

PERSONAL INFORMATION

Daniela Melchiorri

WORK EXPERIENCE

-
- November 2010–Present **IT CHMP Member (2010- April 2013)- IT CHMP alternate (from April 2013-to September 2014) IT CHMP member from September 2014**
European Medicines Agency (EMA) (United Kingdom)
- 2011–2013 **Member of EudraVigilance Steering Committee**
European Medicines Agency (EMA) (United Kingdom)
- 2008–Present **Full Professor of Pharmacology**
University of Rome “Sapienza” Dept. Human Physiology and Pharmacology (Italy)
- 2004–2012 **Member of the Technical Scientific Committee (CTS)**
Italian Medicines Agency, AIFA (Italy)
Dossier evaluation for human medicines, Scientific Advice
- 2001–2008 **Associate Professor of Pharmacology**
University of Rome “Sapienza” Dept. Human Physiology and Pharmacology (Italy)
- 1994–1995 **Scientific research in pharmacology, PhD**
THE UNIVERSITY OF TEXAS AT SAN ANTONIO, TEXAS (United States)
- 1990–1993 **University of Rome “Tor Vergata” Laboratory of Pharmacology**
Internal student and post-doc research fellow (Italy)
Neuro-immune-pharmacology
- July 2012–Present **Member of the scientific secretariat in support of HTA activity**
AIFA (Italy)
HTA evaluation

EDUCATION AND TRAINING

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- 1993–1997 **PhD**
University of Rome “Sapienza” (Italy)
Neuro-immune pharmacology
- 1987–1991 **University degree in Pharmacy**
University of Rome “Sapienza” (Italy)
- 1983–1987 **University degree in Literature**
University of Rome “Sapienza” (Italy)

ADDITIONAL INFORMATION

Expertise Neuropharmacology, immune and endocrine pharmacology, oncology, vaccines. Embryonic, neural and cancer stem cells,

- Publications**
1. Iacovelli L, Orlando R, Rossi A, Spinsanti P, Melchiorri D, Nicoletti F. Targeting metabotropic glutamate receptors in the treatment of primary brain tumors. *Curr Opin Pharmacol*. 2018 Feb;38:59-64.
 2. Stanel SC, Sjöberg J, Salmonson T, Foggi P, Caleno M, Melchiorri D, Gravanis I, Tzogani K, Pignatti F. European Medicines Agency approval summary: Zaltrap for the treatment of patients with oxaliplatin-resistant metastatic colorectal cancer. *ESMO Open*. 2017 May 2;2(2):e000190. doi: 10.1136/esmoopen-2017-000190.
 3. Borg JJ, Tomasi P, Pani L, Aislaitner G, Pirozynski M, Leufkens H, Melchiorri D. Licensing of Generic Medicines: Are There Any Challenges Left? A Pharmaceutical Regulatory Perspective. *Sci Pharm*. 2014 May 22;82(4):847-56. doi: 10.3797/scipharm.1312-10.
 4. Luciani F, Galluzzo S, Gaggioli A, Kruse NA, Venneugues P, Schneider CK, Pini C, Melchiorri D. Implementing quality by design for biotech products: Are regulators on track? *MAbs*. 2015;7(3):451-5. doi: 10.1080/19420862.2015.1023058.
 5. Borg JJ, Laslop A, Pani L, Maciulaitis R, Melchiorri D. Reflections on Decisions Made on the Well-Established Use of Medicinal Products by EU Regulators and the ECJ. *Sci Pharm*. 2014 Mar 24;82(3):541-54. doi: 10.3797/scipharm.1402-14.
 6. Montilla S, Marchesini G, Sammarco A, Trotta MP, Siviero PD, Tomino C, Melchiorri D, Pani L; AIFA Anti-diabetics Monitoring Group. Drug utilization, safety, and effectiveness of exenatide, sitagliptin, and vildagliptin for type 2 diabetes in the real world: Data from the Italian AIFA Anti-diabetics Monitoring Registry. *Nutr Metab Cardiovasc Dis*. 2014 Oct 6. pii: S0939-4753(14)00259-2.
 7. Boix-Perales H, Borregaard J, Jensen KB, Ersbøll J, Galluzzo S, Giuliani R, Ciceroni C, Melchiorri D, Salmonson T, Bergh J, Schellens JH, Pignatti F. The European Medicines Agency Review of Pertuzumab for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer: summary of the scientific assessment of the committee for medicinal products for human use. *Oncologist*. 2014 Jul;19(7):766-731.
 8. Melchiorri D, Pani L, Gasparini P, Cossu G, Ancans J, Borg JJ, Drai C, Fiedor P, Flory E, Hudson I, Leufkens HG, Muller-Berghaus J, Narayanan G, Neugebauer B, Pokrotnieks J, Robert JL, Salmonson T, Schneider CK. Regulatory evaluation of Glybera in Europe - two committees, one mission. *Nat Rev Drug Discov*. 2013 Sep;12(9):719.
 9. Sancho A, Melchiorri D, Abadie E; Committee for Medicinal Products for Human Use, European Medicines Agency. More on influenza vaccine in young children. *N. Engl J Med*. 2012 Jun 28;366(26):2528;
 10. Matrisciano F, Busceti CL, Bucci D, Orlando R, Caruso A, Molinaro G, Cappuccio I, Rizzo B, Gradini R, Motolese M, Caraci F, Copani A, Scaccianoce S, Melchiorri D, Bruno V, Battaglia G, Nicoletti F. Induction of the Wnt antagonist Dickkopf-1 is involved in stress-induced hippocampal damage. *PLoS One*. 2011 Jan 27;6(1):e16447.
 11. Bernabei R, Caputi A, Di Cioccio L, Fini M, Gallo PF, Marchionni N, Marrocco W, Melchiorri D, Mugelli A, Pilotto A, Rasi G, Zuccaro SM. Need for redesigning pharmacologic research in older individuals. A position statement of the Geriatric Working Group of the Agenzia Italiana del Farmaco (AIFA). *J Gerontol A Biol Sci Med Sci*. 2011 Jan;66(1):66-7.
 12. Cappuccio I, Colapicchioni C, Santangelo V, Sale P, Blandini F, Bonelli M, Nicolini C, Busceti C, Bucci D, Nicoletti F, Melchiorri D. The origin recognition complex subunit, ORC3, is developmentally regulated and supports the expression of biochemical markers of neuronal maturation in cultured cerebellar granule cells. *Brain Res*. 2010 Oct 28;1358:1-10.
 13. Piccinin S, Cinque C, Calò L, Molinaro G, Battaglia G, Maggi L, Nicoletti F, Melchiorri D, Eusebi F, Massey PV, Bashir ZI. Interaction between Ephrins and mGlu5 metabotropic glutamate receptors in the induction of long-term synaptic depression in the hippocampus. *J Neurosci*. 2010 Feb 24;30(8):2835-43.
 14. Ciceroni C, Mosillo P, Mastrantoni E, Sale P, Ricci-Vitiani L, Biagioni F, Stocchi F, Nicoletti F, Melchiorri D. mGlu3 metabotropic glutamate receptors modulate the differentiation of SVZ-derived neural stem cells towards the astrocytic lineage. *Glia*. 2010 May;58(7):813-22.
 15. Crespo-Biel N, Camins A, Gutiérrez-Cuesta J, Melchiorri D, Nicoletti F, Pallàs M, Canudas AM. Regulation of GSK-3 β by calpain in the 3-nitropropionic acid model. *Hippocampus*. 2010 Aug;20(8):962-70.
 16. Ciceroni C, Arcella A, Mosillo P, Battaglia G, Mastrantoni E, Oliva MA, Capinelli G, Santoro F, Sale P, Ricci-Vitiani L, De Maria R, Pallini R, Gingaspero F, Nicoletti F, Melchiorri D. Type-3 metabotropic

- glutamate receptors negatively modulate bone morphogenetic protein receptor signaling and support the tumorigenic potential of glioma-initiating cells. *Neuropharmacology*. 2008 Sep;55(4):568-76.
17. Matrisciano F, Caruso A, Orlando R, Marchiafava M, Bruno V, Battaglia G, Gruber SH, Melchiorri D, Tatarelli R, Girardi P, Mathè AA, Nicoletti F. Defective group-II metabotropic glutamate receptors in the hippocampus of spontaneously depressed rats. *Neuropharmacology*. 2008 Sep;55(4):525-31.
18. Sarichelou I, Cappuccio I, Ferranti F, Mosillo P, Ciceroni C, Sale P, Stocchi F, Battaglia G, Nicoletti F, Melchiorri D. Metabotropic glutamate receptors regulate differentiation of embryonic stem cells into GABAergic neurons. *Cell Death Differ*. 2008 Apr;15(4):700-7.
19. Matrisciano F, Zusso M, Panaccione I, Turriziani B, Caruso A, Iacovelli L, Noviello L, Togna G, Melchiorri D, Debetto P, Tatarelli R, Battaglia G, Nicoletti F, Giusti P, Girardi P. Synergism between fluoxetine and the mGlu2/3 receptor agonist, LY379268, in an in vitro model for antidepressant drug-induced neurogenesis. *Neuropharmacology*. 2008 Feb;54(2):428-37.
20. Spinsanti P, De Vita T, Caruso A, Melchiorri D, Misasi R, Caricasole A, Nicoletti F. Differential activation of the calcium/protein kinase C and the canonical beta-catenin pathway by Wnt1 and Wnt7a produces opposite effects on cell proliferation in PC12 cells. *J Neurochem*. 2008 Mar;104(6):1588-98.
21. Melchiorri D, Cappuccio I, Ciceroni C, Spinsanti P, Mosillo P, Sarichelou I, Sale P, Nicoletti F. Metabotropic glutamate receptors in stem/progenitor cells. *Neuropharmacology*. 2007 Sep;53(4):473-80.
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23. Nicoletti F, Battaglia G, Storto M, Ngomba RT, Iacovelli L, Arcella A, Gradini R, Sale P, Rampello L, De Vita T, Di Marco R, Melchiorri D, Bruno V. Metabotropic glutamate receptors: beyond the regulation of synaptic transmission. *Psychoneuroendocrinology*. 2007 Aug;32 Suppl 1:S40-5. Epub 2007 Jul 24.
24. Muscaritoli M, Molfino A, Chiappini MG, Laviano A, Ammann T, Spinsanti P, Melchiorri D, Inui A, Alegiani F, Rossi Fanelli F. Anorexia in hemodialysis patients: the possible role of des-acyl ghrelin. *Am J Nephrol*. 2007;27(4):360-5.
25. Nicoletti F, Arcella A, Iacovelli L, Battaglia G, Giangaspero F, Melchiorri D. Metabotropic glutamate receptors: new targets for the control of tumor growth? *Trends Pharmacol Sci*. 2007 May;28(5):206-13.
26. Verani R, Cappuccio I, Spinsanti P, Gradini R, Caruso A, Magnotti MC, Motolese M, Nicoletti F, Melchiorri D. Expression of the Wnt inhibitor Dickkopf-1 is required for the induction of neural markers in mouse embryonic stem cells differentiating in response to retinoic acid. *J Neurochem*. 2007 Jan;100(1):242-50.
27. Spinsanti P, De Vita T, Di Castro S, Storto M, Formisano P, Nicoletti F, Melchiorri D. Endogenously activated mGlu5 metabotropic glutamate receptors sustain the increase in c-Myc expression induced by leukaemia inhibitory factor in cultured mouse embryonic stem cells. *J Neurochem*. 2006 Oct;99(1):299-307.
28. Cappuccio I, Verani R, Spinsanti P, Niccolini C, Gradini R, Costantino S, Nicoletti F, Melchiorri D. Context-dependent regulation of embryonic stem cell differentiation by mGlu4 metabotropic glutamate receptors. *Neuropharmacology*. 2006 Sep;51(3):606-11.
29. Calò L, Cinque C, Patanè M, Schillaci D, Battaglia G, Melchiorri D, Nicoletti F, Bruno V. Interaction between ephrins/Eph receptors and excitatory amino acid receptors: possible relevance in the regulation of synaptic plasticity and in the pathophysiology of neuronal degeneration. *J Neurochem*. 2006 Jul;98(1):1-10.
30. Marganella C, Bruno V, Matrisciano F, Reale C, Nicoletti F, Melchiorri D. Comparative effects of levobupivacaine and racemic bupivacaine on excitotoxic neuronal death in culture and N-methyl-D-aspartate-induced seizures in mice. *Eur J Pharmacol*. 2005 Aug 22;518(2-3):111-5.
31. Cappuccio I, Spinsanti P, Porcellini A, Desiderati F, De Vita T, Storto M, Capobianco L, Battaglia G, Nicoletti F, Melchiorri D. Endogenous activation of mGlu5 metabotropic glutamate receptors supports self-renewal of cultured mouse embryonic stem cells. *Neuropharmacology*. 2005;49 Suppl 1:196-205.
32. Di Giorgi-Gerevini V, Melchiorri D, Battaglia G, Ricci-Vitiani L, Ciceroni C, Busceti CL, Biagioni F, Iacovelli L, Canudas AM, Parati E, De Maria R, Nicoletti F. Endogenous activation of metabotropic glutamate receptors supports the proliferation and survival of neural progenitor cells. *Cell Death Differ*. 2005 Aug;12(8):1124-33.
33. Matrisciano F, Scaccianoce S, Del Bianco P, Panaccione I, Canudas AM, Battaglia G, Rizzo B, Ngomba RT, Molinaro G, Tatarelli R, Melchiorri D, Nicoletti F. Metabotropic glutamate receptors and neuroadaptation to antidepressants: imipramine-induced down-regulation of beta-adrenergic receptors in mice treated with metabotropic glutamate 2/3 receptor ligands. *J Neurochem*. 2005

Jun;93(5):1345-52.

34. Cappuccio I, Calderone A, Busceti CL, Biagioni F, Pontarelli F, Bruno V, Storto M, Terstappen GT, Gaviraghi G, Fornai F, Battaglia G, Melchiorri D, Zukin RS, Nicoletti F, Caricasole A. Induction of Dickkopf-1, a negative modulator of the Wnt pathway, is required for the development of ischemic neuronal death. *J Neurosci*. 2005 Mar 9;25(10):2647-57. Erratum in: *J Neurosci*. 2005 Mar 23;25(12):table of contents. Zukin, Suzanne [corrected to Zukin, R Suzanne].
35. Calò L, Bruno V, Spinsanti P, Molinari G, Korkhov V, Esposito Z, Patanè M, Melchiorri D, Freissmuth M, Nicoletti F. Interactions between ephrin-B and metabotropic glutamate 1 receptors in brain tissue and cultured neurons. *J Neurosci*. 2005 Mar 2;25(9):2245-54.
36. Canudas AM, Di Giorgi-Gerevini V, Iacovelli L, Nano G, D'Onofrio M, Arcella A, Giangaspero F, Busceti C, Ricci-Vitiani L, Battaglia G, Nicoletti F, Melchiorri D. PHCCC, a specific enhancer of type 4 metabotropic glutamate receptors, reduces proliferation and promotes differentiation of cerebellar granule cell neuroprecursors. *J Neurosci*. 2004 Nov 17;24(46):10343-52.
37. Chiechio S, Copani A, Melchiorri D, Canudas AM, Storto M, Calvani M, Nicolai R, Nicoletti F. Metabotropic receptors as targets for drugs of potential use in the treatment of neuropathic pain. *J Endocrinol Invest*. 2004;27(6 Suppl):171-6. Review.
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39. Di Giorgi Gerevini VD, Caruso A, Cappuccio I, Ricci Vitiani L, Romeo S, Della Rocca C, Gradini R, Melchiorri D, Nicoletti F. The mGlu5 metabotropic glutamate receptor is expressed in zones of active neurogenesis of the embryonic and postnatal brain. *Brain Res Dev Brain Res*. 2004 May 19;150(1):17-22.
40. Iacovelli L, Capobianco L, Iula M, Di Giorgi Gerevini V, Picascia A, Blahos J, Melchiorri D, Nicoletti F, De Blasi A. Regulation of mGlu4 metabotropic glutamate receptor signaling by type-2 G-protein coupled receptor kinase (GRK2). *Mol Pharmacol*. 2004 May;65(5):1103-10.
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42. Cinque C, Zuena AR, Casolini P, Ngomba RT, Melchiorri D, Maccari S, Nicoletti F, DiGiorgi Gerevini, Catalani A. Reduced activity of hippocampal group-I metabotropic glutamate receptors in learning-prone rats. *Neuroscience*. 2003;122(1):277-84.
43. Caricasole A, Ferraro T, Iacovelli L, Barletta E, Caruso A, Melchiorri D, Terstappen GC, Nicoletti F. Functional characterization of WNT7A signaling in PC12 cells: interaction with AFD5 x LRP6 receptor complex and modulation by Dickkopf proteins. *J Biol Chem*. 2003 Sep 26;278(39):37024-31. Epub 2003 Jul 11.
44. Scaccianoce S, Matrisciano F, Del Bianco P, Caricasole A, Di Giorgi Gerevini V, Cappuccio I, Melchiorri D, Battaglia G, Nicoletti F. Endogenous activation of group-II metabotropic glutamate receptors inhibits the hypothalamic-pituitary-adrenocortical axis. *Neuropharmacology*. 2003 Apr;44(5):555-61.
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46. Matrisciano F, Storto M, Ngomba RT, Cappuccio I, Caricasole A, Scaccianoce S, Riozzi B, Melchiorri D, Nicoletti F. Imipramine treatment up-regulates the expression and function of mGlu2/3 metabotropic glutamate receptors in the rat hippocampus. *Neuropharmacology*. 2002 Jun;42(8):1008-15.
47. Iacovelli L, Bruno V, Salvatore L, Melchiorri D, Gradini R, Caricasole A, Barletta E, De Blasi A, Nicoletti F. Native group-III metabotropic glutamate receptors are coupled to the mitogen-activated protein kinase/phosphatidylinositol-3-kinase pathways. *J Neurochem*. 2002 Jul;82(2):216-23.
48. Melchiorri D, Martini F, Lococo E, Gradini R, Barletta E, De Maria R, Caricasole A, Nicoletti F, Lenti L. An early increase in the disialoganglioside GD3 contributes to the development of neuronal apoptosis in culture. *Cell Death Differ*. 2002 Jun;9(6):609-15.
49. Copani A, Melchiorri D, Caricasole A, Martini F, Sale P, Carnevale R, Gradini R, Sortino MA, Lenti L, De Maria R, Nicoletti F. Beta-amyloid-induced synthesis of the ganglioside GD3 is a requisite for cell cycle reactivation and apoptosis in neurons. *J Neurosci*. 2002 May 15;22(10):3963-8.
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- mGlu2 metabotropic glutamate receptors. *Mol Pharmacol*. 2002 May;61(5):989-96.
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54. Ortiz GG, Reiter RJ, Zúñiga G, Melchiorri D, Sewerynek E, Pablos MI, Oh CS, García JJ, Bitzer-Quintero OK. Genotoxicity of paraquat: micronuclei induced in bone marrow and peripheral blood are inhibited by melatonin. *Mutat Res*. 2000 Jan 24;464(2):239-45.
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Projects

Memberships

Other Relevant Information