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PERSONALIZED MEDICINE SYMPOSIUM

Targeting the HER/EGFR family in breast, lung and colorectal cancers

SIGNALLING PATHWAYS IN CANCER Programme Book

Sitges-Barcelona, Spain **1-2 March 2013**



European Society for Medical Oncology

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Excellence in cancer treatment is a shared goal: we can all provide better care when we exchange expertise and knowledge. ESMO's regular congresses, multidisciplinary meetings, and topic-specific events keep you in the loop, sharing the latest information and making new contacts.



MARK YOUR CALENDAR!

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9-11 May 2013, Lugano, Switzerland European Multidisciplinary Conference in Thoracic Oncology - EMCTO

27 September - 1 October 2013, Amsterdam, Netherlands European Cancer Congress - 17th ECCO - 38th ESMO - 32nd ESTRO

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SYMPOSIUM INTRODUCTION

On behalf of the European Society for Medical Oncology (ESMO) it gives us great pleasure to welcome you to the first series of symposia on personalized medicine, the ESMO Symposium on Signalling Pathways in Cancer.

The HER membrane receptors are a logical point to start the series from the biological perspective, due to its clinical relevance for medical oncologists. We are pleased to have brought together academic, clinical and industry researchers working in these tumour settings to share knowledge through interactive sessions and workshops.

We trust participants will benefit from this attractive programme comprising of plenary sessions on the principles of signalling transduction, mechanisms of primary and secondary resistance to targeted therapies, preclinical models and biomarkers, with parallel sessions on dysregulation of HER receptors and potential targeting strategies in breast, lung and colorectal cancers.

Leading clinical researchers in the field will present a synthesis of the presentations, address the complexity of the current challenges and provide perspectives on areas for future innovation and collaboration. We highly recommend you to attend the round table discussion on the final day that will gather both academic, clinical and industry leaders.

A sincere thank you to the Scientific Committee, invited speakers, organizers and sponsors for their commitment to this symposium on personalized medicine. We hope that you enjoy the meeting enough to join us again for the next symposium of the personalized medicine series.



Fortunato Ciardiello Naples, Italy Co-chair



Josep Tabernero Barcelona, Spain Co-chair

ABOUT ESMO

European Society for Medical Oncology (ESMO) Via Luigi Taddei 4, 6962 Viganello Switzerland

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ESMO is the leading non-profit, European professional organization, committed to advancing the specialty of medical oncology and promoting a multidisciplinary approach to cancer treatment and care.

Since 1975 ESMO's mission has been to advance cancer care and cure. We achieve this through fostering and disseminating good science that leads to better medicine and determines best practice. The ESMO community is a powerful alliance of more than 7,000 committed oncology professionals from over 120 countries. As a trusted organization with 35 years of experience and over 500 expert committee members, ESMO serves its members and the oncology community.

SYMPOSIUM ORGANIZATION

ESMO

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Venue

Meliá Sitges

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SYMPOSIUM OFFICERS

Chairs

Fortunato Ciardiello, Naples, Italy Josep Tabernero, Barcelona, Spain

Scientific Committee

Jean-Yves Douillard, St. Herblain, France Andrés Cervantes, Valencia, Spain Martine Piccart, Brussels, Belgium Cristiana Sessa, Bellinzona, Switzerland Rolf A. Stahel, Zurich, Switzerland Eric Van Cutsem, Leuven, Belgium

ACKNOWLEDGMENTS

ESMO wishes to express its gratitude to companies supporting the first ESMO Symposium on Signalling Pathways in Cancer.



Product promotion at ESMO events

Advertising of a specific product does not mean acceptance by ESMO, and it is the full responsibility of the corporation that it is in accordance with the Swiss, Spanish and European law, where applicable. ESMO accepts no responsibility for misprints.

GENERAL INFORMATION

Symposium venue

The event will be held at the Hotel Meliá Sitges, located 30 minutes away from Barcelona International airport.

Official language

The official language of the Symposium is English. Sessions will not be translated.

Participation

About 150 specialists in breast, lung and colorectal cancers are expected to join the Symposium.

CME accreditation

The ESMO Symposium on Signalling Pathways in Cancer scientific programme has been designated for a maximum of 8 hours of European CME credits (ECMEC's).

ACOE works in conjunction with the European Accreditation Council for Continuing Medical Education (EACCME) operating under the umbrella of the European Union of Medical Specialists (UEMS). The EACCME plays the role of a clearinghouse, facilitating the accreditation endorsement by the national CME regulatory bodies.

CME credits gained by your participation in the ESMO Symposium on Signalling Pathways in Cancer are recognised by most of the national CME authorities in Europe, which have agreed to cooperate in this European system.

Through a mutual agreement between the UEMS and the American Medical Association (AMA), the European CME credits are also recognized towards the Physician's Recognition Award (PRA). To convert European CME credits to AMA PRA Category 1 credits, contact AMA (www.ama-assn.org).

The Symposium has also been accredited with 11 ESMO-MORA category 1 points.

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Certificate of Attendance

All participants are entitled to request a Certificate of Attendance at the on-site registration desk. The Certificate will be available for collection in return for the completed evaluation form, from Saturday morning 2 March.

The Certificate of Attendance will indicate the maximum number of credit points (1 credit point per 1 hour of programme attended up to a maximum of 3 credits per half day) related to the Symposium. However, it is the participant's responsibility to complete the Certificate of Attendance with the number of hours of scientific programme (= number of credit points) that he/she has actually attended.

OncologyPRO

Access to the highest quality scientific knowledge at a click. In addition to a wider range of scientific information and news services, OncologyPRO provides access to materials developed by ESMO. Webcasts and reports from the Symposium will be available at http:// oncologypro.esmo.org/ ESMO designed OncologyPRO in partnership with Thomson Reuters specifically to foster the sharing of knowledge and best practice for both clinical practice and research. OncologyPRO offers ESMO members an unparalleled resource - integrating regularly updated oncology news, clinical research, biomarker and drug databases, practice guidelines and tools, clinical trial information, abstracts from more than 110 oncology-relevant journals and more, in a simple, searchable platform.

Symposium Webcast

The webcast of the Symposium will include all the sessions of the official programme, where speaker permission is granted, and will be made available within 48 hours on:

- OncologyPRO for ESMO members
- The Symposium Website for all delegates for 3 months after the Symposium.

Important: keep your badge as you will be requested to enter your badge ID code and last name to log in.

Internet WiFi access

Symposium delegates will receive a free ticket onsite with username and password to connect to the basic WiFi.







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ESMO membership and other activities

For matters regarding ESMO membership and other ESMO activities, participants are cordially invited to visit the ESMO booth in the display area.

Insurance

The organizers bear no responsibility for untoward events in connection with, before, during and after the Symposium.

Passport/visa

A valid identity card is sufficient for entry into Spain for citizens of EU member countries.

Speaker Preview Centre

Speakers should deliver and check their presentation at the Speakers Preview Centre located in the "Mestral 1" room on level -1 no later than 3 hours before the start of their session. For the first sessions of the day, presentations can be delivered from 11:00. Speakers are kindly asked to keep their presentation within the given time limits, including discussion time.

Speaker Preview Centre opening hours

| Friday, 1 March | 11:00-18:00 |
|-------------------|-------------|
| Saturday, 2 March | 08:00-15:30 |

Badge

The badge is the only official evidence of registration, thus, participants not wearing their badge do not have access to the Symposium. Loss of badge is loss of registration and a new badge will be issued only upon payment of the pro-rata fee.

Registration desk opening hours

| Friday, 1 March | 12:00-18:00 |
|-------------------|-------------|
| Saturday, 2 March | 08:00-16:00 |

Full registration fees

The registration fee includes access to the Symposium, Symposium material, the ESMO Glossary in molecular biology of cancer, welcome reception, lunch on Saturday, coffee breaks and VAT.

| Early registration, until 11 January 2013 | |
|---|---------|
| Non ESMO member fee | EUR 200 |
| ESMO Member fee | EUR 100 |
| Junior ESMO Member fee | EUR 50 |
| Late registration, until 13 February 2013 | |
| Non ESMO member fee | EUR 250 |
| ESMO member fee | EUR 150 |
| Junior ESMO Member fee | EUR 50 |
| Full registration, from 14 February 2013 | |
| Non ESMO member fee | EUR 300 |
| ESMO member fee | EUR 300 |
| Junior ESMO Member fee | EUR 50 |

Industry display area opening hours

| Friday, 1 March | 14:00-19:00 |
|-------------------|-------------|
| Saturday, 2 March | 09:30-15:30 |

Filming, Recording and Photography

Symposium content is copyright of ESMO. It is strictly forbidden to record or capture in any way the Symposium programme and display area.

No-smoking policy

The ESMO Symposium on Signalling Pathways in Cancer and the concomitant display area have been designated as non-smoking events throughout the entire venue, including all meeting rooms, functions, registration and catering areas. All delegates are kindly required to respect the no-smoking policy.

SYMPOSIUM PROGRAMME

Friday, 1 March 2013

| 14:00/ 14:20 | Introduction Chairs: Fortunato Ciardiello, Naples, Italy and Josep Tabernero, Barcelona, Spain |
|-----------------|--|
| 14:00 | ESMO Educational activities: From past to future. Focus on personalized medicine Jean-Yves Douillard, St. Herblain, France |
| MODULE 1: | PRINCIPLES OF TARGETED THERAPY |
| 14:20/ 15:20 | The basis of targeted therapy Chair: Fortunato Ciardiello, Naples, Italy |
| 14:20 | The principles of signal transduction Yosef Yarden, Rehovot, Israel |
| 14:50 | Mechanisms of primary and secondary resistance Giampaolo Tortora, Verona, Italy |
| 15:20/ 16:00 | Pre-clinical models Chair: Josep Tabernero, Barcelona, Spain |
| 15:20 | Conventional preclinical models Joaquín Arribas, Barcelona, Spain |
| 15:40 | Tumour patient derived models Livio Trusolino, Candiolo, Italy |
| 16:00 | Coffee break |
| 16:20/ 18:00 | Dissecting the field of biomarkers Chair: Fortunato Ciardiello, Naples, Italy |
| 16:20 | Large scale datasets: Picking-up the complexity Emile E. Voest, Utrecht, Netherlands |
| 16:40 | Lively biomarkers: Opportunities for the liquid biopsy Alberto Bardelli, Candiolo, Italy |
| 17:00 | Characterization of one disease in different subtypes Aleix Prat, Barcelona, Spain |
| 17:20 | Pitfalls and challenges with tumour tissue specimens Federico Rojo, Madrid, Spain |
| 17:40 | Tumour-host interaction: Focus on immune response and microenvironment Giuseppe Curigliano, Milan, Italy |
| 18:00 | Welcome reception |

Saturday, 2 March 2013

| 08:30/ 09:20 | Clinical pharmacology concepts of targeted therapy Chair: Josep Tabernero, Barcelona, Spain |
|-----------------------|---|
| 08:30 | Pharmacology basis of targeted therapy Fortunato Ciardiello, Naples, Italy |
| 09:00 | How to maximize smart clinical development from phase I Cristiana Sessa, Bellinzona, Switzerland |
| 09:20/ | Guidelines |
| 09:40 | Chair: Fortunato Ciardiello, Naples, Italy |
| 09:40 09:20 | |

MODULE 2: EGFR/HER FAMILY TARGETED THERAPY IN BREAST, COLORECTAL AND LUNG CANCER (PARALLEL SESSIONS)

| 10:00/ 12.20 | Breast cancer Chair: Martine Piccart, Brussels, Belgium |
|-----------------------|---|
| 10:00 | Characterization of HER-2/neu breast cancer Monica Arnedos, Villejuif, France |
| 10:30 | The hallmark of trastuzumab in the treatment of breast cancer Fatima Cardoso, Lisbon, Portugal |
| 11:00 | Is there a role for personalization between trastuzumab and lapatinib? Christoph Zielinski, Vienna, Austria |
| 11:20 | Adjuvant and neoadjuvant strategies in HER-2/neu disease Luca Gianni, Milan, Italy |
| 11:50 | The landscape of new anti-HER-2/neu treatments Martine Piccart, Brussels, Belgium |
| | Martine Flocart, Drussels, Dergium |
| 10:00/ 12.20 | Colorectal cancer Chair: Eric Van Cutsem, Leuven, Belgium |
| | Colorectal cancer |
| 12.20 | Colorectal cancer Chair: Eric Van Cutsem, Leuven, Belgium Signatures of EGFR dependence: Are we there yet? |
| 12.20 10:00 | Colorectal cancer Chair: Eric Van Cutsem, Leuven, Belgium Signatures of EGFR dependence: Are we there yet? Gabriel Capellà, Barcelona, Spain Clinical evidence of EGFR inhibition in metastatic colorectal cancer |

| 11:30 | Mechanisms of secondary resistance to EGFR inhibition: Role for EGFR inhibition re-challenge Andrea Sartore-Bianchi, Milan, Italy |
|-----------------|---|
| 11:50 | New opportunities for EGFR-pathway inhibition Josep Tabernero, Barcelona, Spain |
| 10:00/ 12.20 | Lung cancer Chair: Rolf A. Stahel, Zurich, Switzerland |
| 10:00 | Current characterization of lung cancer Enriqueta Felip, Barcelona, Spain |
| 10:30 | First generation EGFR inhibitors: The breakthrough in stratified medicine in lung cancer Benjamin Besse, Villejuif, France |
| 11:00 | New EGFR inhibitors: The cutting-edge frontier Rolf A. Stahel, Zurich, Switzerland |
| 11:15 | HER2/neu in non-small cell lung cancer Solange Peters, Lausanne, Switzerland |
| 11:30 | Mechanisms of primary/secondary resistance to EGFR inhibitors Silvia Novello, Orbassano-Turin, Italy |
| 11:50 | Building on EGFR inhibition: Synthetic lethality strategies Rafael Rosell, Badalona, Spain |
| 12:20 | Lunch |
| 13:30/ 15:30 | MODULE 3: CONFRONTING THE COMPLEXITY OF CANCER THROUGH COLLABORATIVE INNOVATION BETWEEN ACADEMIA AND PHARMA Chairs: Fortunato Ciardiello, Naples, Italy and Josep Tabernero, Barcelona, Spain |
| 13:30 | Key take-home messages from the Breast cancer session Martine Piccart, Brussels, Belgium |
| 13:50 | Key take-home messages from the Colorectal cancer session Eric Van Cutsem, Leuven, Belgium |
| 14:10 | Key take-home messages from the Lung cancer session Rolf A. Stahel, Zurich, Switzerland |
| 14:30 | Round-table discussion between Academia and Pharma, moderated by Tim Maughan, Oxford, UK |
| 15:30 | Adjourn |



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- Subscription to Annals of Oncology
- Reduced registration fees to ESMO congresses
- Access to ESMO educational and scientific material
- Subscription to e-News and networking opportunities



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INVITED SPEAKER DISCLOSURES

| Arnedos Monica | The author has declared no conflict of interest |
|----------------------|---|
| Arnold Dirk | Research Support: Merck Serono. Speaker honoraria: Amgen, Merck Serono |
| Arribas Joaquin | The author has declared no conflict of interest |
| Bardelli Alberto | Shareholder Horizon Discovery |
| Besse Benjamin | Research grants from Roche, AstraZeneca, Boehringer Ingelheim and Pfizer |
| Capellà Gabriel | Has conducted and is conducting research in collaboration with Agendia |
| Cardoso Fatima | Honorarium, consultancy, speaker bureau: Roche and GSK |
| Cervantes Andrés | The author has declared no conflict of interest |
| Ciardiello Fortunato | Scientific advisory boards and satellite symposia speaker: Bayer, Merck. Research funding: Bayer, Merck Serono |
| Curigliano Giuseppe | Has any financial interest in, or arrangement with, a company whose products or services are discussed in the lecture |
| Douillard Jean-Yves | Compensated advisory board and lectures in sym- posia: Amgen, Merck Serono, Roche, Boehringer Ingelheim, Pfizer, GSK and Sanofi-Aventis. Research contract: Merck Serono |
| Felip Enriqueta | The author has declared no conflict of interest |
| Gianni Luca | The author has declared no conflict of interest |
| Maughan Tim | The author has declared no conflict of interest |
| Novello Silvia | The author has declared no conflict of interest |
| Peters Solange | The author has declared no conflict of interest |
| Piccart Martine | Consultancy: Sanofi-Aventis, Amgen, Bayer, Roche-Genentech, PharmaMar, AstraZeneca. Honoraria: Sanofi-Aventis, Amgen, Novartis, Roche-Genentech, PharmaMar, AstraZeneca |

| Prat Aleix | The author has declared no conflict of interest |
|------------------------|--|
| Rojo Federico | The author has declared no conflict of interest |
| Rosell Rafael | The author has declared no conflict of interest |
| Sartore-Bianchi Andrea | Received payment for board membership from Amgen and for lectures from Amgen, Roche and Merck Serono |
| Sessa Cristiana | The author has declared no conflict of interest |
| Siena Salvatore | Is a clinical investigator or advisory board member of Amgen, ArQule, AstraZeneca, Bayer, Boehringer Ingelheim, Celgene, Genentech, Genomic Health, GSK, Merck Serono, Merrimack, Pfizer, Nerviano Medical Science, Roche and Sanofi-Aventis |
| Stahel Rolf A. | Advisory board for AstraZeneca, Boehringer Ingelheim and Roche |
| Tabernero Josep | Consultant / Advisory role: Amgen, BMS, Genentech, Merck KGaA, Millennium, Novartis, Onyx, Pfizer, Roche and Sanofi. Honoraria Amgen, Merck KGaA, Novartis, Roche and Sanofi |
| Tortora Giampaolo | The author has declared no conflict of interest |
| Trusolino Livio | Receives research grants from Symphogen and Merck Serono to test lead compounds in patient-derived colorectal cancer xenografts |
| Van Cutsem Eric | Research funding to University of Leuven: Amgen, Bayer, Merck, Novartis, Roche and Sanofi |
| Voest Emile E. | The author has declared no conflict of interest |
| Yarden Yosef | The author has declared no conflict of interest |
| Zielinski Christoph | Honoraria from Roche. |
| | |

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Display no. 3

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Astellas Pharma Europe Ltd.

Display no. 2

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Astellas is already an established player in the fields of Transplantation, Urology, Dermatology, Anti-Infectives and Pain Management. We are now bringing our expertise to the field of Oncology. With no fewer than 12 separate therapies currently under clinical development, we aim to fulfil not just our potential, but our promise to change tomorrow for patients suffering with conditions such as prostate cancer, advanced renal cell carcinoma and haematological malignancies. With our dynamic partners and our focus on innovative solutions, Astellas is advancing research and development of a robust portfolio of oncology therapeutics targeting fundamental aspects of cancer biology and supportive care.

Display no. 1

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Changing tomorrow

Astellas has made a commitment to change tomorrow – a commitment that we are bringing to the field of oncology. We aim to create innovative treatments that will genuinely improve the lives of cancer patients. To do this we are focusing our R&D and partnership efforts into precision medicine that will create first-in-class or best-in-class programmes. This has resulted in no fewer than 12 separate therapies under clinical development into conditions including prostate cancer, other solid tumours like pancreatic cancer, breast cancer and advanced renal cell carcinoma, as well as haematological malignancies.

These are the challenges we have set ourselves because CHANGING TOMORROW is more than just words – it is what we must do to give cancer patients real hope of a tomorrow worth looking forward to.



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