

Alessandra di Pietro, MD, PhD
Curriculum Vitae et Studiorum

Curriculum vitae

Date of birth: April 1, 1978
Nationality: Italian
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Mother Language: Italian
Spoken Languages: English, Dutch, Spanish; French

PERSONAL SUMMARY

Proven track record of successful clinical leadership and product strategy development built over last 27 years across academia and industry, as leader, mentor and coach across multiple diverse geographies US, Italy and Netherlands. A dynamic, agile leader, managing significant complexity as GPT lead to achieve 5 product approvals in last 12 months.

Deep clinical expertise of working within therapeutic areas Oncology (Thoracic, Precision Medicine, GI, Melanoma and Gyn; GU; IO ;Breast) across Drug Development Strategy, Global Submission (RTOR, ORBIS), Label negotiation, BD evaluation and execution strategy.

Passionate about leading teams (direct people leadership and matrix teams) developing a strong culture of engagement to achieve positive outcomes. A strong external ambassador who works collaboratively with key opinion leaders across multiple fields to develop Global relationships

CAREER HISTORY PFIZER 2015 – 2024

Product Team Leader :Thoracic, Precision Med, GI, Mel and Gyn (Sept'23 – Current)

- Leadership of GPT XF matrix team to enable the integrated development and commercialization of new and in-line assets. Acceleration of pipeline development (eg durvalumab, NG-BRAF)
- Responsible for the successful approval of 5 medicines in last 12 months: Tivdak in Cervical Cancer: (US Apr '24), Enco./Bini in NSCLC: (US/EU Oct '23/Aug '24), Axitinib (ped) and tRCC (Jul '24) Avelu in UC (US/EU Jun '20/ EU Jan '21).Avelu + axib in 1st line RCC (US, EU, JPN '19)
- Pediatric development strategy in tRCC and B-Raf\Mek franchise
- Launch of several phase 2 & 3 trials (Melanoma, Bladder. NMBC, RCC, CRC, gastric, mesothelioma)
- Partnership with BD on evaluations for co-development and potential in licensing

- Partnership with Commercial and Global market access for successful commercial launch and reimbursement worldwide (

Executive Director, Clinical Development Oncology, Global Product Development, Italy
(March 2015- Sept 2023)

- Strategic Global Clinical Lead for the GU, GI, Melanoma, Lung, Breast and Pediatric indications in small molecules (Braf, Mek; axitinib, sunitinib, torisel and new small molecules in pipeline) and IO (avelumab; sansalimab and new IO pipeline products): leading the strategic development of the GU, GI, melanoma, lung field from Ph.1b through phase 3 and PMC of IO agents, small molecules and combinations.
- Strategic Global Clinical Lead for new combination in IO (platform studies signal seeking for new indications) and next-Gen TKI\MAP Kinases – early to late stage
- Senior Clinical support to the BD team for identification of compounds for in-licensing and partnering

PREVIOUS CAREER HISTORY 2001 – 2015

Associate Director, Clinical Development Oncology at MedImmune LLC\ AstraZeneca, HQ Gaithersburg, MD, USA, (October 2011- March 2015):

- Global Clinical Development lead for several Immuno-Oncology assets (tremelimumab, durvalumab, Ox-40s, CEA-Bite) and combinations (eg. Dab\ trem + durvalumba, durvalumab-tremelimumab) in different tumour types (GI, GU, Melanoma, Lung).

Responsibilities:

1. Global clinical strategy for the development of late stage (Tremelimumab) and early stage and FIH (durvalumab, ox-40, CeA-bite) assets across several tumour types.
2. Global submission and launch in partnership with regulatory, Med aff, Commercial and Global market access
3. Life cycle development in several tumors types (e.g. advanced lung cancer, breast cancer, gastric cancer, pancreatic cancer)
4. Clinical lead for the pre-clinical drug development of Tim-3 (IMTC- IMunoTherapy-against-Cancer- compound) and mod-RNA (Modulating RNA platform technology)
5. Clinical lead for the coordination between clinical activities and translational research and for the cooperation between clinical activities and drug-labeling/tumor imaging system.
6. MedImmune Clinical Lead for AZ/MedImmune IMTC development program in Asian countries (Asia strategy Committee)
7. MedImmune IMTC clinical lead for AZ small molecule- MedImmune IMTC combination strategy
8. Clinical leader for the immuno-oncology assets communication plan
9. Clinical support to BD team for in-licensing or partnering of assets from other companies.

Core skills Developed:

- a. Overarching Drug development strategy

- b. Landscape analysis for trial development
- c. Clinical support to the cross functional development of the assent in a given tumor type, including competitive landscape and market opportunity
- d. Program Team Management and senior support to selection of CROs and Study sites
- e. Management of cross-functional team members (Clinical Operation, Translational Science, Translational Medicine, Bio-stats, Data managers, clinical manufacturing, publication and scientific coordination)
- f. Clinical evaluation of BD compounds and potential CDP

EORTC Melanoma Steering committee member (October 2007- July 2011)

Associate Professor at Melanoma and Sarcomas Division and Medical Oncology Department, IEO “European Institute of Oncology”, Milan, Italy (June 2007-July 2011)

- PI and subI for several Phase 1b through 3 programs in Melanoma and Breast cancer:
- Ph. 3 DTIC + Ipilimumab vs DTIC + Placebo in first line unresectable Stage III-Stage IV melanoma patients (BMS)
- Ph. 3 Ipilimumab vs Placebo in resected Stage III Melanoma (BMS)
- Ph. 3 Anti-BRAF vs DTIC in first line unresectable Stage III-Stage IV melanoma B-Raf Melanoma Patients (Roche)
- Ph. 3 MAGE-A3 vaccine vs Placebo as adjuvant treatment in resected stage III patients (GSK)
- Ph. 3 MAGE-A3 vaccine vs DTIC/ TMZ in Stage IVa melanoma patients -PREDICT (GSK).
- Ph.2/3 rec-PRAME vaccine in Stage IVa melanoma patients (GSK)
- Ph.2 Ipilimumab + Fotemustine in pre-treated advanced melanoma patients (NIBIT)
- Ph. 2 DTIC + Bevacizumab in first line Stage IV melanoma patients (Roche)
- Ph. 3 Allovectin-7 vs DTIC/ TMZ in advanced melanoma patients (Vical).
- E7080 vs Paclitaxel in pretreated unresectable Stage III-Stage IV melanoma (EISAI).
- Ph.3 Nilotinib vs DTIC in first-line c-kit mutant unresectable Stage III-Stage IV melanoma patients (Novartis)
- Ph.3 Masitinib vs DTIC in second line Stage III/IV c-kit mutant melanoma patients (AB Science).
- Ipilimumab Expanded Access in pre-treated advanced melanoma patients.
- Ph. 3 Abraxane vs DTIC in first line unresectable Stage III-Stage IV melanoma patients (Abraxis).
- Ph.2 Mek-Inhibitor vs Taxol in first/second line B-Raf positive unresectable Stage III-Stage IV melanoma patients (GSK).
- Ph. 1b Fotemustine + TMZ in unresectable Stage III-Stage IV melanoma (Italfarmaco).
- Ph. 2 Oral Vinorelbine in heavily pre-treated advanced breast cancer patients
- Ph.3 Taxol + Bevacizumab vs Taxol + Placebo in advanced breast cancer patients

- Ph.3 Letrozole vs Anastrozole in the adjuvant treatment of post-menopausal hormone responsive breast cancer patients (Novartis).
- Ph.2 biweekly Caelix in heavily pre-treated advanced breast cancer patients (ITT)

Core skills:

1. Clinical trials development and management
2. Collaborations with pharma for the development of new assets from early to late stage.
3. Collaborations with biotech and pharma for the execution and evaluation of pre-clinical work
4. Clinical research coordinator
5. Clinical practice with experimental and standard therapy for the best tailored treatment of each patients during the disease
6. IRB member at the IEO

People management:

1. Up to 12 direct reports (Fellow MDs, Research nurses and Clinical trial managers)
2. Mentor for fellowship MDs

Associate Professor Oncology & Translational Medicine at Department of Medical Oncology, UMCG, Groningen, The Netherlands, (January 2004- June 2007)

Oncology & Translational Medicine and Apoptosis Researcher at Medical Oncology Research Laboratory, Department of Medical Oncology, UMCG, Groningen, The Netherlands, (July-October 2003)

Internal Medicine department coordinator at ER, MMSS “Casa di Cura Multi Medica” University Hospital, Sesto San Giovanni, Milan, Italy (July 2011- Sept 2011)

Internal Medicine department coordinator at ER, PSD “Policlinico Universitario San Donato” University Hospital, San Donato Milanese, Milan, Italy (March 2010- Sept 2011)

Internal Medicine department coordinator at RSA “Casa di Cura per Coniugi”, Italy, (Oct 2009- Sept 2011)

Internal Medicine department coordinator at FSM “Fondazione Salvatore Maugeri”, Cardio-Pulmonary rehabilitation and internal medicine rehabilitation, Italy (May 2008- Aug 2011)

Collaboration with IMSW society, Paris France, for the translation of medical books from English into Italian – Nov 2003

Collaboration with IMS society for Cancer Management and Marketing enquiries – Nov 2002.

Tutoring and training to medical students at Università Cattolica del Sacro Cuore, Rome, Italy (Oct 2001 – Oct 2002)

EDUCATION

- November, 16th 2009: Medical Oncology MD, PhD graduation in Translational Oncology.
Thesis: “*Role of Apoptosis Pathways Chemosensitivity of Testicular Germ Cell Tumours*”,
defensors Prof. Dr. E. G. E. de Vries, dr. J. A. Gietema, co-defensor: dr. S. de Jong,
Department of Medical Oncology, UMCG, Groningen, The Netherlands
- November 2006- November 2009: PhD, University Medical Center Groningen (UMCG),
Groningen, The Netherlands
- November, 9th 2006 Medical Oncology Graduation. 50/50 Magna Cum Laude at Università
Cattolica del Sacro Cuore, Rome, Italy
Thesis: “*Testicular Germ Cell Tumours, a paradigm of chemosensibility for solid tumours*”,
defensor Prof. Dr. A. R.M Cittadini, supervisor Prof. Dr. E. G.E. de Vries.
- November 2002- November 2006: Recidency in Medical Oncology at Università
Cattolica del Sacro Cuore, Rome, Italy
- July, 24th 2002: Medicine and Surgery Graduation - 110/110 Magna Cum Laude and Notable
Mention, at Università Cattolica del Sacro Cuore, Rome, Italy.
Thesis: “Molecular evaluation of the correlation between susceptibility factors and precocious
alterations in superficial bladder cancer, by means of a non-invasive method”, defensor Prof.
Dr. G. Flamini, co-defensor Prof. Dr. A. R. M. Cittadini, Oncology Department.
- October 1996- July 2002 Medical School at Università Cattolica Sacro Cuore, Rome, Italy
- 1991-1996: Secondary School Diploma, Benevento (60/60), at the Gymnasium Lyceum
“Pietro Giannone”, Benevento, Italy

FURTHER EDUCATION

- April 2010: Advanced Life Support-D intensive training, organized by IRC (Italian
Resuscitation Council) at IEO, Milan, Italy
- November 2007: Basic Life Support-Defibrillator intensive training; organized by IRC
(Italian Resuscitation Council) at Cardiological Hospital “Monzino”, Milan, Italy
- January 2007: SPSS Statistics Intensive training, UMCG Groningen, The Netherlands
- November 2005: Automatisatation for Physicians, UMCG Groningen, The Netherlands
- July 2004: Evidence Based Oncology Intensive Training, organized by ESO (European
School of Oncology), Antwerp, Belgium
- March 2004: VTM course for Safe Microbiological Techniques, UMCG Groningen, The
Netherlands

- May 2002: Basic Life Support (BLS) - B category intensive training (final exam score:- Theoretic total score 100%, Practical total score 98%) organized by IRC (Italian Resuscitation Council) at Università Cattolica Sacro Cuore, Rome, Italy
- March 1999-November 2003: Fellow at the Oncology Research Centre Giovanni XXIII - Università Cattolica del Sacro Cuore, Rome, Italy

- OTHER QUALIFICATIONS AND ACHEIVEMENTS

- May 2007: Command of Dutch language, fourth level- Letters faculty RUG University, Groningen, The Netherlands
- July 2005: Command of Dutch language NT2 Staatsexaman “Nederlands Als Tweede Taal”, for all the four the subparts writing, speaking, listening and reading- IB Groep, Groningen, The Netherlands
- May 2005: Command of Dutch language, second level- letters faculty RUG University, Groningen, The Netherlands
- May 2004: Command of the Dutch language, first level - Letters Faculty RUG University, Groningen, The Netherlands
- May 2003: Winner of Residency in Oncology at National Cancer Institute, Milan, Italy
- April 2003: Winner of Residency in Oncology at Università Cattolica Sacro Cuore, Rome, Italy
- June 1996: Classic & Contemporary Dance Diploma, Dance School Academy, Benevento, Italy
- July 1994: Command of the English language at Bootham School of English, York, UK

- SCHOLARSHIPS & PRIZES

- April 2009: December 200 April 2009: Abstract: “New Apoptosis Markers in Melanoma”. A. di Pietro, P.F.F. Ferrucci, A. Testori. AACR 2009. *Winner of BMS prize as best work of Clinical Research session.*
- November 2005: WEA (Working Experience Abroad) Scholarship, assigned from Università Cattolica “Sacro Cuore”- Rome, Italy
- November 2005: “Foundation for Education in Oncology” (Fondazione per la Formazione Oncologica) scholarship
- October 2005: Doctor Renato Russo Prize, as best young doctor of the year 2005, Ordine dei Medici e degli Odontoiatri, Benevento, Italy
- September 2005: Teaching ESO Oncology Scholarship, to attend the congress on Colorectal cancer, London 1-3 December 2005
- October 2004: Università Cattolica Sacro Cuore “Education Abroad” Scholarship

- March 2004: “Foundation for Education in Oncology” (Fondazione per la Formazione Oncologica) Scholarship
- November 2002: Leonardo da Vinci scholarship, in relation to the project L-WAY
- October 2002: FIRC (Italian Cancer Research Federation) Scholarship
- April 2002: Best student of the year Scholarship
- October 1996: INPDAP Scholarship

- INFORMATICS SKILL

- Teams\Zoom\ WeBex
- Copilot\VOX
- Microsoft Office (Word, PPT, Excel)
- Sharepoint Access
- Argos
- Sinfonia
- Sygma Plot
- SPSS ver. 12 & 14
- Acrobat Prof
- Reference Manager
- GraphPad
- Media Player/ Mediavideo- photographs

Most relevant Publications

Articles:

Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma.

Powles et al. *N Engl J Med.* 2020; DOI: 10.1056/NEJMoa2002788

Avelumab plus axitinib versus sunitinib in advanced renal cell carcinoma: biomarker analysis of the phase 3 JAVELIN Renal 101 trial

Motzer et al. *Nat Med.* 2020;

<https://doi.org/10.1038/s41591-020-1044-8>

Updated efficacy results from the JAVELIN Renal 101 trial: first-line avelumab plus axitinib versus sunitinib in patients with advanced renal cell carcinoma

Choueiri et al

Annals of Oncology 2020

Efficacy and biomarker analysis of first-line avelumab plus axitinib versus sunitinib in advanced renal cell carcinoma with sarcomatoid histology

Choueiri et al Submitted

Avelumab flat dose regimen: Justification for use in advanced renal cell carcinoma

(aRCC). Haanen J, Masters JC, Huang B, Choueiri TK, Motzer, RJ, Khandelwal A, Dai I, di Pietro A, Brar S, Rini BI, Albiges L, Larkin J. *J Clin Oncol.* 2020;83(no. 5_suppl),32.

Avelumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma.

Motzer RJ, Penkov K, Haanen J, Rini B, Albiges L, Campbell MT, Venugopal B, Kollmannsberger C, Negrier S, Uemura M, Lee JL, Vasiliev A, Miller WH Jr, Gurney H, Schmidinger M, Larkin J, Atkins MB, Bedke J, Alekseev B, Wang J, Mariani M, Robbins PB, Chudnovsky A, Fowst C, Hariharan S, Huang B, di Pietro A, Choueiri TK. *N Engl J Med.* 2019 Mar 21

Primary renal tumor shrinkage in patients who did not undergo upfront cytoreductive

nephrectomy: subgroup analysis from the phase 3 JAVELIN Renal 101 trial.

Albiges L, Rini BI, Haanen J, Motzer RJ, Kollmannsberger C, Negrier S, Nole F, Bedke J, Bilen MA, Nathan P, Tomita Y, Huang B, Ching KA, Chudnovsky A, Robbins PB, di Pietro A, Thomaidou D, Choueiri TK. *Annals of Oncology.* 2019;30(5),v356-v402.

Efficacy and biomarker analysis of patients (pts) with advanced renal cell carcinoma

(aRCC) with sarcomatoid histology (sRCC): Subgroup analysis from the phase III JAVELIN renal 101 trial of first-line avelumab plus axitinib (A 1 Ax) vs sunitinib (S)

Choueiri TK, Larkin JMG, Pal SK, Motzer RJ, Venugopal B, Alekseev BY, Miyake H, Gravis G, Billen MA, Chudnovsky A, Ching KA, Mariani M, Robbins PB, Huang B, di Pietro A, Albiges L. *Ann Oncol.* 2019;30(Supplement 5),v361.

Depth of response analysis and correlation with clinical outcomes from JAVELIN Renal 101. Voss MH, Motzer RJ, Albiges L, Rini BI, Schmidinger M, Larkin J, Haanen J, Kollmannsberger C, Campbell MT, Pal SK, Gravis G, Atkins MB, Huang B, Chudnovsky A, di Pietro A, Thomaidou D, Choueiri TK. *J Clin Oncol.* 2020;38(no. 6_suppl),690.

Avelumab plus axitinib vs sunitinib for advanced renal cell carcinoma: Japanese subgroup analysis from JAVELIN Renal 101 Uemura M, Tomita Y, Miyake H, Hatakeyama S, Kanayama HO, Numakura K, Takagi T, Kato T, Eto M, Obara W, Uemura H, Choueiri TK, Motzer RJ, Fujii Y, Kamei Y, Umeyama Y, di Pietro A, Oya M. *Cancer Sci.* 2020;111(3),907-923.

Molecular characteristics of renal cell carcinoma (RCC) risk groups from JAVELIN Renal 101 Choueiri TK, Haanen J, Larkin JMG, Rini BI, Albiges L, Motzer RJ, di Pietro A, Mu XJ, Ching KA, Hariharan S, Robbins PB. *J Clin Oncol.* 2020;38(6_suppl),744.

Evaluation of brain metastasis in JAVELIN Renal 101: Efficacy of avelumab + axitinib (A+Ax) versus sunitinib (S). Jonasch E, Hasanov E, Motzer RJ, Hariharan S, Choueiri TK, Huang B, Haanen J, Albiges L, Venugopal B, Schmidinger M, Larkin JMG, Grimm MO, Negrier S, Wang J, Mariani M, Chudnovsky A, di Pietro A, Rini BI. *J Clin Oncol.* 2020;38(6_suppl),687.

Subgroup analysis from JAVELIN Renal 101: Outcomes for avelumab plus axitinib (A + Ax) versus sunitinib (S) in advanced renal cell carcinoma (aRCC). Choueiri TK, Motzer RJ, Campbell MT, Alekseev BY, Uemura M, Kollmannsberger CK, Gravis G, Bjarnason GA, Gurney H, Chung J, Haanen JBAG, Rini BI, Larkin JMG, Schmidinger M, Nole F, Chudnovsky A, Huang B, Hariharan S, di Pietro A, Albiges L. *J Clin Oncol.* 2019;37(no. 7_suppl),544.

JAVELIN renal 101: A randomized, phase III study of avelumab + axitinib vs sunitinib as first-line treatment of advanced renal cell carcinoma (aRCC) Motzer RJ, Penkov K, Haanen JBAG, Rini BI, Albiges L, Campbell MT, Kollmannsberger CK, Negrier S, Uemura M, Lee JL, Gurney H, Berger R, Schmidinger M, Larkin J, Atkins MB, Wang J, Robbins PB, Chudnovsky A, Di Pietro A, Choueiri TK. *Ann Oncol.* 2018;29(suppl_8),LBA6_PR.

Biomarker analyses from JAVELIN Renal 101: Avelumab + axitinib (A+Ax) versus sunitinib (S) in advanced renal cell carcinoma (aRCC). Choueiri TK, Albiges L, Haanen JBAG, Larkin JMG, Uemura M, Pal SK, Gravis G, Campbell MT, Penkov K, Lee JL, Ching KA, Mu XJ, Wang X, Zhang W, Wang J, Chudnovsky A, di Pietro A, Robbins PB, Motzer RJ. *J Clin Oncol.* 2019;37(15_suppl),101.

Preliminary results for avelumab plus axitinib as first-line therapy in patients with advanced clear-cell renal-cell carcinoma (JAVELIN Renal 100): an open-label, dose-finding and dose-expansion, phase 1b trial. Choueiri TK¹, Larkin J², Oya M³, Thistlethwaite F⁴, Martignoni M⁵, Nathan P⁶, Powles T⁷, McDermott D⁸, Robbins PB⁹, Chism DD¹⁰, Cho D¹¹, Atkins MB¹², Gordon MS¹³, Gupta S¹⁴, Uemura H¹⁵, Tomita Y¹⁶, Compagnoni A⁵, Fowst C⁵, di Pietro A⁵, Rini BI¹⁷. *Lancet Oncol.* 2018 Apr;19(4):451-460

Potential impact of avelumab+axitinib (A+Ax) on tumor size (TS) compared with historical data of sunitinib (S) as evaluated by a modeling and simulation (MS) approach Zheng J, Chang A, Larkin J, Motzer RJ, Amantea M, Bello C, Pavlov D, Geraldles M, Martignoni M, Di Pietro A, Andrews G. *Ann Oncol.* 2017;28(suppl_5),882P.

JAVELIN renal 101: a phase 3 study of avelumab in combination with axitinib vs sunitinib as first-line treatment for patients with advanced renal cell carcinoma (aRCC). Choueiri TK, Rini BI, Cosgriff T, Miyake H, Vogelzang NJ, Kannourakis G, Mariani M, Chiruzzi C, Albiges L, Haanen JB, Schmidinger M, Magazzu D, Di Pietro A, Motzer RJ. *BJU Int.* 2016;118(S5),29.

Phase 3 study of avelumab in combination with axitinib versus sunitinib as first-line treatment for patients with advanced renal cell carcinoma (aRCC). Motzer RJ, Choueiri T, Larkin J, Albiges L, Haanen JB, Schmidinger M, Atkins MB, Mariani M, Shnaidman M, Di Pietro A, Rini BI. *Ann Oncol.* 2016;27(Supplement 6),vi266-vi295.

Phase 1b dose-finding study of avelumab (anti-PD-L1) + axitinib in treatment-naïve patients with advanced renal cell carcinoma Larkin J, Rini BI, Nathan P, Thistlethwaite F, Gordon M, Martignoni M, Magazzu D, Chiruzzi C, Di Pietro A, Choueiri TK. *Ann Oncol.* 2016;27(Supplement 6),vi266-vi295.

Avelumab (MSB0010718C; anti-PD-L1) in combination with axitinib as first-line treatment for patients with advanced renal cell carcinoma Larkin J, Gordon M, Thistlethwaite F, Nathan P, Rini BI, Martignoni M, Shnaidman M, Chiruzzi C, Di Pietro A, Choueiri TK. *J Clin Oncol.* 2016;34(no.15_suppl)

CTLA4 blockade in mesothelioma: finally a competing strategy over cytotoxic/target therapy? Calabrò L, Ceresoli GL, di Pietro A, Cutaia O, Morra A, Ibrahim R, Maio M. *Cancer Immunol Immunother.* 2015 Jan;64(1):105-12. doi: 10.1007/s00262-014-1609-9. Epub 2014 Sep 19

Randomized, double-blind, placebo-controlled study of tremelimumab for second- and third-line treatment of unresectable pleural or peritoneal mesothelioma. Michele Maio, Scherpereel A, di Pietro A, Vasey P, Tsao A S, Calabrò L, Fu D, Robbins P B, Ibrahim R A, Kindler H L. *ASCO 2014. J Clin Oncol* 32:5s, 2014 (suppl; abstr TPS7609^)

Phase 1 study of MEDI4736, an anti-PD-L1 antibody, in combination with dabrafenib and trametinib or trametinib alone in patients with unresectable or metastatic melanoma. Gordon M S, Lutzky J, Lawrence D P, Orford K W, Blake-Haskins A, di Pietro A, Robbins P B, Dar M M, Ribas A. *ASCO 2014. J Clin Oncol* 32:5s, 2014 (suppl; abstr TPS9108)

A phase 2 randomized, double-blind, placebo-controlled study of tremelimumab for second and third line treatment in patients with unresectable pleural or peritoneal mesothelioma Lee Krug, Alessandra di Pietro, Rajesh Narwal, Paul Robbins, Dongyue Fu, Aiman Shalabi, Ramy Ibrahim, Luana Calabro, Hedy Kindler. *Journal for ImmunoTherapy of Cancer* 2013, 1(Suppl 1):P132

Pro- and anti-apoptotic effects of p53 in cisplatin-treated human testicular cancer are cell context-dependent. di Pietro A, Koster R, Boersma-van Eck W, Dam WA, Mulder NH, Gietema JA, de Vries EG, de Jong S. *Cell Cycle*. 2012 Nov 19;11(24).

Newly Identified Tumor Antigens as Promising Cancer Vaccine Targets for Malignant Melanoma treatment. Ferrucci PF, Tosti G, di Pietro A, Passoni C, Pari C, Tedeschi I, Cataldo F, Martinoli C, Testori A. *Curr Top Med Chem*. 2012 Jan.

The immunological era in melanoma treatment: new challenges for heat shock protein-based vaccine in the advanced disease. di Pietro A, Tosti G, Ferrucci PF, Testori A. *Expert Opin Biol Ther*. 2011 Oct.

Hormonal and reproductive factors in relation to melanoma in women: current review and meta-analysis. Gandini S, Iodice S, Koomen E, Di Pietro A, Sera F, Caini S. *Eur J Cancer*. 2011 Nov.

Cytoplasmic p21 expression levels determine cisplatin resistance in human testicular cancer. Koster R, di Pietro A, Timmer-Bosscha H, Gibcus JH, van den Berg A, Suurmeijer AJ, Bischoff R, Gietema JA, de Jong S. *J Clin Invest*. 2010 Oct 1;120(10):3594-605.

Electrochemotherapy for cutaneous and subcutaneous tumor lesions: a novel therapeutic approach. Testori A, Tosti G, Martinoli C, Spadola G, Cataldo F, Verrecchia F, Baldini F, Mosconi M, Soteldo J, Tedeschi I, Passoni C, Pari C, Di Pietro A, Ferrucci PF. *Dermatol Ther*. 2010 Nov;23(6):651-61. Review.

Presentation of multicentric trial about sentinel node identification with sentinella intraoperative gamma camera versus traditional gamma probe. A. Testori, F. Verrecchia, J. Soteldo, A. Di Pietro, G. Spadola, G.C. Vitali, F. Cataldo, C. Pari and P.F. Ferrucci *Melanoma Research: June 2010 - Volume 20 - Issue - p e52-53* doi: 10.1097/01.cmr.0000382853.14512.34 **MELANOMA II: Surgery - Staging-Prognosis**

Meeting report from the Third Global Workshop on Melanoma. Agarwala SS, di Pietro A, Flaherty KT, Garbe C, Grob JJ, Kashani-Sabet M, Kirkwood JM, Leachman S, Messina J, O'Day S, Ribas A, Sondak V. *Pigment Cell Melanoma Res*. 2010 Oct;23(5):e1-7.

Metronomic administration of pegylated liposomal-doxorubicin in extensively pre-treated metastatic breast cancer patients: A mono-institutional case-series report. Munzone E, Di Pietro A, Goldhirsch A, Minchella I, Verri E, Cossu Rocca M, Marengi C, Curigliano G, Radice D, Adamoli L, Nolè F. *Breast*. 2010

Heat shock protein peptide complex 96-based vaccines in melanoma: How far we are, how far we can get. di Pietro A*, Tosti G*, (*) *Co-authors*, Ferrucci PF, Testori A. *Hum Vaccin*. 2009 Nov 23.

HSPPC-96 vaccine in metastatic melanoma patients: from the state of the art to a possible future. Tosti G*, di Pietro A*, (*) *Co-authors*, Ferrucci PF, Testori A. *Expert Rev Vaccines*. 2009 Nov.

Adjuvant therapy of melanoma. Agarwala S. di Pietro A. *AJHO* May 2009 8, (5)

Biology and clinical use of heat shock proteins GP96 in cancer patients. G. Parmiani, A. M. Di Filippo, L. Pilla, C. Castelli, L. Rivoltini, M. Maio, M. Santinami, V. Mazzaferro, A. di Pietro, A. Testori. *J Immunotherapy. Submitted and accepted*

Oncophage: step to the future for vaccine therapy in melanoma. di Pietro A*, Tosti G*, (*) *Co-authors*, Ferrucci PF, Testori A. *Expert Opin Biol Ther*. 2008 Dec;8(12):1973-84.

Clinical evaluation of M30 and M65 ELISA cell death assays as circulating biomarkers in a drug-sensitive tumor, testicular cancer. de Haas EC*, di Pietro A*, (*) *Co-authors*, Simpson KL, Meijer C, Suurmeijer AJ, Lancashire LJ, Cummings J, de Jong S, de Vries EG, Dive C, Gietema JA. Neoplasia. 2008 Oct

Basosquamous carcinoma of the thoracic: A case report. J Soteldo, L Jimenez, F Verrecchia, G Mazzarol, F De Lorenzi, F Baldini, A di Pietro, A Testori. Division of Melanoma and Sarcoma, European Institute of Oncology, Milan, Italy. The American Journal of Case Report. 2008; 9: 355-358

The treatment of cutaneous and subcutaneous lesions with electrochemotherapy with bleomycin” J. Soteldo, A. di Pietro, G. Tosti, M. Mosconi, F. Baldini, M. Rastrelli, G. Spadola, G. F. Verrecchia and A. Testori. Division of Melanoma and Sarcoma, European Institute of Oncology, Milan, Italy. Internet Article April 2008. http://www.gmmm.com.ve/articulos_01-2010/art_treatmentCutaneous.htm

Testicular germ cells Tumours: the paradigm of chemo- sensitive solid tumour, di Pietro A, de Vries EGE, Gietema JA, Spierings. DCJ and de Jong, S. - Int J Bio Cell Biol 37 (2005) 2437-2456.

Oral Presentation:

ASCO 2020

Maintenance avelumab + best supportive care (Ave + BSC) vs BSC alone after platinum-based first-line (1L) chemotherapy (CTx) in advanced urothelial carcinoma (aUC): results from the JAVELIN Bladder 100 phase 3 trial.

Powles et al ASCO 2020

ASCO 2019

Biomarker analyses from JAVELIN Renal 101: avelumab + axitinib vs sunitinib in advanced renal cell carcinoma

Haanen et al

ASCO-GU 2019

Subgroup analysis from JAVELIN Renal 101: Outcomes for avelumab plus axitinib (A + Ax) versus sunitinib (S) in advanced renal cell carcinoma (aRCC)

Choueiri T, Albiges L, Haanen J, Larkin J, Uemura M, Pal S, et al.

ESMO 2018

JAVELIN Renal 101: Randomised, phase 3 study of avelumab + axitinib vs sunitinib as first-line treatment of advanced renal cell carcinoma.

Motzer et al

ESMO 2018

Asco 2017

First-line avelumab + axitinib therapy in patients with advanced renal cell carcinoma: results from a phase 1b trial. T. K. Choueiri, J. Larkin, M. Oya, F. Thistlethwaite, M. Martignoni, P. Nathan, T. Powles, D. McDermott, P. B. Robbins, D. D. Chism, D. Cho, M. B. Atkins, M. S. Gordon, S. V. Gupta, H. Uemura, Y. Tomita, A. Compagnoni, A. di Pietro, B. I. Rini

Abstracts:

ASCO 2017

Avelumab plus axitinib vs sunitinib as first-line treatment of advanced renal cell carcinoma: phase 3 study (JAVELIN Renal 101) T. K. Choueiri, B. I. Rini, J. Larkin, G. A. Bjarnason, G. Gravis, H. P. Gurney, J. L. Lee, D. Keizman, J. B. Haanen, Y. Tomita, H. Uemura, L. Albiges, M. Schmidinger, M. B. Atkins, M. Mariani, M. Shnaidman, A. di Pietro, R. J. Motzer

SITC 2016

Avelumab in combination with axitinib versus sunitinib as first-line treatment for patients with advanced renal cell carcinoma: the phase III JAVELIN Renal 101 trial
B. I. Rini, T. K. Choueiri, M. Mariani, L. Albiges, J. B. Haanen, M. B. Atkins, J. Larkin, M. Schmidinger, D. Magazzù, A. di Pietro, R. J. Motzer

IKCS 2016

JAVELIN Renal 101: a phase 3 study of avelumab in combination with axitinib vs sunitinib as first-line treatment for patients with advanced renal cell carcinoma (aRCC)

Choueiri TK, Rini BI, Cosgriff T, Miyake H, Vogelzang N, Kannourakis G, Mariani M, Chiruzzi C, Albiges L, Haanen J, Larkin J, Atkins M, Schmidinger, Magazzù D, di Pietro A, Motzer RJ

ESMO 2016

Phase 1b dose-finding study of avelumab (anti-PD-L1) + axitinib in treatment-naïve patients with advanced renal cell carcinoma

Larkin J, Rini BI, Nathan P, Thistlethwaite F, Gordon M, Martignoni M, Magazzu D, Chiruzzi C, di Pietro A, Choueiri TK

Phase 3 study of avelumab in combination with axitinib versus sunitinib as first-line treatment for patients with advanced renal cell carcinoma (aRCC).

Motzer RJ, Choueiri TK, Larkin J, Albiges L, Haanen JB, Schmidinger M, Atkins MB, Mariani M, Shnaidman M, di Pietro A, Rini BI

ASCO 2016

Avelumab (MSB0010718C; anti-PD-L1) in combination with axitinib as first-line treatment for patients with advanced renal cell carcinoma

Larkin J, Gordon M, Thistlethwaite F, Nathan P, Rini BI, Martignoni M, Shnaidman M, Chiruzzi C, di Pietro A, Choueiri T

IMIG 2014

Randomized, Double-blind, Placebo-controlled Study of Tremelimumab for Second- and Third-line Treatment of Unresectable Pleural or Peritoneal Mesothelioma. A. Scherpereel, R. Cornelissen, A. Di Pietro, H.L. Kindler, K. Nackaerts, S.J. Antonia, L. Calabrò, D. Fu, P.B. Robbins, R. Ibrahim, M. Maio

ACCELERATING RECRUITMENT TO MESOTHELIOMA CLINICAL TRIALS

H. Mortimer, M. Phillips, A. Scherpereel, A. di Pietro, K. Nackaerts, L. Calabrò, D. Fu, P. B. Robbins, J. G. Aerts

ESMO 2014

RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF TREMELIMUMAB FOR SECOND-LINE AND THIRD-LINE TREATMENT OF UNRESECTABLE PLEURAL OR PERITONEAL MESOTHELIOMA

A. Scherpereel, R. Cornelissen, A. Di Pietro, H.L. Kindler, K. Nackaerts, S.J. Antonia, L. Calabrò, D. Fu, P.B. Robbins, R. Ibrahim, M. Maio. *Annals of Oncology*, Volume 25, Supplement 4, 2014

Phase 1 Study of MEDI4736, an Anti-PD-L1 Antibody, in Combination with Dabrafenib and Trametinib or Trametinib Alone in Patients with Unresectable or Metastatic Melanoma. M. Gordon, J. Lutzky, D. Lawrence, M. Butler, P.A. Ascierto, B. Hug, A. Blake-Haskins, A. Di Pietro, X. Li, P.B. Robbins, M.M. Dar, A. Ribas

ASCO 2014

Randomized, double-blind, placebo-controlled study of tremelimumab for second- and third-line treatment of unresectable pleural or peritoneal mesothelioma. M. Maio, A. Scherpereel, A. Di Pietro, P. Vasey, A. S. Tsao, L. Calabrò, D. Fu, P. B. Robbins, R. A. Ibrahim and H. L. Kindler. *Journal of Clinical Oncology*, 2014 ASCO Annual Meeting Abstracts. Vol 32, No 15_suppl (May 20 Supplement), 2014: TPS7609

Phase 1 Study of MEDI4736, an Anti-PD-L1 Antibody, in Combination with Dabrafenib and Trametinib or Trametinib Alone in Patients with Unresectable or Metastatic Melanoma. M. Gordon, J. Lutzky, D. Lawrence, K. Orford, A. Blake-Haskins, A. Di Pietro, P. B. Robbins, M. M. Dar, A. Ribas. Abstract ID TPS9108

Phase I (GefTrem), open-label, safety, tolerability and preliminary efficacy study of gefitinib (Gef) in combination with tremelimumab (Trem) in patients with EGFR mutant NSCLC. D. Planchard, N. Chaput-Gras, N. Byrne, F. Barlesi, J. Mazieres, D. Vuillier, L. Lacroix, B. Besse, E. Lanoy, F. Wunder, C. Jannin, M. Ducourtieux, M. Ngocamus, A. F Nash, A. Di Pietro, J-C. Soria

SITC 2013

A phase 2 randomized, double-blind, placebo-controlled study of tremelimumab for second and third line treatment in patients with unresectable pleural or peritoneal mesothelioma. L. Krug, A. di Pietro, R. Narwal, P. Robbins, D. Fu, A. Shalabi, R. Ibrahim, L. Calabro, H. Kindler. Journal for ImmunoTherapy of Cancer 2013, 1(Suppl 1):P132

WCLC 2013

A randomized, double blind study comparing Tremelimumab ro Placebo in second and third line treatment of subjects with unresectable pleural or peritoneal mesothelioma. Kindler H.L., di Pietro A., Robbins P., Hong S., Shalabi A., Ibrahim R., Calabro L., Maio M. Journal of Thoracic Oncology 2013 v. 8 S2

AACR 2011

B-Raf, c-KIT, VEGFR and MGMT Expression Analysis in Advanced Melanoma (MM) Patients (pts) Treated With Dacarbazine (DTIC) + Bevacizumab (B): correlation with response and survival. A. di Pietro, M. Barberis, C. Martinoli, M. Manzotti, C. Passoni, C. Pari, M. Mosconi, F. Cataldo, S. Gandini, A. Testori, P.F. Ferrucci

The M-SKIP Project: an international pooled-analysis on melanocortin-1 receptor (MC1 R) variants and skin carcinogenesis. S. Gandini, A. di Pietro, P. Maisonneuve, P. Autier, M. C. Fargnoli, J. C. García-Borrón, J. Han, P. A. Kanetsky, M. T. Landi, J. Little, J. Newton-Bishop, F. Sera and Sara Raimondi

EORTC-MG Perspectives, Amsterdam 2010

Evaluation of maspin expression in primary tumors of melanoma patients: evidences for prognostic significance. Ferrucci P.F., di Pietro A. et al

ASCO Annual Meeting 2010

Dacarbazine (DTIC) + Bevacizumab (B) in Chemotherapy (CTh)-naïve Advanced Melanoma (MM) Patients (pts): a Phase II Study A. di Pietro, P.F. Ferrucci, E. Munzone*, M. Mosconi, S. Gandini, C. Pari, F. Cataldo, F. Nolè, I. Minchella, A Testori

Electrochemotherapy with bleomycin: a local treatment with possible systemic implication. A. Testori; F. Verrecchia; J. Soteldo; P.F. Ferrucci; C. Martinoli; S. Gandini; A. di Pietro

ASCO Annual Meeting 2009, Orlando June 2009

Circulating endothelial cells (CECs), progenitors (CEPs), and circulating tumor cells (CTCs) for prediction of response in patients with advanced breast cancer (ABC) receiving metronomic oral vinorelbine (oV): Preliminary results. F. Nole, E. Munzone, F. Bertolini, M. T. Sandri, G. Petralia, L. Adamoli, D. Radice, D. Cullura, A. di Pietro, A. Goldhirsch

EORTC-MG Spring 2009, Bruxelles March 2009:

Role of the SOS-1-Rac signalling pathway in melanoma progression A. di Pietro, G. Tosti, S. Gerboth, A. Palamidessi, C. Loise, G. Mazzarol, P. P. Di Fiore, P.F. Ferrucci, A. Testori, G. Scita

AACR Annual Meeting 2009:

Apoptosis markers: A feasible tool to improve prognosis definition and to define therapy response in melanoma A. di Pietro, P.F. Ferrucci, G. Mazzarol, A. Testori

EORTC Fall 2009, Leeds October 2009:

Characterization of cytokeratin 18 expression in malignant melanoma cells: evaluation of a novel biomarker to monitor therapy response. A. di Pietro, C. Martinoli, P.F. Ferrucci, A. Testori

XXI National Congress of Società Polispecialistica Italiana Giovani Chirurghi, June 2008:

A Retrospective Review of Sentinel Node Biopsy for High-Risk Cutaneous Non-Anogenital Squamous Cell Carcinoma, M. Rastrelli, M. Zonta, J. Soteldo, F. Verrecchia, G. Tosti, G. Spadola, A. di Pietro, A. Testori.

1st World Meeting of Interdisciplinary Melanoma Centers, Barcelona, Spain, Sept 2007

New markers of apoptosis: a feasible tool to improve prognostic accuracy and to monitor therapeutic response in melanoma patients. di Pietro A, Zonta M., Jimenez L., Tosti G., Ferrucci P.F., Mazzarol G., Testori A.

Safety, feasibility and toxicity profile of a new immunotherapy protocol for metastatic melanoma patients using in vivo Salmonella typhimurium vaccination and treatment. P. F. Ferrucci, C. Martinoli, A. di Pietro, M. Rastrelli, A. Testori, M. Rescigno

Atypical Spitz nevus and Spitz tumour: a report of 14 cases. G. Tosti, L. Jimenez, A. di Pietro, A. Testori, G. Mazzarol

5th Apoptosis Meeting, “Death among the tulips”, Kerkrade, The Netherlands, May 2006

The p53 pathway effects on cisplatin-induced apoptosis in Testicular Germ Cell Tumours cell lines, depending on the cellular context. A. di Pietro, R. Koster, J. A. Gietema, S. de Jong

97th AACR Annual Meeting, Washington, D.C., USA

p21^{Cip1/Waf1} over-expression protects human testicular germ cell tumour cells from cisplatin induced apoptosis. R. Koster, A. di Pietro, H. Timmer-Bosscha, H. Schepers, R. Bischoff, J. A. Gietema, S. de Jong

The p53 pathway affects cisplatin-induced apoptosis in human testicular germ cell lines depending on the cellular context A. di Pietro, R. Koster, W.A. Dam, N.H. Mulder, J. A. Jourik, E.G. E. de Vries, S. de Jong, *Oncogene; Submitted*

Invited speaker

- January 2011: Ground Rounds for ECM, IEO, Milan Italy. “Melanoma and Cellular Senescence: *a possible step forward in Melanoma treatment?*”
- September 2010: EORTC-Melanoma Group Meeting, Amsterdam, NL. “Dacarbazine (DTIC) + Bevacizumab (B) in Chemotherapy (CTh)-naïve Advanced Melanoma (MM) Patients (pts): a Phase II Study”
- January 2010: Ground Rounds for ECM, IEO, Milan Italy. Anti-angiogenesis: a promising path in the treatment of advanced melanoma”
- November 2009: Faculty Panel Member at Premeeting Third Global Workshop on Malignant Melanoma, Berlin Germany. “Intra-lesional treatment options in melanoma”
- October 2009: EORTC- Melanoma Group Meeting, Leeds, UK. “Characterization of Cytokeratin 18 expression in malignant melanoma cells: evaluation of a novel biomarker to monitor therapy response”
- October 2009: IMI- Italian Melanoma Intergroup Annual Meeting 2009, Genoa Italy. “New Therapy Protocols in Advanced Melanoma”
- March 2009: EORTC-Melanoma Group Meeting, Bruxelles Belgium. “Role of the SOS-1 Rac signalling pathway in melanoma progression”
- September 2008: Ground Rounds for ECM, IEO, Milan Italy. “Anti-CTLA4 Treatment in metastatic Melanoma: IEO experience”.
- June 2008: ICATMM-EADO Meeting 2008, Marseille, France. “Combining chemotherapy and targeted therapy”.
- June 2008: ICATMM-EADO Meeting 2008, Marseille, France. “New apoptosis markers: a feasible tool to improve prognosis definition and to define therapy response”
- January 2008: “Insieme oltre la malattia” (Together beyond cancer disease), Belluno Italy
- November 2007: Diagnosis and treatment of malignant melanoma. “Adjuvant therapy in Melanoma” & “Advanced Melanoma Management”, Caracas Venezuela
- October 2005: “Cancers in the Elderly” Telese Terme, Benevento, Italy. “Bladder cancer”

Leisure activities

- Philosophy & Foreign Languages
- Italian, Greeks and Latin Literatures
- Tango and Caribbean Dances (Competition Level)
- Aerobics and fitness
- Reading, travelling
- Volunteer at reception centers for poor people