

MELANOMA INDEPENDENT BOARD

FIRST MELANOMA MIB CONFERENCE 2013

Roma, 21-22 october 2013

PATIENTS
ASSOCIATIONS

FARMACEUTICAL
INDUSTRIES

REGULATORY
AGENCIES

TECHNOLOGICAL
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MASS MEDIA

CLINICIANS AND
BASIC RESEARCHERS

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Melanoma Independent board

FIRST MELANOMA MIB CONFERENCE 2013 October 21-22

The meeting will discuss two main aspects between the melanoma scientific issues which are actual and of new definition. Firstly the concept of innovation and sustainability of the various developments of cure of this disease, secondly the concept of how the new single drugs and integrated therapeutic approaches available may in future develop in combination modalities and how we may improve the ability in selecting the best treatment proposals to obtain the highest chances to cure the specific disease entity of a single melanoma patient.

The vast majority of research is conducted by pharma and from a pipeline of thousands of drugs, only one reaches the market: this is a crucial aspect in the definition of the difficulty from one side to develop new drugs and explains why this kind of research is in the hands of big companies, while from the other side justifies only in part the increase in prices shown during the last 10 years by new drugs.

Molecular medicine is developing a concept of individualizing the best treatment to be offered to cure the cancer of a single person: it is more than clear that a single drug will not be effective on all patients affected by a specific disease and the most important task will be the selection of the drug to be offered to cure a single patient. Moreover it is becoming more and more clear that the molecular pathways involved in the development and progression of cancer can not be controlled by a single drug, so the association of different compounds will be a strategic task for the next 10 years of cancer research. This aspect brings the discussion to a very delicate but fundamental aspect which is the necessity that different companies will have to play a common job and activate strategies of cooperation within specific collaborative clinical trials.

Immunology and molecular medicine will represent the future of cancer cure when we shall be able to predict the response and we shall make the investment behind a cure proposal really beneficial, making the treatment proposal to a patient unavoidable: if you are proposing a cure to a cancer patient with a probability of success as high as it is now the cure rate of an antibiotic towards a bacterial infection, no price limitations will ever be present, firstly because you select the patient to whom a certain therapy is most probable to be effective, secondly because the selection of the patients will limit the number of patients to whom a certain therapy will be offered. Targets of immune response and pharmacological interaction pathways of molecular medicine drugs are the milestones of cancer cure and require all our efforts to be efficiently discussed and finalized.

The organizational aspects are requiring a new methodology concerning the level of discussion and the rational to guide the decision making processes: new effective treatments are coming available to melanoma patients and we all agree that all new effective therapies should be offered to patients but on the opposite site the NHS budget has to be sustainable as it is not unlimited. This brings the discussion to a setting where different figures should be involved starting from medical experts, pharm company representatives, economists, regulatory agency representatives and patients association representatives; such a panel could be the best scenario to obtain an agreement on the selection of the targets of new therapies, but also on the identification of the characteristics of the centers where a certain treatment could be offered to patients with both the goal of the efficacy but also of the costs control.

Three general sessions

This meeting will discuss the topics within three main frameworks which appear very different only from a superficial analysis:

- Strategic issues
- Scientific issues
- Clinical issues

In the next future we shall not be able to offer everything to every patient, but we must be able to offer the best available therapies to the patients who may benefit from it.

Science and cancer care can no more improve without a discussion which involves different roles, and the target of this meeting will be to create a productive evaluation where strategic and scientific issues should be put together.

An important role has to be dedicated to the validation of diagnostic and therapeutic pathways with the identification of certified regional institutions where both the quality of care and the economical sustainability will be guaranteed. To reach this objective of auditing and survey the discussion needs to identify precise markers of quality through validated methods of cost-benefit evaluation. This approach needs to be proposed by recognized groups (IMI, AIOM, SICO, SIAPEC etc.) and ultimately be approved by national and regional sanitary authorities from whom this activity has been formally devoted.

The topics listed below represent the background of the discussion of the first melanoma independent board meeting, from which new topics will be proposed for future discussions and meeting.

Roma

21-22 October 2013

AGENDA

21 October

First session 10.30-13.30

- "Introduction: The Independent Melanoma Board" Dr. Alessandro Testori
- Welcome message from authorities representative of AIFA/health Ministry/Assessori salute regionali
- "Melanoma as a model for clinical research: the mile stone trials from WHO melanoma, program in memory of Natale Cascinelli" Dr Alessandro Testori & Prof. Nicola Mozzillo
- "Melanoma socio-economic epidemiology" PhD Sara Gandini
- "Patients associations: a must for the future" Dr Francesco De Lorenzo
- "Sustainability in oncology: the pharm companies view point" Dr Maurizio de Cicco
- "Pipeline Medical Device Industrial Research: Cost&Benefit" Dr. Ruggero Cadossi

13.00-13.30 discussion

13.30 lunch

Second session 14.30- 17.30

- "Pipeline Institutional research: Costs&Benefit" Prof. Pier Giuseppe Pelicci
- "The role of scientific societies in the relationship with regulatory agencies" Dr. Stefano Cascinu
- New drugs for melanoma: are these sustainable? Dr Gianluigi Casadei
- "Sustainability of new technologies: Cost-Effectiveness analysis of Palliative Treatments of Advanced Melanoma Skin Metastases" Prof. Giorgio L. Colombo
- The hospital management of new drugs in:
 - Veneto Pharmacy IOV Padova
 - Lombardia Dr Mario Cesana

15.30-15.40 discussion

- "Ipilimumab and PD-1: from pipeline to market" BMS representative
- "Planning Ipilimumab therapy in a single institution" Dr Ruggero Ridolfi
- "B_Raf inhibitors: from pipeline to market" Dott.ssa Luisa Veronese
- "From pipeline to clinical research" Dr Axel Hoos

16.40-16.50 discussion

- "Research: from pipeline to clinical research" TBA
- "Cancer Center certification program in Germany" Dr Claus Garbe
- "Centers certification for cancer care in Italy TBA"
- "ESO education, how to integrate the developments of oncology in Western into Eastern Europe" Dr Alberto Costa

17.50-18.00 discussion

18.00- 20.00

Workshops: parallel sessions

Room 1)

Strategic issues

Definition of a melanoma unit and picture of the local organization of hospitals dedicated to melanoma patients care.

Definition of melanoma cancer center and identification of the institutions where, following documented diagnostic and therapeutic pathways, treatments of first, second and third level of care can be "authorized" by the regional sanitary authorities.

Chair: representative from Institutional Regional health assessorati (i.e. lombardia, lazio campania etc.) Dr. Carmine Pinto Dr. Alberto Costa, Prof. Claudio Jommi

- Melanoma as a model to built new relationships between different institutional roles to improve patients care Dr.Carmine Pinto
- Where to be cured? What are the aspects that help patients to choose the hospital/doctor to cure his/her disease Dr.Bettina Ryll
- Risk management and quality of therapeutical outcomes. The concept of Excellency is a self referral issue? Dr.Massimo Monturano
- Sustainability of new drugs Prof. Claudio Jommi

19.30-20.00 discussion

18.00- 20.00

Room 2)

Scientific issues

Molecular markers and translational research.

New target therapies and future combinations

Consolidation of immunotherapy as effective therapy on advanced melanoma

Chair Dr Massimo C.P. Barberis, Dr Paola Queirolo, Dr Michele Maio, Dr Maria Rescigno

- From histopathology to molecular markers in the definition of prognosis of melanoma patients and in solid tumors: the point of view of the molecular pathology Dr Massimo C.P. Barberis
- From histopathology to molecular markers in the definition of prognosis of melanoma patients and in solid tumors: the point of view of the clinical biology Dr Francesco Bertolini
- Genetic profiling in melanoma: a step to identify patients susceptibility to target therapy Dr Pier Francesco Ferrucci
- Proteomics in melanoma: a step to identify patients susceptibility to immunotherapy Dr Michele Maio
- Target therapy molecular identification: is it only a qualitative data or there is a quantitative role to identify disease recurrence after response Prof.ssa Daniela Massi (Firenze)

19.40-20.00 discussion

18.00- 20.00

Room 3)

Clinical issues

The “privilege” to cure melanoma patients.

Diagnostic and therapeutic pathways of melanoma care and regional referral centers network

Educational and medical decisional processes issues.

Chair Dr Carlo Riccardo Rossi, Dr Carmine Pinto, Dr Sergio Chimenti, Dr Ignazio Stanganelli

- Who cures melanoma patients? The cooperation of Regional authorities and hospitals management in certification and validation of “melanoma cancer centers” Dr Pier Carlo Muzio
- The diagnosis of primary melanoma Dr Ketty Peris
- Follow up of pigmented lesions Dr Ignazio Stanganelli
- Confocal microscopy: role and future Prof. Giovanni Pellacani
- after the diagnosis of primary melanoma Dr Franco Di Filippo
- diagnosis and cure of stage III melanoma Dr Nicola Mozzillo
- diagnosis and medical cure of stage IV melanoma Dr Paolo Marchetti
- diagnosis and surgical cure of stage IV melanoma Dr Carlo Riccardo Rossi

19.40-20.00 discussion

20.30 transfer to Group dinner

AGENDA

22nd October

Room 1) strategic issues
continued

8.30-11.00

Chair: representative from Institutional Regional health assessorati (i.e. representatives from different Regioni Italiane), Dr Carmine Pinto, Dr Alberto Costa, Prof. Claudio Jommi

- “New Medical Device Therapies for Advanced Tumor Treatment; Regulatory aspects of innovative technologies and Path of funding: The example of electrochemotherapy” Dr. Paolo Gazzaniga
- Cost analysis of limb perfusions: a limb saving treatment orphan of a dedicated DRG and reimbursement
- “How to manage the budget in front of new drugs available?” Representative of Regione Lombardia/ministero della salute
- “What to do when the budget is spent with new patients? File “F” and hospital budget
- “4th quarter 2013: the frontiers of National NHS will be opened throughout Europe and patients will be able to choose the country where to be treated; are we ready?” Dott.ssa Marianna Cavazza
- “Bocconi University in the management of strategies to improve the collaboration between political regional and national health institutions, university and hospitals in defining the priorities.” Prof Claudio Jommi
- “Collaborating with patients associations: a must for the future.” Dr Francesco De Lorenzo

11.00-11.30 discussion

Room 2) scientific issues

Continued 8.30-11.00

Chair Dr Massimo C.P. Barberis, Dott.ssa Paola Queirolo, Dr Michele Maio, Dr.ssa Maria Rescigno

- “Next generation strategies for improving efficacy of B-RAF mutant melanoma therapy.” Dr Paolo Ascierto
- “Melanoma heterogeneity and drug response: stem cells and cell lines in preclinical studies.” Dott.ssa Luisa Lanfrancone
- “Mechanisms of resistance to target therapy.” Dott.ssa Caroline Robert
- “B-RAF inhibition is associated with T cell activation and abrogated with CD8 depletion.” Dott.ssa Maria Rescigno
- “From CTLA-4 to PD-1 to combination approaches” Dr Vincenzo Russo
- “Combination therapies: immunotherapy plus target therapy and conventional therapies can be effective cocktails?” Dott.ssa Paola Queirolo
- “AIOM IMI SIAPEC target therapy projects.” Dr Giovanni Mazzarol
- “Advanced Therapies in Melanoma: traslational and regulatory issues in Italy.” Dr Massimo Guidoboni
- “Immune system response during electrochemotherapy” Dr Gianni Gerlini

11.00-11.30 discussion

Room 3) clinical issues

continued

8.30-11.00

Chair Dr Carlo Riccardo Rossi, Dr Carmine Pinto, Dr Sergio Chimenti, Dr Ignazio Stanganelli

- "Treatment of cutaneous metastases: Clinical evidence and European Guidelines for electrochemotherapy in melanoma patients" Dr. Julie Ghel
- "Diagnosis and treatment of cutaneous side effects of target therapies" Dr Giuseppe Spadola
- "Follow up Strategies" Dr. Claus Garbe
- "Development of the concept of quality of life and how to measure it" Prof.ssa Gabriella Pravettoni
- "The QALY concept QALY= quality adjusted life year Cost-effectiveness from the payers point of view to patients quantification value " Dr Bettina Ryll
- "The psychologist experience as a member of the IEO Melanoma Division" Dott.ssa Beatrice Colombo

11.00-11.30 discussion

11.30-13-30

Consolidation of the discussion: Reports from the three sessions:

Dr Bettina Ryll

1. strategic issues rapporteur Dr Bettina Ryll and Dr Massimo Monturano

Discussion

Chair Dr Bettina Ryll, Dr Massimo Monturano, Prof. Claudio Jommi ,Prof. Giorgio Colombo, Dr Ruggero Cadossi, Dr Paolo Gazzaniga, Dr Marianna Cavazza, Dr Francesco De Lorenzo

2. Scientific issues rapporteur Dr Massimo C.P. Barberis and Dott.ssa Maria Rescigno

Discussion

Chair: Dr Pier Francesco Ferrucci, Dr Francesco Bertolini, Dr Michele Maio, Dr Caroline Robert, Dr Giovanni Mazarol, Prof.ssa Daniela Massi, Dr Paolo Ascierto, Dr Paola Queirolo, Dr Luisa Lanfrancone, Dr Massimo Guidoboni, Dr Vincenzo Russo, Dr Giorgio Parmiani

3. Clinical issues rapporteur Dr Giuseppe Spadola and Dr Carlo Riccardo Rossi

Discussion

Chair Dr Sergio Chimenti, Dr Ketty Peris, Dr Muzio, Prof. Giovanni Pellacani, dr Claus Garbe Dr Ignazio Stanganelli, Dr Nicola Mozzillo, Dr Franco Di Filippo, Dr Paolo Marchetti, Dr Julie Ghel, Dr Giuseppe Spadola, Dr.ssa Gabriella Pravettoni, Dr Beatrice Colombo

The 3 Reports should focus specifically on

- Italian Regional authorities definition of the authorisational pathway of each treatment by stage and by dedicated institutional contracts: DRG recognized to specific Institutions.
- Pharmacological industrial research and cooperation with scientific groups
- Patients associations: national and European perspectives
- Interaction between patients, doctors, politicians (payers) and regulatory agencies
- Interaction of Big Pharma and academic research towards:
- Activation of collaborative “spontaneous studies”
- Guide lines of research in molecular therapies
- Consolidation of immunotherapy in melanoma
- The management of the contractual “privilege” of treating melanoma patients
- Clinical & diagnostic and therapeutical pathways

Preparation of a publication in cooperation between regional authorities scientists clinicians and patients representatives on the topics of the meeting

Conclusions and Planning of next meeting Alessandro Testori

Adjourn

13.30 lunch

FACULTY

- **Dr. Paolo A. Ascierto** Istituto Nazionale dei Tumori Fondazione “G. Pascale”
- **BMS representative**
- **Dr. Massimo C.P. Barberis** Clinic Unit Director Histopathology and Molecular Diagnostics Unit European Institute of Oncology
- **Dr. Francesco Bertolini**, IEO Istituto Europeo di Oncologia Milano
- **Dr. Ruggero Cadossi** President of IGEA Medical SpA Carpi
- **Dr Gianluigi Casadei**
- **Dott.ssa Marianna Cavazza** Bocconi University

- **Dr. Francesco Cascino** President AIOM

- The hospital management of new drugs in:
 - **Veneto director Pharmacy IOV Padova**
 - **Lombardia Mario Cesana Administration director IEO Milan**
- **Dr. Sergio Chimenti** Clinica Dermatologica Tor Vergata Roma
- **Dott.ssa Beatrice Sofia Colombo** IEO Istituto Europeo di Oncologia Milano
- **Prof. Giorgio Colombo**, Scientific Director S.A.V.E. Studi Analisi Valutazioni Economiche srl
- **Dr. Alberto Costa** European School of Oncology
- **Dr. Maurizio de Cicco** Vice Presidente Farindustria
- **Dr. Francesco De Lorenzo** Volontariato in Oncologia
- **Dr. Franco Di Filippo** Istituto Regina Elena Roma

- **Dr. Pier Francesco Ferrucci**, Director Oncology of Melanoma Unit IEO Istituto Europeo di Oncologia Milano

- **PhD Sara Gandini** Senior Staff Scientist Division of Epidemiology and Biostatistics IEO
- **Dr. Claus Garbe** University of Tuebingen European School of Oncology
- **Dr. Paolo Gazzaniga**, Direttore Centro Studi Assobiomedica
- **Dr. Gianni Gerlini** Firenze
- **Dott.ssa Julie Ghel** Chief of Dep. Of Oncology, Univ Hospital Herlev, Copenhagen Denmark
- **Dr. Massimo Guidoboni** Immunoterapy and Cell Therapy Lab IRST-IRCCS- Meldola (FC)
- **Dr Axel Hoos** GSK
- **Prof. Claudio Jommi** Pharmaceutical Observatory CERGAS, Bocconi University, Milano
- **Dott.ssa Luisa Lanfrancone** IEO Istituto Europeo di Oncologia Milano
- **Dr. Michele Maio** Chairman Division of Medical Oncology and Immunotherapy Department of Oncology University Hospital of Siena
- **Dr. Paolo Marchetti** Istituto Dermopatico Dell’Immacolata, Roma
- **Prof.ssa Daniela Massi**, Associate Professor of Pathology Division of Pathological Anatomy University of Florence
- **Dr. Giovanni Mazzarol** Istituto Europeo di Oncologia
- **Dr. Massimo Monturano** IEO Istituto Europeo di Oncologia Milano

- **Dr. Nicola Mozzillo** Istituto Nazionale dei Tumori Napoli
- **Dr. Pier Carlo Muzio** Istituto Oncologico Veneto – University of Padova
- **Prof. Pier Giuseppe Pelicci** Chairman, Department of Experimental Oncology European Institute of Oncology Campus IFOM-IEO
- **Prof. Giovanni Pellacani** Full Professor and Chair of Dermatology at the University of Modena and Reggio Emilia, Italy
- **Dott.ssa Ketty Peris** University of L'Aquila (PG)
- **Dr. Carmine Pinto** AIOM
- **Prof.ssa Gabriella Pravettoni** IEO Istituto Europeo di Oncologia Milano
- **Dott.ssa Paola Queirolo** Istituto Nazionale Tumori Genova
- **Representative of AIFA/health ministry/ regional health advisors**
- **Dott.ssa. Maria Rescigno** Istituto Europeo di Oncologia San Raffaele Milano
- **Representative of region Lombardy, Department of Health**
- **Dr. Ruggero Ridolfi** Direttore U.O. Immunoterapia e Terapia Cellulare Somatica IOR Meldola
- **PhD Bettina Ryll** University of Uppsala, Sweden
- **Dott.ssa Caroline Robert**
- **Dr. Carlo Riccardo Rossi** Istituto Oncologico Veneto – University of Padova
- **Dr. Vincenzo Russo** Head, Cancer Gene Therapy Unit Program of Immunology Biolummunotherapy and Gene Therapy of Cancer Division of Molecular Oncology San Raffaele Scientific Institute
- **Dr. Giuseppe Spadola** Specialista in Dermatologia e Venereologia IEO Istituto Europeo di Oncologia Milano
- **Dr. Ignazio Stanganelli** IRST Meldola
- **TBA**
- **Dr. Alessandro Testori direttore divisione melanoma e sarcomi** IEO Istituto Europeo di Oncologia Milano
- **Dott.ssa Luisa Veronese** Senior International Medical Leader F. Hoffmann-La Roche Ltd

SPECIFIC ORGANIZATIONAL

In each session 2 rapporteurs will make a summary the next day and prepare a document for a joint publication starting from abstracts sent before the meeting by each speaker.

Specifically the discussion will be oriented towards the creation of an active collaboration with the federazione italiana delle associazioni di volontariato in oncologia (FAVO) and associazione italiana malati di cancro parenti e amici (AIMaC) and a link at an European level with associations of patients and relatives like European Cancer Patients Coalition (ECPC, prof De Lorenzo being Vice President), the European Alliance for Personalised Medicine (EAPM) and with the scientific societies like ESMO.

First step should be to involve all Italian melanoma associations with the goal of creating a consortium of melanoma patients associations which may bring to the coexistence of the single identities but obtaining the definition of common strategies within the FAVO.