Curriculum Vitae of Luca Gianni

Luca Gianni was born in Milan, Italy on April 3, 1951. He married in 1983, and he is father of two.

Private Address:

Via Francesco Sforza, 48
20122 – Milano
Italy
lucagi@mac.com

Business Address:

Director, Department of Medical Oncology,
Ospedale San Raffaele Scientific Institute
Via Olgettina, 60
20132 – Milan, Italy
Phone: +39 02 2643 6531;
Fax: +39 02 2643 6521
Email: gianni.luca@hsr.it

Curriculum Vitae of Luca Gianni

Education:

1976: State University of Milan, Milan, Italy: *Medical Doctor with honors*

1981: State University of Milan, Milan, Italy: *Board-Certified in Internal Medicine*

Brief Chronology of Activities

1976-1978: Internship, Clinica Medica III, University of Milan.

1979-1980: Fellowship in Medical Oncology at the Division of Clinical Oncology directed by Dr. G. Bonadonna, Istituto Nazionale per lo Studio e la Cura dei Tumori, Milan.

1980-1983: Visiting Fellow, Clinical Pharmacology Branch, National Cancer Institute, Bethesda, Maryland, USA.

1983-1991: Scientist & Senior Staff Member, Division of Medical Oncology, Istituto Nazionale dei Tumori, Milan.

1984 to date: Head, Laboratory of Clinical Pharmacology, Istituto Nazionale dei Tumori, Milan.

1991-1998: Associate-Director, Division of Medical Oncology, Istituto Nazionale dei Tumori, Milan.

1998-2011: Director, Division of Medical Oncology 1, Istituto Nazionale dei Tumori, Milan.

2001-2011: Head, Strategic Project of New Drug Development in solid Tumors, Istituto Nazionale dei Tumori, Milan

2011 to date: Director, Department of Medical Oncology, San Raffaele Hospital – Research Institute, Milan

Editorial Boards

1994-2000: Cancer Chemotherapy and Pharmacology

1994 to date: Clinical Cancer Research

1998-2004: Investigational New Drugs

2000 to date: Clinical Breast Cancer

2001-2004 and 2008 to date: Journal of Clinical Oncology

2001 to 2007: Journal of Clinical Investigation

2000 to date: Nature Practice Clinical Oncology, currently renamed Nature Reviews Clinical Oncology

Awards

2011 ASCO Gianni Bonadonna Breast Cancer Award and Research Fellowship

2010 Premio alla ricerca scientifica "Francesca Mancuso"

2010 Premio Luigi Castagnetta Award in Cancer Research

Memberships and Affiliations

Member of the Pharmacology and Molecular Mechanisms (PAMM) Group of the European Organization for Research and Treatment of Cancer (EORTC)

Member of the PAMM Group Committee (from 1993 to 2000)

Member of "Gruppo di Farmacologia Antineoplastica della Società Italiana di Cancerologia"

Member of the American Association for Cancer Research (AACR)

Member of the European Society of Medical Oncology (ESMO)

Member of the American Society of Clinical Oncology (ASCO)

Member of the Decision Network of the Southern Europe New Drug Office (SENDO) (2000-2011)

Member of the Executive Committee of SENDO (2007-2011)

Present/past member of Scientific Advisory Boards for:

Agouron, Ariad; BiogenIDEC; Bristol Myers Squibb; Celgene; Eisai; Eli Lilly; Genentech; GSK; ImClone; Merrimack; Millenium; Novartis; Pfizer; Roche; sanofi-aventis; Sugen; Sython; Takeda; Tahio; Wyeth, Zensun.

Present/past member/chair of Independent Data Monitoring Committees of international clinical trials.

Scientific Committees

Since 1992 to 2004 member of the Scientific Committee of Istituto Nazionale dei Tumori, Milan,

Since 1999 to 2009 member of the Ethical Coommittee of the Cancer Institute of Candiolo (Turin), Italy.

Since 1998 to date: Advisor and Expert for research applications to the Italian Ministry of University and Research.

2004: Expert Reviewer of the European Commission for the Work Programme of Health, Cancer (FP6

Programme)

2007: Expert Reviewer of the European Commission for Work Programme of Health, Cancer (FP7 Programme)

2006 to 2008: Member of the Scientific Committee for breast Cancer of the American Society of Clinical Oncology (ASCO)

2008, 2010, 2012-2014: Member of the Scientific Program Committee of the Congress of the European Society of Medical Oncology (ESMO)

2010 to 2011, and 2013 to date: Member of the Scientific Program Committee of the San Antonio Breast Cancer Symposium (SABCS)

2010 to date: Expert reviewer and member of the Panel Review of the "Integrated Cancer Research Site Designation – SIRIC" of the Institut National de Cancer (INCa) of France

2010: Member of the evaluation committee (President) for the designation of early Phase clinical trials centers of the INCa of France

2011 to date: Member of the Scientific Board of the IARC (International Agency for Research on Cancer), Lyon, France

Chairperson/Organizer

1997 Founder of the Michelangelo Foundation for the Advancement of Science and Treatment in Oncology

1997 to date: Chairman, International Board of the Michelangelo Foundation Breast Cancer Study Group.

Present/past recipient of several grants from the National Research Council of Italy, the Associazione Italiana Ricerca sul Cancro and the Pharmaceutical industry.

From October 1983 to July 1992 Dr. Luca Gianni has worked as Consultant to the Clinical Pharmacology Branch, National Cancer Institute, NIH, USA.

Brief Chronology of Research Activities

During his career Dr. Gianni has worked on new drug development in the field of oncology and on the definition of innovative drug therapies in Medical Oncology. Since 1995 he focused on clinical and translational research in women with breast cancer.

As a fellow in the Biochemical Pharmacology Section of the Clinical Pharmacology Branch of NCI, he contributed to the clarification of the reaction of metal ions with anthracyclines, and to the definition of the actual occurrence of the reaction in vivo through iron de-compartmentalization from ferritin. His work has been key to the clarification of the leading theory about the biochemical mechanism of anthracycline-induced cardiac toxicity, and supported the use of dexrazoxane as a clinical scavenger of that type of toxicity.

Dr. Gianni has also contributed to the study of drug disposition of several new anticancer agents. In cooperation with Dr. J.M. Collins, now Head of the Developmental Therapeutics Program of the National Cancer Institute in USA, he applied new pharmacologically-guided criteria to Phase I studies, showing the applicability of pharmacokinetics to the early clinical development of new drugs in humans, and elucidating the role of metabolism to new anthracyclines in the pharmacological effects of iodo-doxorubicin. In addition, following a serendipitous observation, he showed that iodo-doxorubicin is capable of specifically bind to and disrupt the amyloid deposits associated with myeloma.

Dr. Gianni has been involved in the development of paclitaxel in ovarian and breast cancer. In this respect, he designed a new approach of clinical and pharmacological evaluation that has brought to the clarification of some key aspects of the human disposition of paclitaxel alone and in combination with anthracyclines. His studies led to the definition of a successful new regimen for breast cancer as well as the clarification of the role of paclitaxel formulation with cremophor EL in the mechanisms of drug-drug enhancement with doxorubicin. Following this work, Dr. Gianni launched and coordinated an international multicenter study (ECTO) that explored the use of the new paclitaxel-containing regimen as adjuvant or primary chemotherapy in women with operable breast cancer. An improved efficacy for the paclitaxel containing regimen was shown.

From January 1996 Dr. Luca Gianni is Chairman and Coordinator of European Cooperative Trials in Women with Operable Breast Cancer involving several hospitals and cancer Institutions in Italy, Spain, Germany, Austria, Poland, Hungary, Latvia and the Russian Federation. Within such collaborative effort in 2002 Dr. Gianni has designed and launched the first international neoadjuvant study of Herceptin plus chemotherapy in women with locally advanced breast cancer (NOAH trial). The result of the study were the basis for extending the label and indication of

Herceptin by EMA in 2011 as neoadjuvant therapy in women with HER2-positive breast cancer.

From 2005 Dr. Gianni was involved and directly contributed to the development of the HER2-directed monoclonal antibody Pertuzumab in metastatic breast cancer, showing the low level of activity of the antibody in breast cancers expressing low levels of HER2, but very high antitumor activity in tumors with high expresisone of the receptor upon addition of pertuzumab to trastuzumab in cases progressing on trastuzumab. Dr. Gianni designed and chaired the neoadjuvant trial known as NeoSphere, a collaboration of the Michelangelo Breast Cancer study group and Roche/Genentech, that has established the role of the combination of trastuzumab and pertuzumab for dual targeting of HER2, showed that antitumor activity was different depending on the negative or positive status of the estrogen receptor. The NeoSphere was used to design the very successful trial known as Cleopatra in HER2+ metastatic breast cancer. The results of NeoSphere also led to the first accelerated approval of a drug (pertuzumab) by the FDA in early breast cancer base don the findings of pathologic complete response. The results of the study have prompted the conduct of an ongoing Phase III international adjuvant trial, Aphinity. Finally, Neosphere was the first trial that clearly illustrated how the antitumor activity and rate of pathologic complete response in HER2+ positive breast cancers undergoing therapy with HER2-directed monoclonal antibodies greatly depends on the immune mechanisms and may be enhanced by addition of drugs targeting immune check points.

In his activity of new drug development in recent years Dr. Gianni has designed and conducted Phase I and Phase II trials with HER2-directed therapies, imatininib, mTOR-inhibitors, PI3K-inhibitors, anti-angiogenics, agents modulating T-cell response, antivascular agents, and several other new small molecules and monoclonal antibodies.

In his scientific career Dr. Gianni has published more than 200 articles/reviews in peer reviewed journals. A list of 20 representative publication is attached.

Dr. Luca Gianni has conducted clinical trials according to ICH / GCP. Last training on Sept 24th, 2013 (Clinical Trial SIV)
Authorizing the processing of personal data as defined by D. Decree Law 196/2003.

1 DEC 2014
Dott. LUCA GIANNI
Direttore
Dipartimento di Oncologia Medica