

Curriculum Vitae

Name: **Michele Del Vecchio**

Place and date of birth: Bari, 23/10/1966

Marital Status:

Residence:

Address:

Place of work: Unit of Melanoma Medical Oncology (Head)
Department of Medical Oncology and Hematology
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Military Service: Discharge to the reserve

ENGLISH

- Reading skills level: excellent
- Writing skills level: excellent
- Verbal skills level: excellent

Education

- High school Diploma Liceo Classico “F. De Sanctis”, Trani (BARI): 60/60.
- After having passed the admission examination, I attended the “Università Cattolica del Sacro Cuore (Policlinico Gemelli)”, Rome, and obtained the Degree in Medicine and Surgery on 19/10/1992: 110/110.
Clinical-experimental thesis titled “Hematophagic Histiocytosis: *revision of the literature and clinic-pathologic contribution*”, prepared at the Department of Internal Medicine of the over mentioned University (Tutors: Prof. G. Gambassi and Dr. R. Manna).
- Licensure at the Medical professional activity obtained on November 1992 at the Università Cattolica in Rome.
- Specialty in Oncology obtained in November 1997, 70/70 cum laude, at the University of Milan, presenting a

clinical-experimental thesis titled "*Use of Interleukin-12 in the treatment of metastatic melanoma*" (Tutors: Prof. E. Clerici, Prof. E. Bajetta).

- I passed step 1 and step 2, currently step 2CK and TOEFL test in the context of the U.S.M.L.E. examinations requested for obtaining the E.C.F.M.G. Certification necessary for the licensure of the medical activity in the U.S.
- I obtained the European Certification in Medical Oncology (E.S.M.O.), after passing the examination held in Vienna (Austria) on September 12, 1999.
- In 2001 I passed the TOEFL *testing* (English language proficiency test)

Work Experience

- In 1986-87, I attended the Department of Normal Human Anatomy, where I assisted, as *tutor*, the students of the first year of the course in Medicine and Surgery, regarding the anatomy of the heart during the autopsies.
 - During the University years 1987-88 and 1988-89, I attended the Departments of General Pathology, Immunology and Experimental Oncology.
 - From November 1989 to November 1992, I attended the Department of Internal Medicine, participating to clinical-experimental studies of immunology and immunopathology.
 - In 1993 I won a fellowship of the A.I.L. (Italian Association for Leukemia), which allowed me to work in the lab of Immunology of the Department of Oncology of the University of Padua on research projects regarding cancer immunotherapy and chemoimmunotherapy. In particular, I performed a research regarding the antitumor efficacy, in murine models, of the LAK cells loaded with toxins (Ricin-A) or with antitlastic drugs (Antracyclins). Then, I took part to the initial studies on the use of LAK cells loaded with antitumoral antibiotics and vehicled to the tumor by bifunctional monoclonal antibodies.
 - In December 1993 I ended the work related to my fellowship: "*LGL (large granular lymphocytes) lymphoproliferative disease with particular regard to the role of the Protein-Tyrosin-Kinase (PTK) in the cytotoxic activity of the (CD3+; CD3-) LGL populations*".
 - In 1994 I was offered a fellowship from the Tumor Institute "*F. Addarii*" of Bologna, directed by Prof. C. Maltoni.
 - From January 1994 to December 1997 I attended the School of Specialty in Oncology at the University of Milan for the Division of Medical Oncology of the Istituto Nazionale Tumori, directed by Prof. E. Bajetta.
 - I was involved in research programs of the Medical Oncology B Division regarding the treatment and data processing of several different study protocols on melanoma, gastro-intestinal tumors, kidney and breast cancer.
 - Since 2000 I have been the Responsible Investigator of several Italian and International trials on melanoma, both in adjuvant and metastatic settings.
 - Since June 1994, member of AIOM (Italian Association of Medical Oncology).
 - Since May 1996, member of ESMO (European Society for Medical Oncology).
 - Since April 2000, member of ASCO (American Society of Clinical Oncology).
 - Since 2004 - present –Founding Member of the "Society for Melanoma Research".

- From December 2013 to December 2016, Vice President of the Italian Melanoma Intergroup (IMI).
- Since January 2017, Coordinator of the Translational Medical Area of the Italian Melanoma Intergroup
- I have been taking part to national and international Advisory Boards of different pharmaceutical companies (Roche, GSK, Novartis, MSD, BMS, Sanofi, Pierre Fabre, Immunocore, Regeneron)
- I have also been taking part to several different national and international meetings and symposia both as invited speaker and/or chairman
- I performed, as Responsible Investigator, the trial *“Pilot Study of weekly subcutaneous administration of Interleukin-12 (RO 24-7472) in patients with advanced/metastatic melanoma”*. I presented the data of this study at the ASCO Conference held in Philadelphia on May 21, 1996 (oral presentation).
- In 1996 I attended, as *visiting researcher*, the Department of Surgery and Biologic Therapies of the Pittsburgh Cancer Institute, directed by Prof. M.T. Lotze.
- Following the requested exams (written and oral), I was accepted for the 1998 PhD programme of the *Open University* of London, presenting a research project titled: *“Generation and use of genetically modified HLA-A2-compatible allogeneic melanoma cells to express B7.1 costimulatory molecule and to release IL-2”*. Tutors: G. Parmiani, Director of the Unit of Immunotherapy of Human Tumors, Istituto Nazionale Tumori, Milan, and F. Balkwill, Imperial Cancer Research Fund., London.
- I contributed to develop the *Guidelines* and to write the *booklet* for the treatment of melanoma of the Istituto Nazionale Tumori di Milan (Malignant Melanoma *Booklet*, I.N.T. Milan, 1998; E-Book Melanoma, I.N.T. Milan, 2002).
- From January 1998 to January 2000, fellowship for the Ph.D. programme at the Unit of Immunotherapy of Human Tumors, Istituto Nazionale Tumori, Milan, directed by Dr. G. Parmiani..
- From June 1999 to May 2001 activity of Consultancy for the Pharmaceutical Company ASTA MEDICA.
- ➤ Since June 2000, fixed position of “Dirigente Medico di I Livello” at the Department of Medical Oncology, Istituto Nazionale per lo Studio e la Cura dei Tumori, Milan.
- Since 2017 Head of the Unit of the Melanoma Medical Oncology, Department of Medical Oncology and Hematology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
- Since 2003 activity of Consultancy, as expert on melanoma, for the following Pharmaceutical Companies: Chiron, Schering-Plough, Italfarmaco, Roche, Merck, Novartis and BMS.
- Since 2011 activity in the context of Italian and International Advisory Boards, as expert on melanoma, for the following Pharmaceutical Companies: Roche, MSD, Novartis, BMS, Pierre Fabre, Immunocore, Regeneron.
- I carried-out the *“Italian multicenter randomized phase III trial comparing polychemotherapy (CVD regimen – Cisplatin/Vindesine/Dacarbazine) with the same chemotherapy in combination with IFN- α 2b/IL-2-based immunotherapy as first-line treatment of metastatic melanoma*. I presented the study results at the ASCO Conference held in Chicago from May 31 to June 3, 2003 (oral presentation).
- I wrote a research protocol regarding the use of fotemustine and Bevacizumab as first-line therapy of metastatic melanoma patients (a phase II trial)”, which was approved and, consequently, supported by Roche, USA.

➤ In 2007 and 2008 I attended the Cell and Gene Therapy Department of the Baylor College of Medicine, Houston and the Melanoma Medical Oncology Department of the M.D. Anderson Cancer Center (MDACC), Houston (TX), USA, working on CAR T cells in solid tumors. I participated to get the patent for a construct “CSGP4” - Specific Chimeric Antigen Receptor for Cancer, set forth in United States Application No. 15/038,997 filed May 24, 2016; International Patent Application No. PCT/US2014/066953 filed on November 21, 2014 and United States Provisional Application No. 61/909,788 filed November 27, 2013

- I received grants together with Anichini's group at the Istituto Nazionale dei Tumori, Milan for research projects regarding immunotherapy of melanoma (AIRC).
- Spontaneous melanoma research projects were written and obtained funds from companies, e.g. BMS (Identification of Biomarkers predicting resistance to PD-1 pathway blockade in stage III unresectable/stage IV melanoma – Protocol number CA209-895), recently approved by EC of the Istituto Nazionale dei Tumori, Milan
- I was and I am the PI (Principal Investigator) of several different trials on melanoma at the Fondazione IRCCS Istituto Nazionale dei Tumori, Milan also, in some cases, as Coordinating Center in Italy:
 - ✓ A randomized, Phase III study of Fotemustine versus the Combination of Fotemustine and Ipilimumab in Patients with Metastatic Melanoma with brain metastasis
 - ✓ MK3475-022 – Phase I/II Study to evaluate the safety and effectiveness of MK-3475 in combination with trametinib and dabrafenib in patients with advanced melanoma
 - ✓ Clinical Trial of nivolumab (BMS-936558) in combination with ipilimumab followed by nivolumab in monotherapy as first-line therapy of patients affected by histologically confirmed stage III (unresectable) or stage IV
 - ✓ Phase III, randomized, double blind, placebo-controlled Trial with pembrolizumab (MK-3475) in combination with epacadostat or placebo in unresectable or metastatic melanoma patients (Keynote-252/ECHO-301)
 - ✓ A Prospective Observational Safety Study of Patients with BRAFV600 Mutation-positive Unresectable or Metastatic Melanoma Treated with Vemurafenib
 - ✓ The NEMO trial (NRAS melanoma and MEK inhibitor): A randomized Phase III, open label, multicenter, two-arm study comparing the efficacy of MEK162 versus dacarbazine in patients with advanced unresectable or metastatic NRAS mutation-positive melanoma (submitted to FDA Audit in November 2016)
 - ✓ Overall Survival in patients affected by metastatic melanoma with and without BRAF V600 mutation: Cohort Observation Study on the effectiveness of BRAF inhibitors and of the current therapies – BOOST STUDY
 - ✓ BRF117277: A Phase II, Open-Label, Multicentre Study of Dabrafenib plus Trametinib in Subjects with BRAF Mutation-Positive Melanoma that has Metastasized to the Brain
 - ✓ Sequential Combo Immuno and Target therapy (SECOMBIT) study Three arm Phase II randomized prospective clinical trial evaluating the best sequential approach with combo

immunotherapy (ipilimumab/nivolumab) and combo targeted therapy (LGX818/MEK162) in BRAF mutated metastatic melanoma patients

- ✓ A phase III, double-blinded, randomized, placebo controlled study of Atezolizumab plus COBIMETINIB and VEMURAFENIB versus placebo plus COBIMETINIB and VEMURAFENIB in previously untreated BRAF V600 mutation positive patients with unresectable locally advanced or metastatic melanoma
 - ✓ A Randomized Double-Blind Phase III Study of Ipilimumab Administered at 3 mg/kg vs at 10 mg/kg in Subjects with Previously Treated or Untreated Unresectable or Metastatic Melanoma
 - ✓ Phase IIIb/IV, randomized, double blinded, study of nivolumab 3 mg/Kg in combination with ipilimumab 1 mg/kg vs Nivolumab 1 mg/kg in combination with ipilimumab 3 mg/kg in subjects with previously untreated, unresectable or metastatic melanoma
 - ✓ CA209-172: Multicenter, single-arm, open-label, Clinical Trial with Nivolumab (BMS-936558) in histologically confirmed unresectable stage III or stage IV melanoma patients progressing after a previous treatment containing anti-CTLA-4 monoclonal antibody
 - ✓ Observation Study to evaluate the effectiveness and safety of ipilimumab, administered during the Expanded Access Program in previously treated patients affected by advanced (unresectable or metastatic) melanoma
 - ✓ A Phase 3, Randomized, Double-Blind Study of Nivolumab Monotherapy or Nivolumab Combined with Ipilimumab Versus Ipilimumab Monotherapy in Subjects with Previously Untreated Unresectable or Metastatic Melanoma
 - ✓ Clinical Trial of nivolumab (BMS-936558) in combination with ipilimumab followed by nivolumab in monotherapy as first-line therapy of patients affected by histologically confirmed stage III (unresectable) or stage IV. N. protocollo: CA209-401
 - ✓ A Phase 3, Randomized, Double-blind Study of Adjuvant Immunotherapy with Nivolumab versus Ipilimumab after Complete Resection of Stage IIIb/c or Stage IV Melanoma in Subjects who are at High Risk for Recurrence (Italian Coordinating Center)
 - ✓ A Phase 3, Randomized Study of Adjuvant Immunotherapy with Nivolumab Combined with Ipilimumab Versus Ipilimumab or Nivolumab Monotherapy after Complete Resection of Stage IIIb/c or Stage IV Melanoma in Subjects who are at High Risk for Recurrence (Italian Coordinating Center)
- I participated to several different Italian and International Congresses as invited speaker, organizer, scientific responsible or Chairman
 - I am involved as reviewer on melanoma papers of several journals.

Sincerely,

Dr. Michele Del Vecchio

Milan, April 2025

ASCO ORAL PRESENTATIONS

1. Preliminary experience with rHuIL-12 in the treatment of metastatic melanoma.
Slide presentation at the XXXII American Society of Clinical Oncology (A.S.C.O.) Annual Meeting. Philadelphia, May 18-21, 1996.
2. Multicenter phase III randomized trial of cisplatin, vindesine and dacarbazine (CVD) versus CVD plus subcutaneous (sc) interleukin-2 (IL-2) and interferon-alpha-2b (IFN) in metastatic melanoma patients (pts).
Oral presentation at the 39th American Society of Clinical Oncology (A.S.C.O.) Annual Meeting. Chicago, May 31 – June 3, 2003.

SPECIAL DIDACTIC ACTIVITIES

- ✓ Preparation of the *Guide-Lines* for the treatment of Melanoma for AIOM (Associazione Italiana Oncologia Medica)
- ✓ Participation, as tutor (contract professor at the University of Milan), to lessons on medical and biologic therapy of melanoma, at the School of Specialty in Oncology of the University of Milan, in several Academic years.
- ✓ Member of the AIOM/SIAPEC-IAP work group for the recommendations for the evaluation of the BRAF mutational status in melanoma.
- ✓ 1996 on: Participation both as speaker and organizer to several different National/International Congresses, Hospital Meetings and Masters on melanoma.