

## CURRICULUM VITAE

**BARBARA ENSOLI, MD. PH.D**

### **Current Position & Title:**

Director of the National HIV/AIDS Research Center - Istituto Superiore di Sanità (ISS), Rome, Italy (<http://www.iss.it/aids/>).

### **Personal Statement**

Dr. Ensoli is the Director of the National HIV/AIDS Research Center (CNAIDS) at the Istituto Superiore di Sanità (ISS) (the Italian NIH) in Rome since 1995, after spending 10 years at the Laboratory of Tumor Cell Biology (LTBC), NCI, NIH, where she elucidated the role of the HIV-1 Tat protein in HIV pathogenesis and AIDS-associated tumors.

At ISS, Dr. Ensoli has led a multidisciplinary team in all areas of HIV pathogenesis, including AIDS-associated tumors, has built clinical/research platforms in both Italy and South Africa (SA), and launched a translational program to develop HIV/AIDS preventative and therapeutic vaccines based on HIV-1 Tat. The program led to the conduction of several observational studies on anti-Tat immunity, and preventative and therapeutic trials in HIV-infected and non-infected individuals with the Tat-based vaccine candidate in Italy and SA. The trial in SA was part of a bilateral cooperation aimed at developing in SA a national health programme to fight HIV/AIDS with the National Department of Health and the SA-MRC. The collaborative program foresaw capacity building, vaccine clinical trial conduct, and the transfer of technology for GMP production of the Tat vaccine to SA.

The development of the Tat vaccine candidate required a complex multidisciplinary approach, including the manufacturing and characterization of the Tat protein vaccine (11 GMP-grade batches manufactured, tested and released), the evaluation of its safety, immunogenicity and efficacy in preclinical models, the dossier preparation and approval for human use, and clinical trial conduction. Parallel activities consisted of: (a) studies aimed at defining the role of Tat and the Tat immune response in natural infection to identify correlates of protection and to validate tests to monitor vaccinees, and (b) capacity building to conduct advanced clinical trials in developing countries. As a result of these efforts, I filed 7 patents on HIV/AIDS vaccine development most of which are now granted internationally.

Her scientific accomplishments have resulted in more than 350 publications in international peer-reviewed journals, awards and memberships of the European Research Council (ERC) and the European Molecular Biology Organization (EMBO).

She has coordinated several EU and Italian programs on AIDS-associated tumors and on HIV/AIDS vaccine development from basic research to clinical trials also in South Africa, and have been involved in a number of activities in the fight against HIV/AIDS at the Italian Ministry of Health, and coordinated specific projects for HIV prevention.

My detailed CV is presented in Appendix 1.

## Appendix 1 : detailed curriculum vitae

**Name:** Ensoli Barbara

**Date and Place of Birth:**

**Position title:** Director of the National HIV/AIDS Research Center - Istituto Superiore di Sanità, Rome, Italy (<http://www.iss.it/aids/>)

### Education and Training:

- |      |   |
|------|---|
| 1984 | University of Rome "La Sapienza", Medical School, Rome, Italy : MD in Medicine and Surgery.   |
| 1986 | National Institute of Health (NIH), Bethesda, Maryland, USA: Authorised User for Radioactive Compounds, Radiation safety branch.                                  |
| 1987 | University of Rome "La Sapienza", Rome, Italy: Residency in Allergy and Immunology.   |
| 1988 | Biotrac, Foundation for Advanced Education in the Science, NIH, Bethesda, Maryland, USA: Molecular Biology course "Special topics in recombinant DNA technology". |
| 1989 | Biotrac, Foundation for Advanced Education in the Science, NIH, Bethesda, Maryland, USA: Biochemistry's course "Separation techniques".                           |
| 1990 | Laboratory of Tumor Cell Biology, National Cancer Institute, NIH, Bethesda, Maryland, USA: Postdoctoral in Virology, Immunology, Molecular Biology.               |
| 1991 | University of Bari, Bari, Italy: Ph.D. in Immunology.   |
| 1993 | National Safety Branch (Nuclear Regulatory Committee), NIH, Bethesda, Maryland, USA: Responsible Supervisor for Radioactive compounds.                            |

### Experiences related to HIV/AIDS

Dr. Ensoli has been involved into two main fields of research:

- a) Studies on the pathogenesis of HIV infection, aimed at developing a vaccine against HIV/AIDS, able to either protect from the disease (in HIV-uninfected individuals; preventative vaccine), or to control disease progression (in HIV-infected individuals; therapeutic vaccine);
- b) Studies on pathogenesis of AIDS-associated tumours, in particular of Kaposi's sarcoma and of intra-epithelial neoplasm of uterine cervix.

Studies for the development of a vaccine able to prevent from HIV/AIDS disease in uninfected individuals and/or to control disease progression in seropositive patients have been based on new concepts of vaccinology, that have lead to identify the Tat protein of HIV-1 as the target for immunisation strategies. This protein has, in fact, a key role in the very early phases of HIV infection since it is essential for virus replication and spreading of infection.

The significant results obtained from the basic research and, later on, the preclinical studies on non-human primates, have confirmed that the Tat-based vaccine is safe, induces humoral and cell-mediated immune responses and is able to block or significantly reduce HIV replication and transmission in vaccinated monkeys. Based on these results, phase I clinical vaccine trials with a vaccine based on the Tat protein on uninfected (ISS P-001) and on HIV-infected volunteers (ISS T-001) have begun in 2003 and completed in 2006. These studies have involved 4 clinical Italian centres and have demonstrated that the Tat vaccine candidate is safe and immunogenic when used in both HIV-negative and –positive individuals. Results from these studies have been published on international scientific journals.

Based on the promising results obtained in phase I clinical trials, a phase 2 clinical trial (ISS T-002) was conducted in Italy with the aim of evaluating immunogenicity and efficacy induced by vaccination with the Tat protein in HIV-positive, HAART-treated, individuals. The study, conducted in 11 clinical Centers, has produced important results on therapeutic immunisation with the Tat protein, confirming

that the vaccine is safe, immunogenic and indicating that it is capable of restoring the immune system and of attaching the virus reservoir. A further phase II trial has been completed in South Africa, and has confirmed the data in a different population of subjects (different genetic background) infected with a different virus clade (c).

In parallel with these activities, a bilateral cooperation programme between Italy and South Africa has been conducted, aimed at developing local health programmes to fight HIV/AIDS. The programme started with preliminary clinical observational studies, and has been followed by the phase II clinical trial sponsored by the National AIDS Center of the Istituto Superiore di Sanità in collaboration with the Italian Ministry of Foreign Affairs and the South African Government.

Beside the advanced clinical testing of the Tat-based vaccine, second generation vaccines have been developed for preventative use, in the frame of European research Programmes (An European Programme for the development of a vaccine against HIV/AIDS; AVIP). In particular, a new vaccine candidate, based on the association of the Tat protein with a modified form of the Env protein (an Env protein deleted of its V2 region, ΔV2-Env) has been developed in collaboration with Novartis Vaccines&Diagnostics, that is able to elicit a broader immune response. This vaccine candidate, that has produced promising results in non human primates, has been tested in a phase I clinical trial on healthy volunteers with behaviours at high risk of HIV infection (preventative vaccination).

Her research in the field of HIV pathogenesis and AIDS-related tumours has led to the discovery that HIV protease inhibitors (HIV-PI) have anti-tumour effects. Studies started from observation that incidence of HIV-associated tumours, including Kaposi's sarcoma (KS), non-Hodgkin lymphoma and the intra-epithelial neoplasm of uterine cervix (CIN) went reducing since the introduction of new combined anti-retroviral therapies (HAART), containing protease inhibitors. Results from these researchs have demonstrated that PI are molecules with strong anti-angiogenic effects, able to block the development of new blood vessels that are essential to tumour growth in numerous experimental neoplastic models, including KS and CIN, thus suggesting a possible use of these drugs in the anti-tumour therapy, for both HIV infected patients and patients with HIV unrelated tumours.

Based on these results, a phase II clinical trial has been conducted in Italy in order to evaluate anti-tumour effects of Indinavir, one of the most common HIV-PIs, in HIV-uninfected patients with classic KS. Results from these studies have confirmed that the drug is able to control the progression of the tumour, in particular if given in the early stages of the disease. Due to these promising results, a new "proof-of-concept" clinical study has been conducted, aimed at evaluating the efficacy of this class of drugs in the therapeutic treatment of patients with advanced, HIV unrelated KS, in association with conventional chemotherapy.

The development and the conduct of these programmes in both the oncologic and infectious diseases fields, is an important example of "translational" research, from basic research to clinical advanced testing that assures that a product rapidly reaches the community.

### **Positions and Employment:**

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|-----------|---|
| 1982-1986 | University of Rome "La Sapienza," Italy: Internship, Department of Allergy and Clinical Immunology, Laboratory of Immunology.                   |
| 1986      | National Cancer Institute (NCI), NIH, Bethesda, Maryland, USA: Fellowship, Italian Cancer Society, Laboratory of Tumor Cell Biology (LTCB).     |
| 1986-1990 | NCI, NIH, Bethesda, Maryland, USA: Visiting Fellow, LTCB.   |
| 1990-1993 | NCI, NIH, Bethesda, Maryland, USA: Visiting Associate, LTCB.  |
| 1993-1994 | NCI, NIH, Bethesda, Maryland, USA: Visiting Scientist, LTCB.  |
| 1994-1996 | NCI, NIH, Bethesda, Maryland, USA: Visiting Scientist (Tenure Track), Head of the Vascular Biology and AIDS-associated Malignancies Unit, LTCB. |
| 1996-1999 | Istituto Superiore di Sanità, Rome, Italy: Director of Research, Laboratory of Virology.  |
| 2000-2004 | Istituto Superiore di Sanità, Rome, Italy: Director, Retrovirus Division, Laboratory of Virology.   |

- 2004-2005 Istituto Superiore di Sanità, Rome, Italy: Director, AIDS Division, Department of Infectious, Parasitic and Immune-mediated Diseases.
- 2005-Date Istituto Superiore di Sanità, Rome, Italy: Director, National HIV/AIDS Research Center (CNAIDS)

**Reviewer for Journals:**

AIDS  
AIDS Care  
AIDS Research and Human Retroviruses  
American Journal of Pathology  
Archives of Oral Biology  
Archives of Virology  
Blood  
British Journal of Medicine and Medical Research  
Cancer  
Cancer Letters  
Cancer Research  
Cell Death and Differentiation  
Clinical Cancer Research  
Clinical Experimental Immunology  
Contemporary Clinical Trials  
EMBO Journal  
European Journal of Immunology  
Expert Opinion on Investigational Drugs  
Expert Review of Vaccines  
FEBS Letters  
Future Virology  
Gene Therapy  
Human Gene Therapy  
Human Vaccines  
Immunopharmacology and Immunotoxicology  
Immunological Investigations  
Infectious Agents and Cancer  
International Journal of Cancer  
International Journal of Environmental Research and Public Health  
International Journal of Peptides  
Journal of Acquired Immunodeficiency Syndrome  
Journal of AIDS and Clinical Research (OMICS Publishing Group)  
Journal of Clinical Investigation  
Journal of General Virology  
Journal of Immune-Based Therapies and Vaccines  
Journal of Immunological Methods  
Journal of Immunology  
Journal of Infectious Diseases  
Journal of Neuroscience  
Journal of Virology  
Journal of Virological Methods  
Laboratory Investigation  
Lancet  
Lancet Oncology  
Life Science  
Microvascular Research  
Nature  
Nature Medicine  
New England Journal of Medicine

Oncogene  
PLoS ONE  
Proceedings of the National Academy of Sciences, USA  
Reviews on Recent Clinical Trials  
The American Journal of Pathology  
The Lancet Infectious Disease  
The Open AIDS Journal  
Trends in Biotechnology  
Vaccine  
Virulence  
Virology

**Reviewer of Grants for:**

- Louisiana Education Quality Support Fund, Research and Development Program NIH Grants, USA
- NIH Grants, Ohio State University Comprehensive Cancer, The Ohio State University, USA
- Center National Health Research and Development Program, Canada
- Wellcome Trust registered Charity, London, UK
- Extramural AIDS grants, Ministry of Health, Italy
- European Molecular Organization (EMBO), Germany
- European Research Council (ERC), Belgium
- Ministry of Education, University and Research (MIUR), Italy
- Gilead Fellowship Program
- Université Libre de Bruxelles, Belgium
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**Teaching:**

- Georgetown University, Washington, USA; Tulane University School of Medicine, New Orleans, USA; NIH, Bethesda, Maryland, USA; Columbia University, New York, USA.
- External Examiner: MSc in Medical Sciences (Medical Virology), Candidate Mr. TS Scriba (12721255-1997), University Office Tygerberg Campus, Africa (2002).
- University teacher on "Novelty in oncohaematology", Legnano Hospital, Italy (2002).
- Member of Teaching Scientific Committee of the International PhD courses, University of Ferrara, Stockholm and German Research Center For Biotechnology, Germany.
- Courses to Medical Doctors on AIDS pathogenesis, AIDS-associated tumors, angiogenesis, HIV/AIDS vaccine development at the University of Ferrara, Ferrara, Italy.
- Appointed Professor, Medical School, University of Ferrara, Ferrara, Italy (1999/2000-2007/2008).
- Advisory of the Teaching Scientific Committee of the PhD courses in Experimental Oncology, University of Ferrara, Ferrara, Italy (2004).
- Member of the Microbiology and Virology Post-Graduate School Committee and University teacher for the integrative course "Innovative vaccines", Microbiology and Virology School, Faculty of Medicine, University of Brescia, Italy (2003-2004, 2004-2005).
- Teacher for Medical School, on "HIV infection and AIDS pathogenesis", title of the lecture: "immune-prevention and vaccination and HIV vaccination - new prevention and therapy routes", University of Padua, Padua (2005-2006).
- Teacher for and academic lecture: "anti-Tat HIV-1 vaccine: from basic science to clinical trials" at Biomedical Science Dept., General Pathology Section, University of Modena and Reggio Emilia.
- Member of Teaching Scientific Committee of the International PhD courses in Medical Immunobiology, University of Rome "Tor Vergata", Rome, Italy.
- Warrant (designated by "Centro Nazionale Ricerche") for the disciplinary aggregation of expertise, with the task of proposing the nominees of the members of the boards of examiners recruiting personnel (investigators and technicians) and for personnel promotions (2005).

- External teacher for the Bachelor on Biotechnologies, University of Catania, Catania, Italy (2008).
- Teacher for an academic lecture "HIV-1 Tat therapeutic vaccine: from basic science to clinical trials" PhD Programme in Translational Medicine, Harvey Medical School Department of Molecular Medicine, University of Pavia, Pavia, Italy (April 11, 2019).
- Teacher for an academic lecture "HIV-1 Tat therapeutic vaccine: from basic science to clinical trials" PhD in Medical Biotechnology and Translational Medicine - Department of Biomedicine and Prevention, University of Rome "Tor Vergata", Rome, Italy (June 14, 2019).

**Member of Committees:**

- 1991 VII International AIDS Conference Program Committee (Florence, Italy).  
 1999 Member of the Scientific Committee for the Project: "Epidemiologia e modelli di ricerca assistenziale", National AIDS Program, Ministry of Health (Italy).  
 1999 Member of the Scientific Committee for the program coordination in fighting and preventing from HIV infection and correlated diseases, National AIDS Program, Ministry of Health (Italy).  
 1999 Member of the Scientific Committee for the Project: "Patologia Clinica e Terapia dell'AIDS", National AIDS Program, Ministry of Health (Italy).  
 1999 Committee for patent activity, Istituto Superiore di Sanità, Ministry of Health, Italy.  
 1999 National Committee for AIDS, Ministry of Health (Italy).  
 1999 Organizing Committee, 3<sup>rd</sup> International Conference on Human Herpesvirus 6, 7 and 8 (Tampa, Florida).  
 2000 Responsible for the Scientific Committee "Italy-USA for the development of vaccines against HIV/AIDS", National AIDS Program, Ministry of Health (Italy).  
 2000 Responsible for the Scientific Committee "Vaccine AIDS Project". National Intramural AIDS Program, Ministry of Health (Italy).  
 2000 Responsible for the Scientific Committee "Italy-USA for the development of vaccines against HIV/AIDS", Intervention and Surveillance Program, National AIDS Program, Ministry of Health (Italy).  
 2000 European Molecular Biology Organization (EMBO).  
 2001 Member of the Scientific Committee for the Project: "Patologia Clinica e Terapia dell'AIDS", National AIDS Program, Ministry of Health (Italy).  
 2001 UNESCO delegate for Italy, Vice-President of the Natural Sciences Committee.  
 2001 United Nations General Assembly for HIV/AIDS, member of the delegation representing Italy (New York, USA).  
 2002 Workgroup on Infrastructures and on excellent European networks in the field of biosafety and biotechnology instituted by the National Committee for Biosafety and Biotechnology, Presidenza del Consiglio dei Ministri (Rome, Italy).  
 2002 Conference Organization, XIV International AIDS Conference (Barcelona, Spain).  
 2003-2004 Scientific Responsible of the Concerted Action on HIV/AIDS vaccine development (ICAV), National AIDS Program, Ministry of Health (Italy).  
 2004 Scientific Responsible, Project: "Eziopatogenesi e studi immunologici e virologici dell'HIV/AIDS", National AIDS Program, Ministry of Health (Italy).  
 2004-2005 Member of the WHO-UNAIDS HIV Vaccine Advisory Committee (VAC).  
 2005 Member of Guarantee Committee, Consiglio Nazionale delle Ricerche (CNR) (Rome, Italy).  
 2006 Member of Scientific Program Committee, AIDS Vaccine Conference (Amsterdam, Netherlands).  
 2006 Member of Scientific Committee "Giuseppina Mai Foundation" to promote public and private research and interaction among universities, public institutes and industries for technology transfer activities.

2006	International Committee, 8 <sup>th</sup> European Conference on Experimental AIDS Research (ECEAR) (Naples, Italy).
2006-2008	Vice-President, National Committee for AIDS, Ministry of Health (Italy).
2007	Member of ISS expert panel on Prevention from Infectious and Transmittable Diseases.
2008	Member of the Scientific Program Committee (SPC) for the "National Conference on HIV/AIDS", SIMIT.
2008	Member of the Committee of the "Associazione Nazionale per la lotta contro l'AIDS" (Anlaids Onlus).
2009-2014	Co-Vice President and Member of the Presidential Committee of the AIDS National Commission, Ministry of Health (Italy).
2012-2014	Member of the Editorial Board of the Health Status Report 2011 (RSSP), Ministry of Health (Italy).
2013-2016	Member of the Scientific Council of The European Research Council, ERC.
2013-2014	Member of the EMBO "AcademiaNet-Expert Database for Outstanding Female Scientists and Scholars"
2015-2016	Member of the HIRO (Heads of International Research Organizations) representing ERC.
2016	Member of the "100 women against stereotypes", a database of female excellence (Pavia Media Research Observatory)
2016	Member of "Top Italian Women Scientist 2016" – ONDA (Osservatorio Nazionale sulla Salute della Donna)
2019-2020	Workgroup on "Rules for the management of the Conflict of Interest", Istituto Superiore di Sanità
2020	Working group on Translational Research COVID-19, Istituto Superiore di Sanità
2021	BSL-3 Activities Working Group, Istituto Superiore di Sanità
2021	Commission on issues related to the logistics of the Istituto Superiore di Sanità

#### **Member of Editorial Board:**

Lancet Oncology  
 The Open AIDS Journals  
 Tumor Viruses  
 Vaccine: Development and Therapy  
 Journal of Clinical & Cellular Immunology  
 PLoS ONE  
 Advances in Tumor Virology  
 PeerJ  
 Scientific Reports  
 Bentham Science

#### **Honors and Other Special Scientific Recognition:**

1984	Summa cum laude (M.D. Thesis).
1987	Summa cum laude (Residency).
1990	"Italian Society for AIDS Research" award for the most significant publication in the field of AIDS research for 1989, "AIDS-Kaposi's sarcoma-derived cells express cytokines with autocrine and paracrine growth effects." <i>Science</i> 243: 223-226, 1989.
1991	Summa cum laude (Ph.D. Thesis).
1991	Proposed for Tenure and Head of the Unit of Vascular Biology and AIDS-associated Malignancies by Site Visit Review Board, NCI, NIH, USA.
1992	Award from the NIH for contribution to technology transfer from the LTCB to the private sector.

- 1993 Award from the NIH for contribution to technology transfer from the LTCB to the private sector.
- 1994 Award from the NIH for contribution to technology transfer from the LTCB to the private sector.
- 1994 Grandfathered into Tenure Track Program, NIH, USA.
- 1999 "Italian Society for AIDS Research" award for the most significant publication in the field of AIDS research for 1999, "Control of SHIV-89.6P-infection of cynomolgus monkeys by HIV-1 Tat protein vaccine". *Nature Medicine* 5: 643-650, 1999.
- 1999 "San Valentino d'Oro" International Award for professional activity against AIDS.
- 1999 "Marisa Bellisario" International Award for professional activities.
- 1999 "Inner Weel" International Award for professional merits.
- 2000 "Fiore di Roccia" Award for scientific achievements.
- 2000 Honor for scientific achievements, conferred by the President of the Italian Republic Mr. A. Ciampi.
- 2000 "Eleonora Benvenuti Turziani" Award for the year 2000, Perugia, for scientific and professional merits.
- 2000 "Universum" International Award for the year 2000, Potenza, for scientific and professional merits.
- 2000 "Woman of the year 1999" Award, conferred by the magazine "Grazia" (Mondadori Ed.) for scientific and professional merits.
- 2000 Honorary Member of Medical Women's International Association (M.W.I.A).
- 2001 Honor (Cavaliere dell'Ordine al Merito della Repubblica Italiana), conferred by the President of the Italian Republic Mr. A. Ciampi.
- 2001 "Domenico Marotta" Award for year 2000, conferred from professional merits by the National Academy of Sciences (also known as "National Academy of XL") at the Royal Museum of Mineralogy, Naples.
- 2001 "Graziella Fumagalli" Award for year 2001, conferred from professional merits by the Confartigianato Donna Impresa, Padova.
- 2002 "Santa Caterina" Award for year 2002, conferred from professional merits by "S. Caterina d'Oro" and "Cateriniani nel Mondo", Siena.
- 2002 "Graziella Fumagalli" Award for year 2002, conferred from professional merits by the Confartigianato Donna Impresa, Padova.
- 2002 "Altipiani d'Arcinazzo" Award for year 2002, conferred from scientific and professional merits.
- 2002 "R.O.S.A." Award for year 2002, conferred from professional merits by the Canova Club.
- 2003 "Minerva" Award for the year 2003, conferred for scientific and professional merits.
- 2003 "Italiani nel Mondo" Award for year 2003 (III Edition), conferred for professional merits by the Ministero per gli Italiani nel Mondo (Marzio Tremaglia Foundation), supported by President of the Italian Republic.
- 2004 Honor (Ufficiale), conferred by the President of the Italian Republic Mr. A. Ciampi, 2004
- 2004 "Ordres des femmes de la jarretiere" Award for the year 2004 for scientific and professional merits.
- 2004 "Paul Harris Fellow" International Award, conferred by the Rotary Foundation for professional activities.
- 2004 "Vittorio Bachelet" Award, conferred for her Vaccine against AIDS.
- 2004 "Gentile da Fabriano" National Award, conferred for scientific and professional merits.
- 2004 "Stella" National Award for the year 2004, conferred by the Associazione Italiana Ospedalità Privata (A.I.O.P.) for professional activities.
- 2005 "Donna Emerita" National Award, conferred by the Federazione Italiana "Donne, Arti, Professioni ed Affari", Padova, for scientific and professional merits.
- 2005 "Premio Internazionale alle Libertà", conferred by the Associazione di Cultura Liberale "Società Libera", Milano, for scientific and professional merits.
- 2005 "Eminent Scientist of the Year 2005" International Award for Europe, conferred by the International Research Promotion Council – World Scientist Forum International Award –Science and Medicine, for scientific and professional merits.

2006	"Simpatia" National Award for the year 2006 (Sala della Protomoteca, Campidoglio, Rome), conferred for scientific and professional merits.
2006	"Provincia Capitale" Award (Palazzo Valentini, Rome), conferred by On. Gasbarra, President of the Province, for scientific and professional merits.
2006	"Foyer des Artistes" Award (Teatro Capranica, Rome), conferred by the "Centro Nazionale Arte, Cultura e Scienza", for scientific and professional merits.
2007	"Personalità Europea 2007" Award (Campidoglio, Rome), conferred by the "Centro Europeo per il Turismo, Sport e Spettacolo", for scientific and professional merits.
2008	"Rana d'oro" Award, conferred by the "Centro Culturale Sociale Sansano", for scientific and professional merits.
2008	"Melvin Jones" Award, conferred by the "Lion's Club", for scientific and professional merits.
2009	"Sebetia-Ter" International Award 2009, conferred for scientific and professional merits on the Biomedical Sciences by the Centro di Arti e Cultura "Sebetia-Ter".
2011	"Porto Venere Donna" Award 2011, for scientific and professional merits.
2014	Co- recipient of "The Abraham White Distinguished Science Award", conferred by the Fourth International Symposium on Thymosins in Health and Disease along with The George Washington University School of Medicine and Health Sciences, and the University of Rome "Tor Vergata".
2015	"Rocca d'oro" International Award Professionalism 2015.
2016	"Top Italian Women Scientist 2016" award conferred by Onda (Osservatorio nazionale sulla salute della donna)
2019	"Premio Ondina" award recognition for the Tat therapeutic vaccine experimentation conferred by Fondazione Carnevale di Viareggio
2019	"Il poggio 2019" award conferred by "Educandato Statale SS Annunziata – Villa del Poggio Imperiale" for scientific and professional merits.
2019	"Angelo che Sorride" award conferred by Fondazione Brusutti Onlus for professional merits.
2019	Acqua & Sapone Award recognition to figures who have distinguished themselves in favor of the well-being of humanity
2019	"VI Memorial' Salvo D'acquisto 'award conferred by Ancislink (no profit cultural Association)
2020	Top Italian Women Scientists 2020 recognition for the commitment and high citation number in scientific research conferred by the ONDA Foundation (National Observatory on Women's Health) and TIWS clubs
2023	Researcher.com: "World's Best Medicine Scientists", ranked #392 in Italy and #11408 in the world among Best Scientists for 2023
2023	Researcher.com: "World's Best Medicine Scientists", ranked #32 in Italy and #971 in the world among Best Immunology Scientists for 2023

## Research Support

- IMIBIC Fellowship Programme for Personalised and Precision Medicine (EC H2020 MSCA) Coordinated by IMIBIC - Maimonides Biomedical Research Institute of Cordoba, (2019-2024). Partner.
- "Development of novel vaccines against Herpes simplex virus type 1 and 2". MOH (2020-2025). Principal Investigator/Coordinator.
- "Next generation antiviral agents based on tat ("exigent")". SPRIN-D (2021-2024). Principal Investigator/Coordinator.
- "Evaluations of Tat and Tat-Env as targets for HIV interventions". Bill & Melinda Gates Foundation (2021-2024). Principal Investigator/Coordinator.

### **Completed Research Support (last 10 years)**

- ITALY-USA inter-institute (Istituto Superiore di Sanità and NIH) cooperation on "HIV/AIDS vaccine development". Program Coordinator.
- ICAV (Concerted Action on HIV/AIDS vaccine development), National AIDS Program, Ministry of Health, Italy (2003, 2004). Program Coordinator.
- Concerted Action on "The use of HIV protease inhibitors in AIDS-associated Kaposi's sarcoma", National AIDS Program, Ministry of Health, Italy. Program Coordinator.
- AVIP (AIDS Vaccine Integrated Program), FP6- EU Commission (2004-2010). Program Coordinator.
- MUVEAPRED (Mucosal Vaccines for Poverty Diseases), FP6- EU Commission (2004-2010). Principal Investigator.
- NATIONAL AIDS PROGRAM, Ministry of Health, Italy (2006). Program Coordinator.
- EUROPRISE (European Vaccines and Microbicides Enterprise), FP6-EU Commission (2008-2012). Principal Investigator.
- VIAV (Very Innovative AIDS Vaccine), FP6-EU Commission (2005-2008).
- Italy-USA Joint program for the development of vaccine against HIV/AIDS, MOH (2006-2011). Principal Investigator.
- "Determination of indicators for prevention of HIV infection, as defined by the ECDC and General Assembly UNGASS, in Institutes of Detention in Italian Regions", MOH (2011-2013). Principal Investigator.
- "ARTEMIS", MOH-EU (2011-2012). Program Coordinator.
- "Italy in Europe: national study based on the ECDC indicators", MOH (2010-2011). Program Coordinator.
- "HIV infection and drugs use: determination of ECDC indicators", MOH (2011-2012). Principal Investigator.
- "ECDC indicators for the prevention of HIV infection in the migrant population", MOH (2010-2011). Program Coordinator.
- Model of intervention for the prevention of HIV infection in a young target according to the "good practice" indicated by the European Centre for Disease Control (ECDC), MOH (2013-2015). Principal Investigator.
- MEET Project - Meeting the health literacy needs of immigrant populations. (Funded by the European Commission), NOH (2014-2015) Program Coordinator
- Special Project for the "Development of a vaccine against HIV/AIDS based on the recombinant biologically active HIV-1 Tat protein", Ministry of Health (MOH) (2007-2016). Program Coordinator.
- Phase II Trial for the Treatment of Advanced Classical Kaposi's Sarcoma with the HIV Protease Inhibitor Indinavir in Combination with Chemotherapy, Italian Medicine Agency (2006-2016). Coordinator.
- Program to "Support the MOH of South Africa in the implementation of a national program of global response to HIV & AIDS", Italian Ministry of Foreign Affairs (2008-2017). Program Coordinator.
- Molecular epidemiological monitoring of HIV subtypes and circulating recombinant forms as an intervention for HIV prevention" indicated by the European Centre for Disease Control (ECDC), MOH (2015-2016). Principal Investigator.
- "Structure and biology of the Tat/Env complex and role of anti-Tat/Env antibodies in HIV infection: implication for HIV/AIDS preventative vaccine development". MOH (2015-2017). Co-investigator

### **Completed Cooperation with Industries**

- "Therapy of AIDS-associated Kaposi's sarcoma and other AIDS-associated malignancies by using phosphorothioate oligonucleotides and other analogues directed against basic fibroblast growth factor, other cytokines and the HIV-1 Tat protein". Lynx Therapeutics, Inc., Hayward, California, USA (1993-1995). Principal investigator.
- "Joint Program ISS/Chiron (Novartis Vaccines&Diagnostics) for the development of a combined vaccine against HIV/AIDS". Chiron Corporation (Novartis Vaccines&Diagnostics), Emeryville, California, USA (2002-2005). Principal Investigator.
- Master Clinical Study Agreement for the use of the HIV protease inhibitor Indinavir in the treatment of tumors. Merck & Co., New Jersey, USA (2004). Principal Investigator.

## **Patents**

- **Ensoli B.**, Gallo, R.C.: Method for treating Kaposi's sarcoma with antisense oligonucleotides, (priority date June 4, 1993; PCT/US94/05467, Publication N. WO94/29444).
- **Ensoli B.** HIV-1 Tat, or derivates thereof, alone or in combination, for prophylactic and therapeutic vaccination. (priority date December 1, 1997; PCT/EP98/07721, Publication N. WO99/27958).
- **Ensoli, B.** Use of biologically active HIV-1 Tat, fragments or derivatives thereof, to target and/or to activate antigen-presenting cells, and/or to deliver cargo molecules for preventive or therapeutic vaccination and/or to treat infectious diseases, inflammatory and angiogenic diseases, and tumors. (priority date June 26, 2001; PCT/EP02/08377, Publication N. WO03/009867).
- **Ensoli B.** Novel Tat complexes, and vaccines comprising them (priority date March 11, 2004; PCT/EP2005/003043, Publication N. WO2005/090391).
- **Ensoli B.**, Peng B., Voltan R., Robert-Guroff M. Improved replication-competent adenoviral vectors (priority date November 17, 2005; N. US20050282319).
- **Ensoli B.**, Magnani M. Process for the production of vaccine components (priority date February 6, 2008; PCT/EP2009/001198, Publication N. WO2009/098094).
- **Ensoli B.** Immune therapy (priority date March 19, 2010; PCT/EP2011/001606, Publication N. WO2011/113618).

## **Publications:**

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