MARIO BIGIONI
CURRICULUM VITAE

PERSONAL DETAILS

Last Name: Bigioni
First Name: Mario
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Languages: Mother tongue(s) Italian. Other language: English

EDUCATION AND QUALIFICATIONS

2009 **Ph.D. in Body Composition and Human Physiology**.
Division of Clinical Nutrition and Nutrigenomics, Faculty of Surgery and Medicine, "Tor Vergata" University, Rome, Italy.
PhD thesis title "Role of genetics polymorphism in the Normal Weight Obese syndrome". Supervisor, Prof. Antonino De Lorenzo.

2006 State exam for professional qualification in the National Board of **Biologists.**

2006 **M.Sc. Degree in Science of Human Nutrition.**
Faculty of Science, "Tor Vergata" University, Rome, Italy. Thesis title: "Role of IL-6 polymorphism in the hematochemistry parameters of human subjects affected by De Lorenzo syndrome". Supervisor, Prof. Antonino De Lorenzo.

1999 **Specialist in Pharmacology**, achieved at the Specialty School of Pharmacology, Department of Pharmacology, Faculty of Surgery and Medicine, "La Sapienza" University, Rome, Italy. Thesis tile: "Survey data system on the risk factors in the clinical evolution of the diabetic retinopathy". Supervisor: Prof. Angelo Serio.

1990 State exam for professional qualification in the National Board of **Pharmacists.**

1990 **M.Sc. Degree in Pharmacy**. Faculty of Pharmacy, "La Sapienza" University, Rome, Italy. Thesis title: "X-Ray effects on the differentiation of L5 myoblast cell line". "La Sapienza" University, Rome, Italy. Supervisor: Prof. Roberto Strom.

SUMMARY

- **From 1985 to 1990, "La Sapienza University" Rome, Italy**. Undergraduate student at the Department of Human Biopathology, Faculty of Surgery and Medicine, "La Sapienza" University, preparing the experimental thesis, under the supervision of Prof. Roberto Strom. The research carried out during this period was focused on the characterization of X-ray effects on the differentiation of myoblast cell line and the susceptibility to X-Ray damage and repair during in vitro myogenesis. It was also investigated the role of DNA methylation on the differentiation of myoblast cells. Primary areas of study, included: Organic Chemistry, Inorganic Chemistry, Medicinal Chemistry, Biochemistry, Pharmacology, Human anatomy, Physiology, Physics, Botany and related fields.

- **From 1991 to 1994, Istituto Nazionale Studio e Cura dei Tumori, Milan, Italy**. Associated researcher at the Laboratory of Experimental Oncology B, Istituto Nazionale per lo Studio e la Cura dei Tumori, Milan, Director Dr. Franco Zunino. The research carried out in this period of time concerned the role of DNA Topoisomerases as target of antitumor drugs, supervisor Dr. Giovanni Capranico. The research activity was also focused on the development of in vitro and in vivo assays for the preclinical characterization of new therapeutics, with a particular emphasis on in vivo modelling of human tumor xenografts.

- **From 1994 to actually, Menarini Ricerche, Pomezia, Italy.** Staff scientist as Pharmacologist at the Pharmacology Department of Menarini Ricerche in Pomezia, Rome, Italy. During this period of time was covered the position of Pharmacologist in the Pharmacology Department. The experimental activities were focused on the use and development of human tumor models useful for the preclinical development of new identified therapeutics. During this period of time were also covered the positions of: a) component of the projects teams; b) Project leader in the drug discovery projects.

WORK EXPERIENCE

1990-1991	Guest researcher at the Department of Human Biopathology, "La Sapienza" University, Rome. The research carried out during this period was focused on the role of DNA methylation on myoblast differentiation.
1990-1991	Professional experience as Pharmacist in local pharmacies of Rome urban area.
1991-1994	Associated researcher at the Laboratory of Experimental Oncology B, Istituto Nazionale per lo Studio e la Cura dei Tumori, Milan, Director Dr. Franco Zunino. The research carried out in this period of time was under the supervision of Dr. Giovanni Capranico, concerned the role of DNA Topoisomerases as target of antitumor drugs. The research activity was also focused on the development of in vitro and in vivo assays for the preclinical characterization of new therapeutics, with a particular emphasis on in vivo modelling of human tumor xenografts.
From 1994	Staff scientist as Pharmacologist at Menarini Ricerche in Pomezia, Rome Italy.
From January 1997	Head of Experimental Oncology Laboratory, in the Pharmacology Department of Menarini Ricerche, Pomezia, Italy. Principal investigator in the field of experimental oncology with a particular emphasis on in vivo pharmacology of new antitumor agents. The main activity was also focused on the development of cell-based and cell-free in vitro assays for large scale random screening of chemicals, with pharmacological activity on oncology relevant targets such as Topoisomerases and Histone Deacetylase (HDAC). The experimental activity was also oriented to establish a new in vivo models, representative of human pathology and

suitable for the evaluation of antitumor activity of new agents. Supervisor Prof. Federico Maria Arcamone.

Project team member: Identification and development of new antitumor drugs for the treatment of solid tumors.

Project team member: New topoisomerase I inhibitors.

Project leader: Discovery and identification of new HDAC inhibitors.

Actual position

Staff scientist as Pharmacologist at Menarini Ricerche. Head of Laboratory of Tumor models and Pharmacodynamics, in the Experimental and Translational Oncology Department of Menarini Ricerche, Pomezia, Rome, Italy.

Responsible person for research project according to European Direttive 2010/63/EU and the Italian law D.Lgs. 26/2014.

SCIENTIFIC MEMBERSHIP

- Member of the American Association for Cancer Research (AACR) since 1996.
- Member of the Italian Cancer Society (SIC) since 1997.
- Member of the European Association for Cancer Research (EACR) since 2002.
- Member of the reviewer boards in the international journals.

- Attendance at international meeting and author/co-author of more than 50 publications in peer reviewed journals and inventor on international patents.

SCIENTIFIC PUBBLICATIONS

1. Gaudio E, Tarantelli C, Spriano F, Guidetti F, Sartori G, Bordone R, Arribas AJ, Cascione L, Bigioni M, Merlino G, Fiascarelli A, Bressan A, Mensah AA, Golino G, Lucchini R, Bernasconi E, Rossi D, Zucca E, Stussi G, Stathis A, Boyd RS, Dusek RL, Bisht A, Attanasio N, Rohlff C, Pellacani A, Binaschi M, Bertoni F. Targeting CD205 with the antibody drug conjugate MEN1309/OBT076 is an active new therapeutic strategy in lymphoma models. ***Haematologica, 2020*** Jan 9.
2. Merlino G, Fiascarelli A, Bigioni M, Bressan A, Carrisi C, Bellarosa D, Salerno M, Bugianesi R, Manno R, Bernadó Morales C, Arribas J, Dusek RL, Ackroyd JE, Pham PH, Awdew R, Aud D, Trang M, Lynch CM, Terrett J, Wilson KE, Rohlff C, Manzini S, Pellacani A, Binaschi M. MEN1309/OBT076, a First-In-Class Antibody-Drug Conjugate Targeting CD205 in Solid Tumors. ***Mol Cancer Ther. 2019***, Sep;18(9):1533-1543.
3. Colangelo T, Polcaro G, Ziccardi P, Pucci B, Muccillo L, Galgani M, Fucci A, Milone MR, Budillon A, Santopaolo M, Votino C, Pancione M, Piepoli A, Mazzoccoli G, Binaschi M, Bigioni M, Maggi CA, Fassan M, Laudanna C, Matarese G, Sabatino L, Colantuoni V. Proteomic screening identifies calreticulin as a miR-27a direct target repressing MHC class I cell surface exposure in colorectal cancer. ***Cell Death Dis. 2016***, 7: e2120.
4. Marastoni E, Bartoli S, Berettoni M, Cipollone A, Ettorre A, Fincham CI, Mauro S, Paris M, Porcelloni M, Bigioni M, Binaschi M, Nardelli F, Parlani M, Maggi CA, Paoli P, Rossi P, Fattori D. Benzofused hydroxamic acids: Useful fragments for the preparation of histone deacetylase inhibitors. Part 2: 7-Fluorobenzothiophenes and benzofurans.. ***Bioorg Med Chem Lett. 2015*** Feb 24;25, 1603-1606.

5. Colangelo T, Fucci A, Votino C, Sabatino L, Pancione M, Laudanna C, Binaschi M, Bigioni M, Maggi CA, Parente D, Forte N, Colantuoni V. MicroRNA-130b promotes tumor development and is associated with poor prognosis in colorectal cancer. ***Neoplasia. 2013*** Oct;15(10):1218-31.

6. Marastoni E, Bartoli S, Berettoni M, Cipollone A, Ettorre A, Fincham CI, Mauro S, Paris M, Porcelloni M, Bigioni M, Binaschi M, Nardelli F, Parlani M, Maggi CA, Fattori D. Benzofused hydroxamic acids: Useful fragments for the preparation of histone deacetylase inhibitors. Part 1: hit identification. ***Bioorg Med Chem Lett. 2013*** Jul 15;23(14):4091-5.

7. Bellarosa D, Bressan A, Bigioni M, Parlani M, Maggi CA, Binaschi M. SAHA/Vorinostat induces the expression of the CD137 receptor/ligand system and enhances apoptosis mediated by soluble CD137 receptor in a human breast cancer cell line. ***Int J Oncol. 2012*** Oct;41(4):1486-94.

8. Bigioni M, Ettorre A, Felicetti P, Mauro S, Rossi C, Maggi CA, Marastoni E, Binaschi M, Parlani M, Fattori D. Set-up of a new series of HDAC inhibitors: the 5,11-dihydrodibenzo[b,e]azepin-6-ones as privileged structures. ***Bioorg Med Chem Lett. 2012*** Sep 1;22(17).

9. Animati F, Berettoni M, Bigioni M, Binaschi M, Cipollone A, Irrissuto C, Nardelli F, Olivieri L. Synthesis and biological evaluation of rebeccamycin analogues modified at the imide moiety. ***Bioorg Med Chem Lett. 2012*** Aug 1;22(15):5013-7.

10. Rossi C, Fincham CI, D'Andrea P, Porcelloni M, Ettorre A, Mauro S, Bigioni M, Binaschi M, Maggi CA, Nardelli F, Parlani M, Fattori D. 4-N-Hydroxy-4-[1-(sulfonyl)piperidin-4-yl]-butyramides as HDAC inhibitors. ***Bioorg Med Chem Lett. 2011*** Nov 15;21(22):6767-9.

11. Sacco G, Evangelista S, Manzini S, Parlani M, Bigioni M. Combined antihypertensive and cardioprotective effects of nebivolol and hydrochlorothiazide in spontaneous hypertensive rats. ***Future Cardiol. 2011*** Nov;7(6):757-63.

12. Rossi C, Porcelloni M, D'Andrea P, Fincham CI, Ettorre A, Mauro S, Squarcia A, Bigioni M, Parlani M, Nardelli F, Binaschi M, Maggi CA, Fattori D. Alkyl piperidine and piperazine hydroxamic acids as HDAC inhibitors. ***Bioorg Med Chem Lett. 2011*** Apr 15;21(8):2305-8.

13. Binaschi M, Simonelli C, Goso C, Bigioni M, Maggi CA. Maintenance therapy in ovarian cancer: Molecular basis and therapeutic approach. ***Exp Ther Med. 2011*** Mar;2(2):173-180.

14. Binaschi M, Boldetti A, Gianni M, Maggi CA, Gensini M, Bigioni M, Parlani M, Giolitti A, Fratelli M, Valli C, Terao M, Garattini E. Antiproliferative and differentiating activities of a novel series of histone deacetylase inhibitors. ***ACS Med Chem Lett. 2010*** Jul 20;1(8):411-5.

15. Bressan A, Bigioni M, Bellarosa D, Nardelli F, Irrissuto C, Maggi CA, Binaschi M. Induction of a less aggressive phenotype in human colon carcinoma HCT116 cells by chronic exposure to HDAC inhibitor SAHA. ***Oncol Rep. 2010*** Nov;24(5):1249-55.

16. Carbonelli MG, Di Renzo L, Bigioni M, Di Daniele N, De Lorenzo A, Fusco MA. Alpha-lipoic acid supplementation: a tool for obesity therapy? ***Curr Pharm Des. 2010***;16(7):840-6.

17. De Lorenzo A, Noce A, Bigioni M, Calabrese V, Della Rocca DG, Di Daniele N, Tozzo C, Di Renzo L. The effects of Italian Mediterranean organic diet (IMOD) on health status. ***Curr Pharm Des. 2010***;16(7):814-24.

18. Bigioni M, Parlani M, Bressan A, Bellarosa D, Rivoltini L, Animati F, Crea A, Bugianesi R, Maggi CA, Manzini S, Binaschi M. Antitumor activity of delimotecan against human metastatic melanoma: pharmacokinetics and molecular determinants***. Int J Cancer. 2009*** Nov 15;125(10):2456-64.

19. G Sacco, M Bigioni, G Lopez, S Evangelista, S Manzini, C A Maggi. ACE inhibition and protection from doxorubicin-induced cardiotoxicity in the rat. ***Vascular Pharmacology, 2009***, 50:166–170.

20. Di Renzo L, Gloria-Bottini F, Saccucci P, Bigioni M, Abenavoli L, Gasbarrini G, De Lorenzo A. Role of interleukin-15 receptor alpha polymorphisms in normal weight obese syndrome. ***Int J Immunopathol Pharmacol. 2009*** Jan-Mar;22(1):105-13.

21. Bigioni M, Benzo A, Irrissuto C, Lopez G, Curatella B, Maggi CA, Manzini S, Crea A, Caroli S, Cubadda F, Binaschi M. Antitumour effect of combination treatment with Sabarubicin (MEN 10755) and cis-platin (DDP) in human lung tumour xenograft. ***Cancer Chemother Pharmacol. 2008*** Sep;62(4):621-9.

22. Animati F, Berettoni M, Bigioni M, Binaschi M, Felicetti P, Gontrani L, Incani O, Madami A, Monteagudo E, Olivieri L, Resta S, Rossi C, Cipollone A. Synthesis, biological evaluation, and molecular modeling studies of rebeccamycin analogues modified in the carbohydrate moiety. ***ChemMedChem. 2008*** Feb;3(2):266-79.

23. Di Renzo L, Bertoli A, Bigioni M, Del Gobbo V, Premrov MG, Calabrese V, Di Daniele N, De Lorenzo A. Body composition and -174G/C interleukin-6 promoter gene polymorphism: association with progression of insulin resistance in normal weight obese syndrome. ***Curr Pharm Des. 2008***;14(26):2699-706.

24. Bressan A, Nardelli F, Bellarosa D, Bigioni M, Curcurù G, Curatella B, Crea A, Maggi CA, Manzini S, Binaschi M. Sabarubicin (MEN10755)-induced apoptosis is independent from mtDNA in A2780 human ovarian tumor cells***. Anticancer Res. 2007*** Nov-Dec;27(6B):4039-46.

25. Di Renzo L, Di Pierro D, Bigioni M, Sodi V, Galvano F, Cianci R, La Fauci L, De Lorenzo A. Is antioxidant plasma status in humans a consequence of the antioxidant food content influence? ***Eur Rev Med Pharmacol Sci. 2007*** May-Jun;11(3):185-92.

26. Di Renzo L, Bigioni M, Del Gobbo V, Premrov MG, Barbini U, Di Lorenzo N, De Lorenzo A. Interleukin-1 (IL-1) receptor antagonist gene polymorphism in normal weight obese syndrome: relationship to body composition and IL-1 alpha and beta plasma levels. ***Pharmacol Res. 2007*** Feb;55(2):131-8.

27. De Lorenzo A, Del Gobbo V, Premrov MG, Bigioni M, Galvano F, Di Renzo L. Normal-weight obese syndrome: early inflammation? ***Am J Clin Nutr. 2007*** Jan;85(1):40-5.

28. Binaschi M, Parlani M, Bellarosa D, Bigioni M, Salvatore C, Palma C, Crea A, Maggi CA, Manzini S, Goso C. Human and murine macrophages mediate activation of MEN 4901/T-0128: a new promising camptothecin analogue-polysaccharide conjugate***. Anticancer Drugs. 2006*** Nov;17(10):1119-26.

29. Di Renzo L, Bigioni M, Bottini FG, Del Gobbo V, Premrov MG, Cianci R, De Lorenzo A. Normal Weight Obese syndrome: role of single nucleotide polymorphism of IL-1 5Ralpha and MTHFR 677C-->T genes in the relationship between body composition and resting metabolic rate. ***Eur Rev Med Pharmacol Sci. 2006*** Sep-Oct;10(5):235-45.

30. Di Renzo L, Del Gobbo V, Bigioni M, Premrov MG, Cianci R, De Lorenzo A. Body composition analyses in normal weight obese women. ***Eur Rev Med Pharmacol Sci. 2006*** Jul-Aug;10(4):191-6.

31. M. Bigioni, C. Salvatore, A. Cipollone, M. Berettoni, C.A. Maggi and M. Binaschi. Pharmacological profile of new deamino analogues of sabarubicin (MEN10755). ***Letters in Drug Design & Discovery. 2005***. 2:73-78.

32. Bigioni M, Benzo A, Irrissuto C, Maggi CA, Goso C. Role of NK-1 and NK-2 tachykinin receptor antagonism on the growth of human breast carcinoma cell line MDA-MB-231. ***Anticancer Drugs. 2005*** Nov;16(10):1083-9.

33. Sacco G, Evangelista S, Criscuoli M, Goso C, Bigioni M, Binaschi M, Manzini S, Maggi CA. Involvement of nitric oxide in both central and peripheral haemodynamic effect of D/L-nebivolol and its enantiomers in rats. ***Eur J Pharmacol. 2005*** Mar 28;511(2-3):167-74.

34. Salvatore C, Binaschi M, Bigioni M, Camarda G, Maggi CA, Goso C. MEN15658: a new promising anti-tumoral drug active on resistant tumor cells. ***Anticancer Drugs. 2004*** Feb;15(2):151-6.

35. Palma C, Binaschi M, Bigioni M, Maggi CA, Goso C. CD137 and CD137 ligand constitutively coexpressed on human T and B leukemia cells signal proliferation and survival. ***Int J Cancer. 2004*** Jan 20;108(3):390-8.

36. Muratori M, Lippi A, Mancina R, Iafrate EM, Cirillo R, Lopez G, Bigioni M, Maggi M, Criscuoli M, Maggi CA. Pharmacological profile of MEN 11066, a novel potent and selective aromatase inhibitor. ***J Steroid Biochem Mol Biol. 2003*** Apr;84(5):503-12.

37. Cipollone A, Berettoni M, Bigioni M, Binaschi M, Cermele C, Monteagudo E, Olivieri L, Palomba D, Animati F, Goso C, Maggi CA. Novel anthracycline oligosaccharides: influence of chemical modifications of the carbohydrate moiety on biological activity. ***Bioorg Med Chem. 2002*** May;10(5):1459-70.

38. Binaschi M, Bigioni M, Cipollone A, Rossi C, Goso C, Maggi CA, Capranico G, Animati F. Anthracyclines: selected new developments. ***Curr Med Chem Anticancer Agents. 2001*** Aug;1(2):113-30. *Review*.

39. Bigioni M, Salvatore C, Bullo A, Bellarosa D, Iafrate E, Animati F, Capranico G, Goso C, Maggi CA, Pratesi G, Zunino F, Manzini S. A comparative study of cellular and molecular pharmacology of doxorubicin and MEN 10755, a disaccharide analogue. ***Biochem Pharmacol. 2001*** Jul 1;62(1):63-70.

40. Sacco G, Bigioni M, Evangelista S, Goso C, Manzini S, Maggi CA. Cardioprotective effects of zofenopril, a new angiotensin-converting enzyme inhibitor, on doxorubicin-induced cardiotoxicity in the rat. ***Eur J Pharmacol. 2001*** Feb 23;414(1):71-8.

41. Gonzalez-Paz O, Polizzi D, De Cesare M, Zunino F, Bigioni M, Maggi CA, Manzini S, Pratesi G. Tissue distribution, antitumour activity and in vivo apoptosis induction by MEN10755 in nude mice. ***Eur J Cancer***. ***2001*** Feb;37(3):431-7.

42. M Bigioni, P Ganis, A Panunzi, F Ruffo, C Salvatore and A Vito. Electrophilic attack of [I(Py)2]+(NO3-) on three-coordinate Pt0 precursors: synthesis and in vitro antitumor activity of water-soluble, five-coordinate Pt-II complexes. ***European Journal Inorganic Chemistry 2000***, 1717-1721.

43. Palma C, Bigioni M, Irrissuto C, Nardelli F, Maggi CA, Manzini S. Anti-tumour activity of tachykinin NK1 receptor antagonists on human glioma U373 MG xenograft. ***Br J Cancer. 2000*** Jan;82(2):480-7.

44. Salvatore C, Bigioni M, Iafrate EM, Cianfriglia M, Manzini S. FCE 24517-resistant MCF-7 human breast cancer cell line: selection and characterization. ***Anticancer Drugs. 1999*** Aug;10(7):663-9.

45. Guano F, Pourquier P, Tinelli S, Binaschi M, Bigioni M, Animati F, Manzini S, Zunino F, Kohlhagen G, Pommier Y, Capranico G. Topoisomerase poisoning activity of novel disaccharide anthracyclines. ***Mol Pharmacol. 1999*** Jul;56(1):77-84.

46. Arcamone F, Animati F, Bigioni M, Capranico G, Caserini C, Cipollone A, De Cesare M, Ettorre A, Guano F, Manzini S, Monteagudo E, Pratesi G, Salvatore C, Supino R, Zunino F. Configurational requirements of the sugar moiety for the pharmacological activity of anthracycline disaccharides. ***Biochem Pharmacol. 1999*** May 15;57(10):1133-9.

47. Pratesi G, De Cesare M, Caserini C, Perego P, Dal Bo L, Polizzi D, Supino R, Bigioni M, Manzini S, Iafrate E, Salvatore C, Casazza A, Arcamone F, Zunino F. Improved efficacy and enlarged spectrum of activity of a novel anthracycline disaccharide analogue of doxorubicin against human tumor xenografts. ***Clin Cancer Res. 1998*** Nov;4(11):2833-9.

48. Bigioni M, Salvatore C, Palma C, Manzini S, Animati F, Lombardi P, Pratesi G, Supino R, Zunino F. Cytotoxic and antitumor activity of MEN 10710, a novel alkylating derivative of distamycin. ***Anticancer Drugs. 1997*** Oct;8(9):845-52.

49. Arcamone F, Animati F, Berettoni M, Bigioni M, Capranico G, Casazza AM, Caserini C, Cipollone A, De Cesare M, Franciotti M, Lombardi P, Madami A, Manzini S, Monteagudo E, Polizzi D, Pratesi G, Righetti SC, Salvatore C, Supino R, Zunino F. Doxorubicin disaccharide analogue: apoptosis-related improvement of efficacy in vivo. ***J Natl Cancer Inst. 1997*** Aug 20;89(16):1217-23.

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54. Scarpa S, Sapora O, Tabocchini MA, Di Renzo L, Bigioni M, Pazzaglia S, Palitti F, Carotti D, Strom R. Effect of X-rays on the differentiation of L5 myoblast cell line. ***Ital J Biochem. 1989*** Jul-Aug;38(4):263A-265A.

INTERNATIONAL PATENTS

1 International Publication Number: **WO 2018/162727 A1**
Authors: Binaschi M, Bigioni M, Merlino G, Simonelli C, Bertoni F, Pellacani A.
Title: PHARMACEUTICAL COMBINATIONS COMPRISING AN ANTI-LY75 ANTIBODY. Publication date: 09.03.2018.

2 International Publication Number: **WO 2007/063124 A1**
Authors: Binaschi M, Bigioni M.
Title: USE OF A COMPOUND COMPRISING A CAMPTOTHECIN DERIVATIVE FOR PREPARING PHARMACEUTICAL FORMULATION USEFUL IN THE TREATMENT OF MELANOMA. Publication date: 07.06.2007.

3 International Publication Number: **WO 00/53615**.
Authors: Animati F, Berettoni M, Bigioni M, Cipollone A, Maggi CA.
Title: L-ARABINO-DISACCHARIDES OF ANTHRACYCLINES, PROCESSES FOR THEIR PREPARATION, AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM. Publication date: 14.09.2000.

Roma, November 15th, 2021

Mario Bigioni

I hereby authorize the treatment of my personal data according to the current Italian directives (Law No. 196 of 30 June, 2003) Privacy policy.