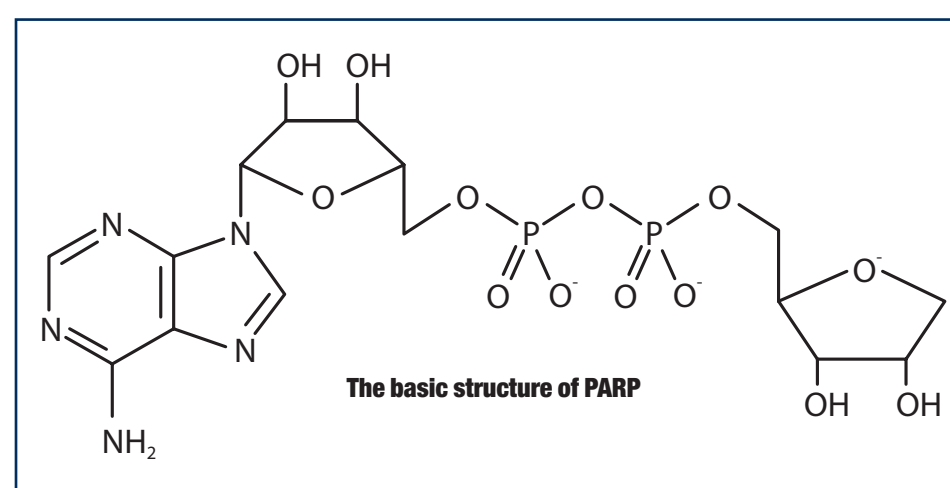
Sunday, 10 October **15.30-17.30**

Violet Hall

PARP INHIBITOR INCREASES SURVIVAL IN TRIPLE-NEGATIVE BREAST CANCER

The final results of a phase II study of the PARP inhibitor iniparib in combination with gemcitabine/carboplatin are presented by Dr. Joyce O'Shaughnessy and colleagues. The results of this study, which enrolled 123 patients with triple-negative breast cancer, confirm that iniparib improves the outcome of this particularly aggressive subtype of breast cancer, without important associated toxicity. This improved outcome includes an increase in median survival, a rare finding in advanced disease. "While results from this relatively small phase II study add to currently available data on this new therapeutic option, any enthusiasm must be balanced with some degree of caution

until data are confirmed by large randomized phase III studies" comments Dr. Fatima Cardoso, Chair. Such studies are currently ongoing in the metastatic setting, evaluating combinations with taxanes and platinum. Additionally, studies in the neoadjuvant setting are in an advanced stage of planning and will include treatment combinations with anthracyclines. Together these studies will provide the evidence needed to confirm if PARP inhibitors are indeed the much needed breakthrough in the treatment of triple-negative breast cancer. Until then, these promising drugs can only be used within the context of a clinical trial.



European Society for Medical Oncology

www.esmo.org

NOT AN ESMO MEMBER YET?

Visit the Membership services center in the registration hall and sign up for your free membership trial.



WELCOME to our new members

Today 522 NEW PEOPLE joined our Growing Community

ander-group.com

Special Symposium

ESMO/AIOM Joint Symposium: Young medical oncologists facing daily difficulties in clinical practice
Sunday, 10 October **13.45-15.15**

Violet Hall

BURNOUT: AFFECTS YOUNG ONCOLOGISTS, BUT IS REVERSIBLE!

Burnout is a syndrome of emotional exhaustion, depersonalization and diminished interest in one's career. Younger doctors, including oncologists, are at high risk of burnout, and this can affect the quality of their work, and thus the quality of care provided to patients. Speakers at a special symposium for young oncologists at this year's Congress call for further research to be performed across Europe, and for the development of specific screening strategies and intervention programs.

Drs Marina Garassino and Massimo di Maio explain some of the issues involved in burnout. "The main factors seem to be, firstly, the emotional load involved in dealing with frequent and repeated losses, which give rise to existential questioning and a feeling of inadequacy. Secondly, factors related to the intern status such as anxiety about their future position, the quality of medical training and tensions with senior physicians due to differing therapeutic choices. Another fundamental cause is the total workload: young physicians are often under pressure from working long hours dedicated to treating patients, doing research and studying, which leaves little time for rest and personal endeavors".

Dr. Laurence Albiges highlights that "Burnout is not an individual problem as it not only affects the physicians' quality of life, but also their work and relationships to patients. It probably also discourages vocations for oncology". Laurence will present the results of a comprehensive nationwide French study that took place in 2009 (Blanchard et al. Eur J Cancer

2010;46:2708-2715). According to the study, 44% of residents experience burnout with 18% of interns showing severely abnormal levels of both emotional exhaustion and depersonalization. Around 20% were taking anxiolytic/hypnotic medications in order to cope.

So what should a medical student consider before embarking on a career in oncology? Dr. Francesco Atzori believes students aiming to go into oncology need to be "highly motivated and committed to patients, as this is a particularly tough field. Moreover, before making a final decision, interns should be able to have a trial period of at least six months in an oncology department". He adds "The high rate of burnout among young oncologists should be a cause for concern. Burnout is reversible, so we need a simple screening instrument that can be used by senior physicians to detect interns at risk. Secondly, intervention programs need to be encouraged to improve the well being of interns in medical oncology. These should include the establishment of support groups, more intense coaching by senior physicians and training programs on communication and stress management. The positive news is that recovery from burnout is possible".



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Merck Serono Oncology
combines approaches that target



Tumor cell
Tumor environment
Immune system

to optimize therapeutic success



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SPOTLIGHT ON CIRCULATING TUMOR CELLS

Circulating tumor cells (CTCs) became an interesting subject to researchers because of their predictive and prognostic potential; for example the presence of CTCs in peripheral blood of metastatic breast cancer patients seems to be an independent predictor of progression-free survival (PFS) and overall survival (OS). Another attraction is the possibility to sample tumor cells for 'omics analyses repetitively in a less invasive way than repeat biopsies.

A group of UK researchers (see abstract 172PD) evaluated the use of CTC counts to further improve the utility of the Royal Marsden Hospital prognostic score which has been validated in prospective analyses for patient selection in phase I clinical trials. Prognostic value of relevant baseline patients characteristics, including those in the Royal Marsden Hospital phase I Prognostic Score (albumin, lactate dehydrogenase and number of sites of metastases) were analyzed. The addition of baseline CTC counts enhanced the performance of the prognostic score and classified patients eligible to participate in phase I clinical trials into 3 prognostic groups: (1) Good prognosis (score 0-1; median OS 63.7 weeks); (2) Intermediate prognosis (score 2-3; median OS 37.3 weeks) and (3) Poor prognosis (score 4; median OS 13.4 weeks).

To date, all methods used to isolate CTCs facilitate the identification of epithelial circulating tumour cells, thus excluding other cell types, for instance those expressing mesenchymal traits. According to recent findings, more invasive CTCs may lose their epithelial antigens by the epithelial to mesenchymal transition (EMT) process. The aim of the study performed by researchers (see abstract 170PD) from Italy was to analyze the presence of EMT and stemness markers in CTCs isolated from breast cancer patients. Among those patients analyzed, 66% were found positive for CTCs. In a limited number of patients the authors found CTCs expressing both EMT (vimentin, fibronectin) and stemness markers (ALDH1). These patients were characterized by unfavorable classical prognostic factors (stage IV disease, a Ki 67 score >15; G2-3 grading of disease).

The objective of another CTC study (see abstract 171PD) was to compare the prognostic significance of lymphopenia, CTC count and extensive bone metastases (>2 lesions) in patients with metastatic breast cancer. In 195 assessable patients, the median OS time was 17 months and baseline lymphopenia, CTC counts, and bone metastases were found to be significantly associated with OS. In multivariate analysis, lymphopenia, more than five CTCs and estrogen receptor status remained as the only predictive factors for OS.

Enumeration of CTCs (see abstract 173PD) as a prognostic factor for PFS and OS in advanced colorectal cancer has recently been reported by Tol et al (Ann Oncol 2009). To confirm these results an ancillary study, with patients involved in the Spanish TTD MACRO study, treated with XELOX chemotherapy plus bevacizumab will be reported here. Blood samples for CTCs were collected at baseline in 180 patients out of 480 randomized into the trial and a second sample after 3 cycles of XELOX + bevacizumab given as first-line therapy in 149 patients. The investigators found that enumeration of CTCs at baseline and after several cycles of chemotherapy is a prognostic and predictive factor for PFS and OS in patients with metastatic colorectal cancer.

CTCs seem to be promising but need further validation and should not be measured outside clinical trials.

RECIPIENTS OF THE BEST POSTER AWARD

Saturday, 9 October

Posters published in the Abstract USB (distributed at the Pfizer exhibition stand).

Poster Session	Poster number	Author
Breast cancer, advanced	328P	Mafalda Oliveira, Lisbon, Portugal
Gastrointestinal tumors	741P	Hedy Kindler, Chicago, USA
Genitourinary tumors	902P	Yoshihiko Tomita, Yamagata, Japan
Geriatric oncology	577P	Antonella Brunello, Padova, Italy
Melanoma	1329P	Jeffrey Weber, Tampa, USA
Neuroendocrine tumors and CUP	851P	Simron Singh, Toronto, Canada
Sarcoma	1350P	Maria Pantaleo, Bologna, Italy
Upper gastrointestinal tumors	803P	Fernando Rivera, Santander, Spain

LET'S THINK



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LET'S WORK
ONCOLOGY FROM BOEHRINGER INGELHEIM



HEDGEHOG PATHWAY:

An overhyped or perfect target in tumors with cell-autonomous mutations in key regulatory proteins only?



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Abnormal activation of the Hedgehog pathway is linked to tumorigenesis of a number of human malignancies. Deregulated Hedgehog signaling in tumors can be classified into two types: the first is defined by cell-autonomous mutations in key regulatory proteins, observed in basal cell carcinoma and medulloblastoma; and the second is characterized by inappropriate ligand expression and is seen in cancers of the breast, colon, prostate and pancreatic ductal adenocarcinoma. This ESMO Congress presents five reports on Hedgehog inhibition, which follow from the proof-of-concept study in basal cell carcinoma (one year ago), new observations in the pathway, evidence of acquired resistance to therapy and development of new targeted agents.

Two phase II placebo-controlled randomized studies were designed to assess efficacy and safety of GDC-0449 (see LBAs 21 and 25) in first-line treatment of metastatic colorectal cancer, and as maintenance therapy in patients with ovarian cancer in second or third complete remission.

In both settings, results do not demonstrate a clinical benefit and early drug discontinuation due to adverse events may suggest a lower tolerance in the maintenance setting. Another potent, selective Hedgehog inhibitor, LDE225 (see abstract 502PD), has been assessed in the "first-in-human study" with observed good tolerance, a favorable PK profile and target modulation. An anti-tumor response was noted in patients with recurrent medulloblastoma, and disease stabilization in patients with basal cell carcinoma, spindle cell and osteosarcoma. A report of the first clinical experience of IPI-926 (see abstract 501PD) shows preliminary evidence of clinical activity in patients with basal cell carcinoma, medulloblastoma and chondrosarcoma. In addition, a small preclinical study shows heterogeneous expression patterns of the Hedgehog pathway in biliary tract cancer cell lines (see abstract 95P). Even though markers predicting the efficiency of pathway inhibition are yet to be identified, such an approach may prove valid for novel treatment strategies in

these difficult to treat cancers. Most of the currently active pancreatic cancer studies are recruiting well.

Data from 501PD and 502PD will be presented at the Poster Symposium (Discussion session) on Developmental therapeutics which will take place on Sunday, 10 October 2010 at 12.30-13.30 in Yellow Hall 1.

Data from LBA21 will be presented at the Proffered Paper session on Colorectal cancer which will take place on Sunday, 10 October 2010 at 13.30-15.00 in the Gold Hall.

Data from LBA25 will be presented at the Proffered Paper session on Gynecological cancer which will take place on Monday, 11 October 2010 at 10.45-12.30 in the Pink Hall.

Data from 95P will be presented at the Poster Presentation (Display) on Basic science and translational research which will take place on Monday, 11 October 2010 at 12.30-13.30 in Hall 3.

ESMO HIGHLIGHTS 2010 NOW AVAILABLE

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.

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Special Symposium

Targeting molecular pathways in the jungle of soft tissue sarcoma histology
Sunday, 10 October **11:00-12:30**

Blue Hall

SARCOMAS - "ONE SIZE NO LONGER FITS ALL"

Paolo Casali is a Board Member of ESMO, Medical Oncologist at the National Cancer Institute in Milan, and an international expert on sarcomas. He remembers the time when soft tissue sarcomas were treated in exactly the same way, lumped together as one rare disease. After (failed) surgery, either doxorubicin, or ifosfamide and mesna, or all three were given, irrespective of histotype. One size fitted all. This Special Symposium on sarcomas blows that strategy out the water. Not only are the new targeted drugs dependant on histological subtype (imatinib and GIST led the way), but it seems that on closer scrutiny some of the old fashioned cytotoxic drugs are better in some sarcomas than others. When asked why gemcitabine is active in leiomyosarcomas and angiosarcomas, Paolo admits that the molecular basis "remains a mystery"! Taxanes and dacarbazine are also more useful in angiosarcomas than other subtypes. A recent addition to the cytotoxic armamentarium is trabectedin which acts like a cytotoxic in shrinking leiomyosarcomas and some liposarcomas, but resembles a targeted agent in displaying excellent activity in those myxoid liposarcomas which have a specific translocation.

This symposium will go into detail on why sorafenib and sunitinib have specific activity for instance in solitary fibroid sarcomas, anti-Insulin Growth Factor receptor drugs target Ewing's sarcoma and anti-mTOR drugs may be useful in lymphangiosarcoma. Never has the histopathologist been more important in the cancer management of patients than with these rare tumors, and never has it been so critical that they are always referred to a specialist cancer center. The take-home message is that "One drug does not fit all!"



Prof Paolo Casali



In partnership:



Proffered Paper session Breast cancer, advanced

Sunday, 10 October 15.30-17.30

Violet Hall

POSSIBLE BENEFIT WITH ENDOTAG-1 WARRANTS FURTHER EVALUATION

Innovation in the therapeutic armamentarium against cancer can also be achieved by new formulations of 'old' drugs. Examples of successes in this area are capecitabine and liposomal anthracyclines. Several new formulations of taxanes have been studied which aim to increase efficacy and/or decrease toxicity. EndoTAG-1 is an innovative formulation that tries to capitalize on the potential anti-angiogenic properties of paclitaxel. In this new drug, paclitaxel is embedded in cationic liposomes and targets activated endothelial cells of

tumor vessels. It is also innovative since it targets the environment and not the tumor cell itself. Results from the first randomized phase II study of EndoTAG-1 targeting tumor endothelial cells in advanced triple-negative breast cancer are somewhat disappointing since EndoTAG-1 alone does not seem to be a valid option, with progression-free survival rate at week 16 inferior to paclitaxel alone, albeit with overlapping confidence intervals. Nevertheless, the apparent benefit of the combination arm (also with overlapping confidence

intervals) merits further evaluation in a subsequent study. Fatima Cardoso our assistant editor's suggestion would be to evaluate the combination of EndoTAG-1 with other cytotoxic drugs, particularly those with different mechanisms of action such as anthracyclines and anti-metabolites, to obtain a double-hit effect. These studies should be in the metastatic setting. A detailed evaluation of the toxicity profile of EndoTAG-1 is also necessary before it can be evaluated in studies in the neoadjuvant setting.

Proffered Paper session

Upper gastrointestinal tumors

Sunday, 10 October 09.00-10.30

Violet Hall

TREATMENT OF ADVANCED PANCREATIC CANCER: A CHALLENGE PARTIALLY MET?

Treatment of advanced pancreatic cancer is a significant challenge and the prognosis for patients remains poor. At this year's Congress, Desseigne and colleagues present the impressive final results of the PRODIGE 4/ ACCORD 11 phase III trial that compared the efficacy and safety of FOLFIRINOX versus gemcitabine in patients (n=342) with

metastatic pancreatic cancer. The use of FOLFIRINOX compared with gemcitabine significantly increased response rates, almost doubled PFS and OS, and delayed QoL reduction. While toxicity is significantly higher when using FOLFIRINOX, it is thought by the authors to be manageable, and possibly a price worth paying for the overall benefits delivered.

Special session

Communication skills training

Sunday, 10 October 09.30-11.00

Yellow Hall 2

PROFESSIONAL COMMUNICATION - AN INTEGRAL PART OF ONCOLOGY

Although current thinking suggests communication skills training (CST) for oncologists and oncology nurses should be mandatory, the type of interventions to be used and the amount of training required appears less clear. During this session, Professor Wolf Langewitz will provide a European perspective on mandatory training, minimal requirements, and implementation of communication skills training (CST) in oncology. "When considering if

this training should be mandatory or voluntary, the answer should be clear if the ability to communicate in a professional way is perceived as integral part of any qualification in oncology" comments Wolf. Lack of awareness of communication skills appears partly due to lack of open feedback from patients, particularly from those in cancer care where they don't want to criticise professionals on whom they are (or feel) deeply dependent.

IMAGE OF THE DAY



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*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.