

Melanoma Independent board  
THIRD MELANOMA MIB CONFERENCE 9 November 2015  
INNOVATION AND SUSTAINABILITY

After the success of the previous two meetings, the third edition of the Melanoma Independent Board will discuss three main aspects between the melanoma issues which are actual and under new and continuous development. Firstly the concept of innovation of the various proposals of cure of this disease, 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; consequently, together with the requisite of innovation, the concept of sustainability will focus on organizational aspects with specific attention to the regulatory pathways, the budget applications, the interaction with payers and the point of view of patients not only in the situation of requiring the best available treatment when discovered, but also in terms of managing their lives once cured from a melanoma. Second topic will be the preparation of the national diagnostic and therapeutical pathways to be proposed to our melanoma patients; this project will be characterized by inviting a selected network of melanoma experts in the different fields and involving representatives from the most important scientific societies directly or indirectly dedicated to diagnosis and cure of melanoma patients.

The third topic will be dedicated to the newborn associazione italiana malati di melanoma (AIMAME) that will organize the first general assembly and plan the priority activities for next year.

### Innovation

The vast majority of research is conducted by pharma and from a pipeline of thousands of drugs, only few reach 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. The total pharmacological expenditure for oncological drugs is anyway a real minority of the global balance of sanitary costs in Italy, where a large amount of spending review can be obtained by rationalizing several inefficient costs like the those linked to the excessive number of little hospitals distributed in the national territory and the unexplainable difference of costs of similar devices in different Italian Regions.

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 and the combination of the drugs to be offered to cure a single patient. In-fact it is becoming more and more clear that the molecular pathways involved in the development and progression of cancer cannot 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 high probability of success, 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.

### Sustainability

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 patients association representatives and media and communication experts; 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 efficacy but also efficiency in terms of costs control.

### Discrimination

Patients with melanoma have a 85-90% probability to be cured from this disease. Are we sure that this aspect is well considered in a life time project concerning a melanoma patient? In reality there is a discrimination in various environments in which a cured melanoma patient may be involved every day and where instead this individual person is instead excluded as previously affected by a melanoma. What about if a melanoma patient wants to obtain a health insurance or a life insurance or wants to buy a house with a bank loan and he receives a refusal due to his melanoma history? We may cure biologically and clinically a melanoma patient, but our legislation permits to this person to be cured also from the juridical point of view?

### Diagnostic and therapeutical pathways

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 Italian scientific societies (IMI, AIOM, SICO, SIAPEC etc.) and ultimately be approved by national and regional health authorities from whom this activity has been formally devoted.

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

**Roma**  
**9 November 2015**

**AGENDA**

**8.30-10.00 registration Sheraton parco de' Medici building N° 2**

**First session 10.00 – 11.30 chair Alessandro Testori, ...**  
Introduction (epidemiology and numbers , the authorities)

- 10.00 The Melanoma Independent Board as a model for integrating clinical research and the society  
**Alessandro Testori**
- 10.15 Melanoma socio-economic epidemiology” **Sara Gandini**
- 10.30 “Cancer Center certification program in Germany: strengths and weaknesses **Claus Garbe**
- 10.45 Welcome messages from representatives of Health Ministry **Aldo Morrone**
- 10.55 The role of ISS in supporting Italian clinical research projects **Enrico Proietti**
- 11.05 Welcome messages from Italian Regions representatives  
Regione Lombardia **Maria Teresa Baldini**  
Regione Lazio **Antonello Aurigemma**
- 11.15 *Innovation and sustainability from the point of view of an economist* **Americo Cicchetti**
- 11.35 “Sustainability of new drugs in a global vision of NHS costs” **Massimo Visentin**
11. 55 Communication with patients the goal of ethical journalism health **Maria Emilia Bonaccorso**
- 12.10 “the frontiers of National NHS should have been opened throughout Europe and patients able to choose the country where to be treated”  
**Marianna Cavazza**
- 12.25 Insurance companies approach on cured oncological patients: can we help these people not to be discriminated?  
**Elisabetta Iannelli**
- 12.40 How the point of view on insurance companies is moving on oncological patients **Giuseppe Gionta**
- 12.55 Health and economicity of NHS **Claudio Jommi**

**Second session (lunch box provided)**

**chair Nicola Mozzillo Vanna Chiarion Sileni**

**The companies planning of research for innovation: towards combination / sequencing therapies**

- 13.10 BMS melanoma projects **Cosimo Paga**
- 13.20 "T-VEC: oncolytic immunotherapy platform for the treatment of melanoma" **Zsolt Szabo**
- 13.30 "PD-1, PD-L1 and IFN with new combinations" **Loredana Orsini**
- 13.40 "Roche: Innovation in melanoma: from BRAF to multiple targets"
- 13.50 "Clinical research plans in melanoma" **Eugenio Morsiani**
- 14.00 PV-10: a new opportunity in Europe from Provectus Eric Wachter
- 14.10 reserch plans from Fidia pharmaceuticals speaker TBI
- 14.20 "Electrochemotherapy: Sustainability of innovation in Medical Device Industrial offer"  
**Claudio Viola**
- 14.30 "e-cancer medical science: a new way to manage a scientific journal" **Gordon Mcvie**

### Third session 14.30-16.30 chair Ignazio Stanganelli, Alessandro Testori

Percorsi diagnostico terapeutici Italiani nel melanoma: panel discussion

Ignazio Stanganelli; Giovanni Pellacani ; Giuseppe Spadola; Carlo Riccardo Rossi; Nicola Mozzillo; Daniela Massi; Cristina Montesco Massimo Barberis; Paola Queirolo; Paolo Ascierto; Michele Maio; Vanna Chiarion Sileni; Sara Vigna (presidente AIMAME, associazione italiana malati melanoma); Francesco De Lorenzo (presidente FAVO e ECPC) dott. Gian Marco Tomassini delegato ADOI; dr Domenico Piccolo Presidente e delegato AIDA; Dott Alessandro Di Stefani presidente e delegato AIDNID; dr. Pierluigi Zanco delegato AINM; Alessandro Minisini e Virginia Ferraresi delegati AIOM; **delegato AIRO tbi**; dr Marco Simonacci Coordinatore e delegato GIPME; **delegati IMI tbi**; Anna Maria di Giacomo delegata NIBIT; **delegato ISPLAD tbi**; Claudio Clemente, Gerardo Botti, Stefania Staibano delegati SIAPEC; Dr. Ettore Capoluongo delegato SIBIOC; **delegato SIC tbi**; **delegato SICADS tbi**; Corrado Caracò delegato SICO; **delegato SICPRE tbi**; Dott. Fabrizio Fantini e Dott. Antonio Ascari Raccagni delegati SIDCO; Ketty Peris e Giuseppe Argenziano delegati SIDEMAST; **delegato SIRM tbi**; Franco di Filippo Responsabile Chirurgia Generale e della Mammella Istituto Nazionale Tumori Regina Elena IRCCS - Roma

14.40

Dermatologic area

Management of pigmented lesions

15.00

Dermatologic and pathologic areas

From clinical diagnosis to histological confirmation of melanoma/nevi

Global network

Management of atypical tumoral melanocytic lesions

Management of melanocytic lesions presenting from 50% to 100% regression

16.00

Dermatologic and surgical area

Stages I & II

Instrumental preoperative staging

Laboratory tests

Molecular mutations and receptorial analysis therapy oriented

Therapeutical indications on the basis of each T parameter: Tis, T 0-1mm, T 1.1-2 mm, T 2.1-4 mm, T>4 mm, +/- ulceration and mitosis or microsatellites

Surgery

Adjuvant therapy

Neoadjuvant approaches for locally advanced primaries

Surgical indications for primaries on extremities or face

17.00

Surgical and oncological areas

Stage III

N+ any

N- with in transit metastases (or satellites)

N+ any with in transit metastases (or satellites)  
Instrumental preoperative staging  
Laboratory tests  
Molecular mutations and receptorial analysis therapy oriented  
Surgery  
Adjuvant therapy  
Locoregional /intralesional treatments  
18.00  
Surgical and oncological areas  
Stage IV  
M1a, M1b,M1c  
Instrumental staging  
Laboratory tests  
Molecular mutations and receptorial analysis therapy oriented  
Surgery  
Medical therapies  
Radiotherapy  
Locoregional/Intralesional treatments  
19.00  
Dermatologic, surgical and oncological areas  
Follow up at any stages  
Rehabilitation and management of long term complications

**Fourth session 17.00-19.00 chair Sara Vigna, Francesco de Lorenzo, psico oncologo**

**General assembly of the associazione italiana malati di melanoma (AIMAME)**

17.00 introduzione e presentazione dell'agenda dell'assemblea

Sara Vigna

Membership approval

Finances

tesoriere aimame

**Approval of the scientific committee members and chairman**

**Sara Vigna**

**Primary goals to be reached by the association**

**AIMAME projects**

**varia**

Discussion

**Conclusions and Planning of next meeting () Alessandro Testori**

Adjourn

At the end of each session the selected rapporteurs will record a summary of the presentations:

Session 1 (preparation of the report by Dr)

Session 2 (preparation of the report by Dr)

Session 3 (preparation of the report by Dr)

Session 4 (preparation of the report by Dr)

**MEETING CHAIRMAN**

**Alessandro Testori**

**Istituto Europeo di Oncologia, Milano**

**MEETING BOARD**

**Paola Queirolo**

**Ospedale San Martino Genova**

**Nicola Mozzillo**

**Istituto Tumori di Napoli Pascale**

**Francesco de Lorenzo**

**president European cancer patients coalition (ECPC)**

**Carlo Riccardo Rossi**

**Istituto oncologico Veneto Padova**

FACULTY