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MELANOMA BRIDGE 2014

Naples, Royal Continental Hotel
December 3rd - 6th, 2014



ORGANIZED BY



Fondazione Melanoma Onlus



National Cancer Institute
"Fondazione G.Pascale"



Sidra Medical and Research
Center



Society for Immunotherapy of
Cancer

UNDER THE AUSPICES OF



Associazione Italiana di
Oncologia Medica



European Society
for Medical Oncology

GENERAL INFORMATION



CME PROVIDER AND ORGANISING AGENCY:

3P Solution Srl
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OFFICIAL LANGUAGE:

The official language is English

REGISTRATION:

Only registered attendees will be admitted to the meeting.

The registration fee includes:

- participation in the scientific program
- CME credits
- coffee breaks and lunches from December 3rd to 6th
- congress bag

Participants are kindly requested to inform us about any dietary habit (i.e. food allergies/intolerances, vegetarian or vegan habits).

Please register at 3P Solution desk (cash or credit card accepted).

CONGRESS VENUE:

Royal Continental Hotel
Via Partenope, 38-44
80121 - Naples
Phone +39 081 245 2068
www.royalgroup.it/royalcontinental/



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CONTINUING MEDICAL EDUCATION

3P Solution has been accredited by the Ministry of Health as a CME Provider (code 327) and has a quality-management system that meets the requirements of UNI EN ISO 9001:2008, with CSQA certificate no. 23887.

3P Solution owns the responsibility for the content, quality and ethical correctness of this CME activity.

Melanoma Bridge 2014 has been accredited with 8.5 CME credits for 200 participants of the following professions: Medical Doctors, Pharmacists, Biologists, and Nurses.

The number of attendees can not exceed the number of accredited participants. If the number of participants is exceeded, attendees will be admitted to the scientific sessions on the basis of registration order.

In order to receive credits, participants must:

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2. Complete the assessment test at the end of the congress (a grade of 75% must be obtained to receive CME credit);
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ESMO-MORA ACCREDITATION:

Melanoma Bridge 2014 is accredited by ESMO for 22, category 1 ESMO-MORA points



MELANOMA
BRIDGE 2014

SCIENTIFIC PROGRAM

SCIENTIFIC PROGRAM

December 3rd, 2014

3rd

OPENING CEREMONY **

Chair: Paolo A. Ascierto, Francesco M. Marincola, Nicola Mozzillo

17:00 Welcome and introduction
Paolo A. Ascierto, Francesco M. Marincola, Nicola Mozzillo

17:30 Award lecture of Fondazione Melanoma:
Melanoma vaccines: New targets and combination therapy
Giorgio Parmiani

18:00 Clinical trial and real world evidence
Paul Lorigan

18:30 Patients meet the melanoma experts

A pan-European policy strategy to overcome inequalities:
Impact on Melanoma
Francesco De Lorenzo (European Cancer Patient Coalition)

The Challenges Ahead for Patient Advocacy
Valerie Guild (AIM at Melanoma)

Patient-centered clinical research in Melanoma
Bettina Ryll (Melanoma Patient Network Europe)

Representatives of Fondazione Melanoma Onlus
Antonio Brancaccio, Elisabetta Colangelo

Roundtable

*Simultaneous translation will be provided.
È prevista la traduzione simultanea*

***Not included in the CME accredited program*

SCIENTIFIC PROGRAM

December 4th, 2014

MOLECULAR AND IMMUNO ADVANCES

Chair: **Gerardo Botti, Ena Wang**

- 09:30 Genetic evolution of melanocytic neoplasia
Boris C. Bastian
- 09:55 The multi-faced roles of the PI3K-AKT pathway in melanoma
Michael Davies
- 10:20 Evolution of resistance to MAPK-targeted therapies
Roger Lo
- 10:45 ErbB3 as a key factor in the development of resistance to RAF/MEK inhibitors in BRAF mutated melanoma
Gennaro Ciliberto
- 11:10 *Break*
- 11:25 Tumor Infiltrating Lymphocytes (TIL's) Rule in Melanoma Prognosis
Martin Mihm
- 11:50 Molecular enhancement of sentinel node evaluation
Alistair Cochran
- 12:15 Mechanisms of synergy of radiotherapy and immunotherapy
Sandra Demaria
- 12:40 Discussion on the best abstracts submitted on Molecular and Immuno advances
Gerardo Botti, Ena Wang

4th

SCIENTIFIC PROGRAM

December 4th, 2014

Cytokine Induced Killer cells effectively kill chemo-resistant melanoma cancer stem cells

Loretta Gammaitoni, Lidia Giraud, Valeria Leuci, Giulia Mesiano, Michela Cangemi, Alessandro Zaccagna, Alberto Pisacane, Susanna Gallo, Fabrizio Carnevale-Schianca, Massimo Aglietta, Dario Sangiolo

RSK1 activation promotes invasion in nodular melanoma

Amel Salhi, Joshua A. Farhadian, Keith M. Giles, Eleazar Vega-Saenz de Miera, Ines P. Silva, Caitlin Bourque, Karen Yeh, Sagar Chhangawala, Jinhua Wang, Fei Ye, David Y.Zhang, Eva Hernando, Yariv Houvras, Iman Osman

10:00 Launch of the Patients and Clinicians Italian Working Group on Melanoma**

Roundtable

Paolo A. Ascierto, Antonio Brancaccio, Alberto Cerretti, Elisabetta Colangelo, Francesco De Lorenzo, Valerie Guild, Nicola Mozzillo, Chiara Puri Purini, Paola Queirolo, Carlo Riccardo Rossi, Alessandro Testori, Sara Vigna

SALA CAPUANA

13:30 *Lunch and Poster Session*



**Not included in the CME accredited program

SCIENTIFIC PROGRAM

December 4th, 2014

COMBINATION THERAPIES

Chair: **Paolo A. Ascierto, Giuseppe Palmieri**

- 14:30 Beyond BRAFi/MEK/i: Combination and sequencing approaches for patients with BRAF mutant melanoma
Michael Atkins
- 14:55 Novel combination therapies for BRAF-mutant melanoma
Grant McArthur
- 15:20 MEK + CDK4 a regimen for non-BRAF V6000 melanoma
Jeff Sosman
- 15:45 Combining targeted drugs and immunotherapy for melanoma
Igor Puzanov
- 16:10 *Break*
- 16:25 Combination therapies based on PD-1/PDL-1 pathway antagonists
Mario Sznol
- 16:50 Strategies and designs for combination immune therapy
Samir Khleif
- 17:15 Combining radiation therapy with immunotherapy: clinical translation
Silvia Formenti
- 17:40 Surgery in the combination therapies era
Nicola Mozzillo

4th

SCIENTIFIC PROGRAM

December 4th, 2014

18:05 Discussion on the best abstracts submitted on Combination Therapies

Paolo A. Ascierto, Giuseppe Palmieri

Long-term overall survival from a phase I trial using intratumoral plasmid interleukin-12 with electroporation in patients with melanoma

Adil Daud, Kathryn Toshimi Takamura, Tu Diep, Richard Heller, Robert H. Pierce

coBRIM: A Phase 3, Double-Blind, Placebo-Controlled Study of Vemurafenib Versus Vemurafenib + Cobimetinib in Previously Untreated BRAF V600 Mutation-Positive Patients With Unresectable Locally Advanced or Metastatic Melanoma (NCT01689519)

Paolo A. Ascierto, Grant A. McArthur, Brigitte Dréno, James Larkin, Gabriella Liszkay, Michele Maio, Mario Mandala, Lev Demidov, Daniil Stroyakovskiy, Luc Thomas, Luis de la Cruz-Merino, Victoria Atkinson, Caroline Dutriaux, Claus Garbe, Ilsung Chang, Stephen P. Hack, Antoni Ribas

18:35 Closing remarks and summing up for the next day

Paolo A. Ascierto, Francesco M. Marincola, Nicola Mozzillo



SCIENTIFIC PROGRAM

December 5th, 2014

NEWS IN IMMUNOTHERAPY

Chair: **Claus Garbe, Alessandro Testori**

09:20 Adjuvant therapy of melanoma in 2014
John Kirkwood

09:45 Grp94-specific monoclonal antibody to counteract
BRAF inhibitor resistance in BRAF^{V600E} melanoma
Soldano Ferrone

10:10 Myeloid derived suppressor cells in malignant melanoma
are inhibitors of adaptive and innate immunity
Rolf Kiessling

10:35 Targeting multiple inhibitory receptors to reverse
melanoma-induced T cell dysfunction
Hassane M. Zarour

11:00 *Break*

11:20 Role of signal transduction and microRNAs on
the immunogenicity of melanoma cells
Barbara Seliger

11:45 Advances in adoptive cellular therapy of cancer
David Stroncek

12:35 Discussion on the best abstracts submitted on News
in immunotherapy
Claus Garbe, Alessandro Testori

5th

SCIENTIFIC PROGRAM

December 5th, 2014

A randomized controlled comparison of pembrolizumab and chemotherapy in patients with ipilimumab-refractory melanoma

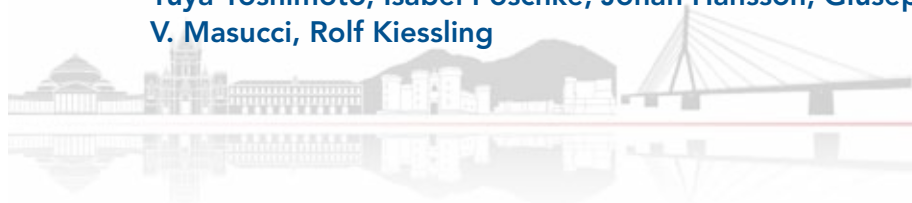
Reinhard Dummer, Adil Daud, Igor Puzanov, Omid Hamid, Dirk Schadendorf, Caroline Robert, Jacob Schachter, Anna Pavlick, Rene Gonzalez, F. Stephen Hodi, Lee D. Cranmer, Christian Blank, Steven J. O'Day, Paolo A. Ascierto, April K.S. Salama, Nicole Xiaoyun Li, Wei Zhou, Joy Lis, Scot Ebbinghaus, S. Peter Kang, Antoni Ribas

Nivolumab improved survival vs dacarbazine in patients with untreated advanced melanoma

Georgina V. Long, Victoria Atkinson, Paolo A. Ascierto, Benjamin Brady, Caroline Dutriaux, Michele Maio, Laurent Mortier, Jessica C. Hassel, Piotr Rutkowski, Catriona McNeil, Ewa Kalinka-Warzocho, Kerry J. Savage, Micaela Hernberg, Celeste Lebbé, Julie Charles, Catalin Mihalcioiu, Vanna Chiarion-Sileni, Cornelia Mauch, Henrik Schmidt, Dirk Schadendorf, Helen Gogas, Christine Horak, Brian Sharkey, Ian M. Waxman, Caroline Robert

Ipilimumab treatment enhances CD4+ T cell activation while decreasing Treg and MDSC frequency in advanced melanoma patients

Yago Pico de Coaña, Maria Wolodarski, Giusy Gentilcore, Yuya Yoshimoto, Isabel Poschke, Johan Hansson, Giuseppe V. Masucci, Rolf Kiessling



SCIENTIFIC PROGRAM

December 5th, 2014

Analysis of T and NK cells immune response in Ipilimumab treated Melanoma patients

Rossana Tallerico, Costanza M. Cristiani, Mariaelena Capone, Gabriele Madonna, Domenico Mallardo, Ester Simeone, Andrea Dominijanni, Antonio M. Grimaldi, Francesco Colucci, Paolo A. Ascierto, Ennio Carbone

13:20 *Lunch and Poster Session*

TUMOR MICROENVIRONMENT AND BIOMAKERS

Chair: **Giuseppe Masucci, Magdalena Thurin**

14:30 Genetic heterogeneity and transcriptional plasticity drive resistance during immunotherapy and targeted therapy

Reinard Dummer

14:55 The immune-related role of BRAF in melanoma

Sara Tomei

15:20 T cell responses to melanoma antigens

Pedro Romero

15:45 Molecular and cellular basis for immunomodulation with monoclonal antibodies

Ignacio Melero

16:10 *Break*

16:25 PD-LS and PD-1 as predictive markers of response to anti-PD-1

Janis Taube

5th

SCIENTIFIC PROGRAM

December 5th, 2014

16:50 Re-activation of T cells within the tumor microenvironment
Thomas F. Gajewski

17:15 Is there a role for immune checkpoint blockade in metastatic uveal melanoma?
Bastian Schilling

17:40 Discussion on the best abstracts submitted on Tumor Microenvironment and Biomarkers
Giuseppe Masucci, Magdalena Thurin

Tumor-infiltrating lymphocytes predict cutaneous melanoma survival
Cristina Fortes, Simona Mastroeni, Thomas Manooran-paranpampil, Francesca Passarelli, Alba Zappalà, Claudia Marino, Nicoletta Russo, Paola Michelozzi

$\alpha\beta$ -Double Negative CD4/CD8 (CD56) T cell (DNTs) as prognostic markers in metastatic melanoma patients treated with Ipilimumab: preliminary evaluations
Giacoma De Tullio, Sabino Strippoli, Rosa Angarano, Vincenza De Fazio, Nicola Sgherza, Antonio Negri, Anna Albano, Pasquale Iacopino, Attilio Guarini, Michele Guida

Intratatumoral electroporation of plasmid interleukin-12: efficacy and biomarker analyses from a phase 2 study in melanoma (OMS-I100)
Adil Daud, Alain Algazi, Michelle Ashworth, Michael Buljan, Kathryn Toshimi Takamura, Tu Diep, Robert H. Pierce, Shailender Bhatia

18:30 Closing remarks and summing up for the next day
Paolo A. Ascierto, Francesco M. Marincola, Nicola Mozzillo

SCIENTIFIC PROGRAM

December 6th, 2014

WORLD-WIDE IMMUNOSCORE TASK FORCE: AN UPDATE**

Chair: **Paolo A. Ascierto, Jerome Galon, Francesco M. Marincola**

08:30 Immunoscoring participants round table on recent advances

The Worldwide Immunoscoring consortium in the era of tumor immunotherapies

Jerome Galon

Immunoscoring in melanoma

Paolo A. Ascierto

SITC Immunoscoring cloud hosting and an update on the Portland cohort

Carlo Bifulco

Quantitative Pathology for the discovery of immunological biomarkers

sponsored by Definiens

Ralf Huss

Immunoscoring and immunoprofiling in clinical trials

Magdalena Thurin

The implementation of the immunoscoring in the daily diagnostic practice of colorectal cancer: the pathologist's point of view

Alessandro Lugli

The contribution of Karolinska Institute to the immunoscoring task force

Giuseppe Masucci

***Not included in the CME accredited program*

6th

SCIENTIFIC PROGRAM

December 6th, 2014

Qatar Immunoscore update-Breast Cancer Immunoscore Pilot
Project
Shahinaz Bedri

10:30 Discussion
Boris C. Bastian
Gerardo Botti
Sandra Demaria
Reinard Dummer
Thomas F. Gajewski
Martin Mihm
Janis Taube
Magdalena Thurin

11:15 *Break*

REGULATORY SESSION

Chair: **Paolo A. Ascierto, Pier Luigi Canonico**

11:30 Roundtable on the economic sustainability of the new
melanoma treatments: regulatory and market access issues

11:30 Melanoma: the development of a multiprofessional discussion
Alessandro Testori

11:45 Regulatory Updates for Cancer Vaccines, Cellular and Gene
Therapy Products
Raj Puri

12:00 The point of view of EMA
Francesco Pignatti



SCIENTIFIC PROGRAM

December 6th, 2014

- 12:15 The point of view of AIFA
Paolo Foggi*
- 12:30 Expanded Access Program and Compassionate Use
Paul Lorigan
- 12:45 Economic evaluation of new drugs and its role in managing
their market access
Claudio Jommi
- 13:00 Discussion
Francesco De Lorenzo
Teresita Mazzei
Francesco Rossi
- 13:30 *CME test*

6th



**To be confirmed*

POSTER SESSION

MOLECULAR AND IMMUNO ADVANCES

1. Case report: CDK4 germline and BRAF somatic mutations in a patient with multiple primary melanomas and BRAF inhibitor resistance
Maurizio Governa, Evelina Caprarella, Edoardo Dalla Pozza, Enrico Vigato, Monia Maritan, Marina Zannoni, Paolo Rosina, Camilla Stagni, Lisa Elefanti, Chiara Menin

2. AurkA inhibitors enhance the effects of B-RAF and MEK inhibitors in melanoma treatment.

Emilia Caputo, Roberta Miceli, Maria L. Motti, Rosarita Taté, Federica Fratangelo, Gerardo Botti, Nicola Mozzillo, Maria V Carriero, Ernesta Cavalcanti, Giuseppe Palmieri, Gennaro Ciliberto, Giuseppe Pirozzi, Paolo A Ascierto

3. Exome sequencing in primary melanoma identifies novel drivers of melanoma progression

Valentina Montagnani, Matteo Benelli, Alessandro Apollo, Silvia Pandolfi, Gianni Gerlini, Lorenzo Borgognoni, Barbara Stecca

4. The relevance of BRAF G469A mutation in determining the response to therapy in metastatic melanoma

Letizia Porcelli, Gabriella Guida, Tiziana Cocco, Anna E. Quatrala, Rosa M Iacobazzi, Diana A Stolfi, Imma Maida, Anna Ferretta, Claudia Grieco, Stefania Guida, Sabino Strippoli, Stefania Tommasi, Michele Guida, Amalia Azzariti

5. microRNAs and next generation sequencing for the prognosis of the metastatic melanoma

Rosamaria Pinto, Simona De Summa, Sabino Strippoli, Gabriella Guida, Ondina Popescu, Amalia Azzariti, Michele Guida, Stefania Tommasi

POSTER SESSION

6. Melanoma cells with acquired resistance to dabrafenib display changes in miRNA expression pattern and respond to this drug with an increase of invasiveness, which is abrogated by inhibition of NF- κ B or the PI3K/mTOR signalling pathway

Simona Caporali, Ester Alvino, Adriana Amaro, Pedro Lacal, Lauretta Levati, Maria Grazia Atzori, Gian Carlo Antonini Cappellini, Federica Ruffini, Enzo Bonmassar, Ulrich Pfeffer, Stefania D'Atri

7. Neuropilin-1 expressing melanoma cells as a model to study the aggressiveness of metastatic melanoma

Federica Ruffini, Grazia Graziani, Lauretta Levati, Lucio Tentori, Simona Caporali, Stefania D'Atri, Pedro M Lacal

COMBINATION THERAPIES

8. Safety and efficacy of vemurafenib in BRAF V600E mutation-positive metastatic melanomas

Andrea P Sponghini, David Rondonotti, Marco Giavarra, Roberto Giorgione, Francesca Platini

9. BRAFV600E mutation positive metastatic melanoma in a young woman treated with anti-BRAF/anti MEK combination: a case report.

Sara Giovannoni, Federica Urbano, Daniela Modica, Sofia Verkhovskaia, Giuliana Caprio, Silvia Mezi, Enrico Cortesi

POSTER SESSION

TUMOR MICROENVIRONMENT AND BIOMARKERS

10. Simultaneous determination of two serum tumor markers in assessing malignant melanoma patients

Angela Sandru, Silviu Voinea, Eugenia Panaitescu, Madalina Bolovan, Adina Stanciu, Sabin Cinca, Alexandru Blidaru

11. Clinical value of Melanoma Inhibitory Activity in stratifying malignant melanoma patients

Angela Sandru, Silviu Voinea, Eugenia Panaitescu, Madalina Bolovan, Adina Stanciu, Sabin Cinca, Alexandru Blidaru

12. Melanoma Inhibitory Activity and regional lymph node status in malignant melanoma patients

Angela Sandru, Silviu Voinea, Eugenia Panaitescu, Madalina Bolovan, Adina Stanciu, Sabin Cinca, Alexandru Blidaru

13. Immune infiltrates impact on the prediction of prognosis and response to immunotherapy of melanoma patients

Angela Vasaturo, Dagmar Verweij, Lucie Heinzerling, Willeke Blokx, Carl G Figdor

14. Gender differences and outcome of melanoma patients

Francesca Morgese, Rossana Berardi, Caterina Sampaolesi, Mariangela Torniai, Giulia Marcantognini, Alfredo Giacchetti, Stefano Serresi, Azzurra Onofri, Alessandro Bittoni, Alberta Pilone, Giuseppe Ricotti, Stefano Cascinu

15. Circulating dendritic cell levels identify high-risk stage II-III melanoma patients: a potential role as additional prognostic marker

Stucci Stefania, Tucci Marco, Passarelli Anna, Mannavola Francesco, Felici Claudia, Giudice Giuseppe, Silvestris Franco

POSTER SESSION

16. Dendritic cell-derived exosomes (Dex) are potential biomarkers of response to Ipilimumab in metastatic melanoma.

Stucci Stefania, Tucci Marco, Ascierto Paolo Antonio, Passarelli Anna, Capone Mariaelena, Madonna Gabriele, Simeone Ester, Grimaldi Antonio Maria, Silvestris Franco

17. "Immune B Cells know it better": tumorimmunological panel assay to define tumor-associated antigen binding antibodies in patients with metastatic melanomas

Beatrix Kotlan, Timea Balatoni, Katalin Csirbesz, Judit Olasz, Orsolya Csuka, Laszlo Toth, Emil Farkas, Akos Savolt, Andras Szollar, Mihaly Ujhelyi, Szabolcs Horvath, Klara Eles, Miklos Kasler, Francesco M Marincola, Gabriella Liskay





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