



**Prof. LANA E. KANDALAFT, PharmD, PhD**

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**Children:** George (26.10.2011), Marc (08.07.2015)

### **Professional experience:**

#### **Academic**

- 2021- Associate Professor, Faculty of Biology and Medicine, Department of Oncology, UNIL CHUV
- 2016-2021 Assistant Professor, Faculty of Biology and Medicine, Department of Oncology, UNIL CHUV
- 2015-2016 Privat-Docent, Department of Oncology, UNIL CHUV
- 2012-2017- Assistant Professor, Ovarian Cancer Research Center University of Pennsylvania, Philadelphia, USA

#### **Administrative**

- 2024- Chief of clinical and translational research, Swiss Medical Network
- 2024- Director of Vaccine Program, Genolier Innovation Campus
- 2020- Associate Director of Clinical Translation, Ludwig Institute for Cancer Research, Lausanne Branch
- 2017-2024 Chief of service, Center of Experimental Therapeutics, Department of Oncology, UNIL CHUV
- 2013-2017 Director, Center of Experimental Therapeutics, Department of Oncology, UNIL CHUV
- 2008-2013 Director, Translational Research and Clinical Development, Ovarian Cancer Research Center University of Pennsylvania, Philadelphia, USA

#### **Education:**

- 2012 Master of Science in Translational Research, University of Pennsylvania, USA
- 2007-2008 Senior Research Fellow in Carcinogenesis, National Cancer Institute, Maryland, USA
- 2005-2007 Post-Doctoral Research Fellowship in Carcinogenesis, National Cancer Institute, Maryland, USA
- 2004 Ph.D in Pharmaceutical Cell Biology, Cardiff University, Wales, UK
- 2000 Pharm.D (B.Sc. in Clinical Pharmacy), University of Jordan, Amman, Jordan
- 1995 General Certificate of Secondary Education (GSCE), London Examination (graduated with honors)

#### **Biosketch:**

My research activities over the past 15 years have focused on the development of effective cancer vaccines, both in the area of preclinical and clinical development. Another area of focus during the last years was the area of cellular therapy development, notably the process development of new advanced therapy medicinal products (ATMPs). It usually takes 10-20 years to take a biological product from a preclinical concept to the patient and usually most preclinical concepts fail due to the lack of a bridge that links the bench to bedside. The first step of this bridge is the actual clinical adaption of the experimental procedure of producing the biological product to standard operating procedures (SOPs) that can be acceptable in a Good Manufacturing Production (GMP) environment, that could be cost effective and adaptable to be used in large clinical scale production. The second component of the translational bridge between bench to bedside is the design of phase I clinical trials. I have been actively involved in those two steps and have taken several cellular therapy concepts to the clinic. With this translational experience that I have acquired during the years, I would like to spend the next portion of my career to develop and transition promising vaccination cell-based approaches to the clinic and to be actively involved in installing this know-how and culture in the next generation of medical and translational scientists.

## **Professional Expertise and Accomplishments:**

### **Clinical Development and Translation of new Therapeutic Technologies**

- Process development of new advanced therapy medicinal products (ATMPs): It usually takes 10-20 years to take a biological product from a preclinical concept to the patient and usually most preclinical concepts fail due to the lack of a bridge that links the bench to bedside. The first step of this bridge is the actual clinical adaption of the experimental procedure of producing the biological product to standard operating procedures (SOPs) that can be acceptable in a Good Manufacturing Production (GMP) environment, that could be cost effective and adaptable to be used in large clinical scale production. This resulted in several products: cellular manufacturing of dendritic cells vaccines, T cell therapy products from peripheral blood and production of T cells from tumor cells to launch Tumor Infiltrating Lymphocyte (TILs) studies in melanoma and solid tumors.
- Clinical Trial Design and Clinical Development: Another area of focus is the second component of the translational bridge between bench to bedside and this is the design of phase I clinical trials and in this area I have been quite active and involved in the design of several cellular therapy clinical trials but also I have been quite involved in generating drug based clinical trial concepts where various interventions and integration of various modalities within the standard of care is being addressed.

### **Building and managing an entire service – one of its kind in the world dedicated to taking cellular therapies from the bench to the clinic-**

My service of ~ 140 collaborators consist of a clinical development structure to write clinical protocols and compile dossiers and does all the submissions and correspondence with regulatory authorities, cellular manufacturing facilities which produce ATMPs and all the clinical and translational capabilities to aid in translating therapies to the clinic, conducting clinical trials and treating patients under Good Clinical Practice. This service serves the department of oncology and all others departments at the CHUV focusing on cancer patients' treatments. The importance of building this infrastructure and more specifically the manufacturing in house capabilities is fully described in an opinion review paper recently published (Iancu and Kandalaf, Curr Opin Biotechnol. 2020,(19)) Please see Annex 1 for full description .

### **Memberships in Professional and Scientific Societies:**

- Cooperative Ovarian Cancer Group for Immunotherapy (COGI) (2010-present)
- Gynecologic Cancer Intergroup (GCI) Translational Research Committee (2010-present)
- American Association for Cancer Research (AACR) (2006-present)
- American Association for the Advancement of Science (AAAS) (2004-2008)
- Society of Immunotherapy of Cancer (SITC) (2008-2013)
- Translational Research Cancer Centers Consortium (TRC3) (2010-2012)
- American Society of Clinical Oncology (ASCO) (2010-present)
- European Society for Medical Oncology (ESMO) (2014-present)

### **Committees:**

- Institutional Review Board (IRB), University of Pennsylvania, (2010-2012)
- Masters in Regulatory science Committee, University of Pennsylvania (2011)
- Member of the Management Committee (MC) of the COST Action CA16231 ENOVA "European Network of Vaccine Adjuvants" (2017)
- ASCO, Scientific Program Committee member, (2020-present)
- European Society for Medical Oncology ESMO, Steering Committee member (2021-present)

### **Editorial Positions:**

- Editor, J Translational Medicine, Clinical Translation Section (2010-2020)
- Associate Editor, Women's Cancer – specialty section of Frontiers in Oncology (2019-Present)
- Member of Advisory Board, Vaccines and Drug Discovery, EBioMedicine, Lancet (2019-Present)
- Member of Editorial Board, Vaccines (2019-Present)

- Guest Editor, Current Opinion in Biotechnology- Pharmaceutical Biotechnology 2020 (2019-Present)
- Associate Editor, Molecular Cancer (2020- Present)

#### **Editorial and reviewer activities (most relevant):**

Nature Medicine, Nature Cancer, Nature Communication, Science Translational Medicine, The Journal of Clinical Investigation, NPJ Vaccines, Frontiers in Immunology, Journal for Immunotherapy of Cancer, Expert Opinion on Biological Therapy, Journal of Translational Medicine, Vaccines, Oncoimmunology, Pharmacological Reviews, Clinical Cancer Research, Cell Reports, Lancet oncology.

#### **Grant reviewer:**

The Belgium Fund for Scientific Research (FNRS), Italian Association for Cancer Research (AIRC), Dutch Research Council, National Research Foundation Singapore, Geneva University Hospitals and Faculty of Medicine Research Foundation.

#### **Grants obtained:**

- **European Research Council**, Horizon 2020 Cross-priming dendritic cell therapy for Ovary and Prostate cancer Total amount requested: **Role: Co-PI Clinical Development**, (5.75M EUR, Date: 1/3/2015-1/3/2020).
- **Ovacure Grant 2015**, A Phase I/II study to test the feasibility, safety and immunogenicity of a personalized cancer vaccine in primary advanced epithelial ovarian, primary peritoneal, or fallopian tube: **Role: Sponsor/PI** (0.5M CHF, Date: 1/3/2015-1/3/2018).
- **SIO Research Grant 2017**, investigating the Immunobiology of Hepatocellular Carcinoma in Patients undergoing Y90 Radioembolization: **Role: Co-applicant** (100,000 CHF Date: 8/6/2017-8/6/2018).
- **SNF Grant 2017**, Bacteria-mediated Delivery of Polymer Nanomedicines for Cancer Chemo- and Immunotherapy: **Role: Co-applicant** (633'928 CHF Date: 1/10/2017-1/10/2020).
- **Nestle Grant 2017**, Nutrition, Immune Fitness and Anti-Tumor Response: **Role: Project PI** (2'050'000 CHF Date: 1/11/2017 – 1/11/2020).
- **Collaborative Study with BTG 2018**, Translational Approach of Cryoablation Combined with Immune-Oncology: **Role: Co-PI** (723'000 CHF, Date: 01/01/2018 – 01/01/2020).
- **Rivkin Center for Ovarian Cancer Pilot Study grant**. Development of Personalized Cancer Vaccination Strategies in Ovarian Cancer. **Role: PI** (\$75'000, Date 01.04.2019 – 30.03.2020)
- **BMS Grant 2017**, A Pilot study to evaluate the feasibility, safety, immunogenicity and time to progression in patients with surgically resected pancreatic adenocarcinoma upon treatment with an autologous dendritic cell vaccine: **Role: Sponsor/PI**: (1.768 MCHF, Date: 2019-2023)
- **ISREC Foundation**, Development of a Novel B Cell-based Vaccine for Metastatic Solid Cancers. **Role: PI** (395'000 CHF, Date 2020 – 2023)
- **Impact Cancer Foundation**, Development of a lung personalized Dendritic Cell Vaccine. **Role: PI** (Total 500'000 CHF, Date 2020 – 2024)
- **SNF Grant 2023**: PAC-MAN: Peptide-based Theranostic Agents for Clinical targeting of the Macrophage MANnose receptor CD206. **Role: co-PI** (Total 544,686 CHF, Date 2023 – 2026)

#### **Major Academic and Clinical Teaching Responsibilities:**

I have devoted many hours in teaching at various levels (undergraduate, graduate, medical fellows) and have dedicated hours for developing new course and curriculums as detailed below:

- Co-responsible for establishing a bachelor course of Bench to bedside, Faculté de biologie et de médecine, UNIL, Lausanne, Switzerland
- Co-responsible of a tutorial in cellular therapies for PhD students Faculté de biologie et de médecine, UNIL, Lausanne, Switzerland
- Responsible to organize an Option Masters course entitled: Cellular Immunotherapies: From Bench to Bedside”. The objectives of this course are to get students in pharmaceutical/biomedical/medical research programs familiar with the following subjects:
  - Cellular and experimental immunotherapies: What are they? What is their future?
  - Adoptive T cell therapy and Cancer Vaccines in Oncology
  - The regulatory path of taking cellular therapies from basic laboratories to patients’ bedside
- Co-Director of a CAS in “Thérapies Innovantes”. This CAS is a part of the “Centre de recherche et d’innovation en sciences pharmaceutiques cliniques” in collaboration with UNIGE. Students will have a certification from UNIL/UNIGE. It will consist of 6 modules covering an entire gamma of cellular therapies.

### Other teaching responsibilities

- Clinical Pharmacology Instructor, Cardiff School of Pharmacy and Pharmaceutical Sciences) (1998-2000)
- Pharmaceutical Biology Lab Instructor Cardiff School of Pharmacy and Pharmaceutical Sciences) (2001-2003)
- Lung Carcinogenesis Research Lab Mentor, summer students, NCI (2004-2008)
- Clinical Immunotherapy mentor for summer students Upenn (4 students to date), (2009-2014)
- Lecturer, “Bio-Trac, Foundation in Advanced Educations in the Sciences (FAES), NIH, Bethesda, MD.” (2004-2008)
- Mentor (Thesis Supervisor), Wharton Business School student (2010) - Thesis: Factors contributing to the incremental cost effectiveness of a novel immunotherapy for ovarian cancer.
- Mentor (Thesis Supervisor), Medical Fellow (2012) University of Pennsylvania Supervising medical clinical fellows interested in the clinical research track, University of Pennsylvania (2010-2015)
- Lecturer, Masters in Translational Research Program
- Member, Immunology Graduate Group, University of Pennsylvania (2008-2013)
- Board Member of the Fellowship’s Translational Research Program (2012)
- Designed an educational lecture series, University of Pennsylvania (2012)
- Developed a curriculum for a Cellular Therapy Course : *Cellular Therapy - From Bench to Bedside* – Program doctoral school, Faculté de biologie et de médecine, UNIL, Lausanne, Switzerland (2020-present)
- Development of a CAS, Advanced Therapy Medicinal Products, Product manufacturing and clinical use of ATMPs, – UNIL (Lausanne) / UNIGE (Geneva), Switzerland, co-president of the steering committee, member of the scientific committee (2019-present) and lecturer (2023-)
- Standing Lectures and courses, Bachelor course, masters course and PhD tutorial
- Lecturer, Bachelor and Master class in Biology, immunology and vaccine development, UNIL, (2018-present)
- Lecturer, Master Immunology & Cancer, Spring term, UNIL, (2018-present)
- Lecturer, CAS Therapies Innovantes”. UNIL/UNIGE (2023-)
- Lecturer, Tutorial from bench to bedside. UNIL (2018-)
- Thesis direction of PHD students:
  - 2017-2022 Ritaparna Ahmed, Hajer Fritah – PHD obtained in 2022
  - 2022-2026 Rania Soukarieh, Matilde Maria Coppi
- Hosts Masters students in the vaccine development Lab (2018-present)
- Hosts Erasmus interns in the vaccine development lab (2018-present)

### Participation in Round Tables and Evaluation Panels:

- Speaker: New trends in immunotherapy | TedX CHUV, November 2014. L’environnement théarapeutique de la maladie –
- Chairing Panel and Speaker: Bioalps Networking Day, Lausanne, Switzerland, November 2017

- Chairing Panel and Speaker: Academia & Industry: Developing the Future Together – SIP Network West EPFL, Lausanne, Switzerland, March 2018
- Chairing Panel and Speaker: Convergence in oncology summit: Innovations in Therapeutics – Lausanne, Switzerland, September 2018
- Chairing Session: Convergence Oncology 2020, – Lausanne, Switzerland, September 2020
- Co-moderator of the session on GMP manufacturing: Novartis Cell&Gene - GMP manufacturing for Cell Therapies, Stein+Basel, Nov 2020 Switzerland
- Chairing Session: Cancer Vaccines- ESMO Immuno-Oncology Congress, Geneva, Switzerland, December 2019
- Chairing Session: Immunotherapy in gynecologic oncology– 1st International Congress of Gynecological Oncology, Bucharest, Romania, July 2020
- Member of the ASCO Annual Meeting Scientific Program Committee - Developmental Therapeutics – Immunotherapy- 2020-2024
- Member of the ESMO Annual Meeting Scientific Program Committee Investigational Immunotherapy Track- 2022-2024

## Press

- Spy-cells conquer cancer Expat Switzerland, June 2014
- New trends in immunotherapy (G. Coukos, L. Kandalaft) TEDx CHUV, 13 novembre 2014
- Fast and curious (profil Pr. Lana Kandalaft). Le Temps, 12 avril 2017
- Les thérapies cellulaires débiteront cet été. 24 heures, 3 avril 2017
- Progressiver geht es fast nicht. (interview Pr. Lana Kandalaft) NZZ am Sonntag, 14 avril 2017
- Forum des 100 (L. Kandalaft) Le Temps, 11 mai 2017
- Early Promise Is Seen With Immunotherapy in Ovarian Cancer (L. Kandalaft) Targeted Oncology 7 february 2019
- Rencontre avec Lana Kandalaft, une spécialiste de l'immunothérapie RTS CQFD 17 may 20
- Success story: The personal vaccinologist (L. Kandalaft) Ludwig Cancer Research 12 september 2019
- Lana Kandalaft's team new study: Personalized cancer vaccine strategy elicits polyfunctional T cells and demonstrates clinical benefits in ovarian cancer. <https://www.biopole.ch/lana-kandalafts-team-new-study-personalized-cancer-vaccine-strategy-elicits-polyfunctional-t-cells-and-demonstrates-clinical-benefits-in-ovarian-cancer/>. 03.2021
- Heidi. News- Le CHUV lance des essais sur des vaccins anti-cancers révolutionnaires, Feb, 2022
- [https://avisdexperts.ch/experts/lana\\_kandalaft](https://avisdexperts.ch/experts/lana_kandalaft). CQFD 05.2022
- L'arc lémanique, acteur incontournable dans la lutte contre le cancer. Bilan.ch 2022
- Vaccine approaches to immune modulation – VJOnology. Jun 2023
- <https://www.planetesante.ch/Qui-Sommes-nous/Auteurs/Lana-Kandalaft>, 2023
- Une formation pour suivre les dernières thérapies de pointe – Allez Savoir, 12.05.2023
- Le développement de vaccins contre le cancer au CHUV -RTS La Matinale, 14 décembre 2023

## Selected press for popular scientific publications

- GEN Daily- Taking a New Shot at Tumor Vaccines- March 2019
- EureAlert- Ludwig researchers devise and test pioneering personalized ovarian cancer vaccine-April 2018
- NewScientist- Ovarian cancer vaccine improves women's survival rates – April 2018
- Science Daily – Personalized tumor vaccine shows promise in pilot trial- April 2018
- Le Temps- Vers un vaccin personnalisé contre le cancer des ovaires- April 2018
- AAAS- Personalized Vaccine Trains Immune System to Fight Ovarian Cancer- April 2018
- Science Daily -Vaccine against patients' own tumors triggers a broad response, and induced five year remission in one patient with advanced ovarian cancer- March 2018
- OnLive- Novel Two-Step Immunotherapy Shows Promise in Early-Stage Ovarian Cancer Study, July
- Medpagetoday- Immune Therapy Offers Hope in Ovarian Cancer- April 2013
- Bloomberg- Ovarian Cancer Vaccine Made From Tumors Yields Responses- April 2013
- Fox news- Ovarian cancer vaccine shows promise in trial - April 2013

- OncoLive- Novel Two-Step Immunotherapy Shows Promise in Early-Stage Ovarian Cancer Study, July 2013
- Medical Press- Personalized cancer vaccine and adoptive T cell therapy benefits patients with advanced ovarian cancer: Study- Sep 2023
- Science Daily – Combination of cancer vaccine and T cell therapy benefits patients with advanced ovarian cancer- Sep 2023

#### Patents:

- Serial No: E-297-2007/0-US-01); Differentiation-induction and chemosensitizing therapy of cancer using TIMP-2. Lana E. Kandalraft and William Stetler-Stevenson
- B-cell vaccine (Patent in preparation)

#### Peer-reviewed publications:

1. Campbell L., Abulrob A.N., **Kandalraft L.E.**, Plummer S., Hollins A.J., Gibbs A., Gumbleton M. Constitutive expression of p-glycoprotein in normal lung alveolar epithelium and functionality in primary alveolar epithelial cultures. – *J Pharmacol Exp Ther.* 2003 Jan; 304(1):441-52.
2. Siccardi D., **Kandalraft L.E.**, Gumbleton M., McGuigan C. Stereoselective and concentration-dependent polarized epithelial permeability of a series of phosphoramidate triester prodrugs of d4T: an in vitro study in Caco-2 and Madin-Darby canine kidney cell monolayers. – *J Pharmacol Exp Ther.* 2003 Dec; 307(3):1112-9.
3. Siccardi D., **Kandalraft L.E.**, Gumbleton M. and McGuigan C. Transepithelial Permeability of Phosphoramidate Triester Prodrugs of d4T Across Caco-2 and MDCK Cell Monolayers: Evaluation of Bidirectional and Stereoselective Transport- *J. Pharm. Exp. Ther.* 307, 2003 ISSN 0022-3565.
4. Morris C.J., Sherwood A., **Kandalraft L.E.**, Stephens D.J., Jones A.T., Gumbleton M. Alveolar epithelium is able to internalize macromolecules via the caveolae membrane system- *J. Pharm. Pharmacol*, 2004, 56(1): 447-56.
5. Sakagami M., Omidi Y., Campbell L., **Kandalraft L.E.**, Barar J., Gumbleton M. Molecular evidence for the expression of MHC Class I-like IgG receptor FcRn within intact rat lung alveolar epithelium and in primary alveolar cell cultures-*Proc.Resp.Drug Deliv.* IX. 2004, Volume II, 885-888. ISBN 1-930114-52-4.
6. Sakagami M., Omidi Y., Campbell L., **Kandalraft L.E.**, Morris C.J., Barar J., Gumbleton M. Expression and transport functionality of FcRn within rat alveolar epithelium: a study in primary cell culture and in the isolated perfused lung. – *Pharm Res.* 2006 Feb; 23(2):270-9. Epub 2006 Jan 1.
7. **Kandalraft L.E.**, Zudaire E., Portal-Núñez S., Cuttitta F., Jakowlew S.B. Differentially expressed nucleolar transforming growth factor-beta1 target (DENTT) exhibits an inhibitory role on tumorigenesis. – *Carcinogenesis.* 2008 Jun; 29(6):1282-9.
8. **Kandalraft L.E.**, Facciabene A., Buckanovich R.J., Coukos G. Endothelin B receptor, a new target in cancer immune therapy. – *Clin Cancer Res.* 2009 Jul 15; 15(14):4521-8.
9. **Kandalraft L.E.**, Singh N., Liao J.B., Facciabene A., Berek J.S., Powell D.J. Jr., Coukos G. The emergence of immunomodulation: combinatorial immunochemotherapy opportunities for the next decade. – *Gynecol Oncol.* 2010 Feb; 116(2):222-33.
10. **Kandalraft L.E.**, Powell D.J. Jr., Singh N., Coukos G. Immunotherapy for ovarian cancer: what's next? – *J Clin Oncol.* 2011 Mar 1; 29(7):925-33.
11. **Kandalraft L.E.**, Coukos G. The microenvironment of ovarian cancer: lessons on immune mediated tumor rejection or tolerance. In: *Immunologic signatures of rejection.* Wang E, Marincola FM, editor. Ney York: Springer; 2010, pp. 211–228.

12. **Kandalraft L.E.**, Motz G.T., Busch J., Coukos G. Angiogenesis and the tumor vasculature as antitumor immune modulators: the role of vascular endothelial growth factor and endothelin. – *Curr Top Microbiol Immunol*. 2011; 344:129-48.
13. **Kandalraft L.E.**, Motz G.T., Duraiswamy J., Coukos G. Tumor immune surveillance and ovarian cancer: lessons on immune mediated tumor rejection or tolerance. – *Cancer Metastasis Rev*. 2011 Mar; 30(1):141-51.
14. Chiang C.L., **Kandalraft L.E.**, Coukos G. Adjuvants for enhancing the immunogenicity of whole tumor cell vaccines. – *Int Rev Immunol*. 2011 Apr-Jun; 30(2-3):150-82.
15. **Kandalraft L.E.**, Coukos G. Clinical translation section: accelerating the pace from bench to bedside. – *J Transl Med*. 2011 Jul 21; 9:116.
16. Chiang C.L., Maier D.A., **Kandalraft L.E.**, Brennan A.L., Lanitis E., Ye Q., Levine B.L., Czerniecki B.J., Powell D.J. Jr., Coukos G. Optimizing parameters for clinical-scale production of high IL-12 secreting dendritic cells pulsed with oxidized whole tumor cell lysate. – *J Transl Med*. 2011 Nov 14; 9:198.
17. Chiang C.L., Hagemann A.R., Leskowitz R., Mick R., Garrabrant T., Czerniecki B.J., **Kandalraft L.E.**, Powell D.J. Jr., Coukos G. Day-4 myeloid dendritic cells pulsed with whole tumor lysate are highly immunogenic and elicit potent anti-tumor responses. – *PLoS One*. 2011; 6(12):e28732.
18. **Kandalraft L.E.**, Kalos M., Melief C.J., Speiser D.E., Coukos G. Conference scene: Immune signatures in the tumor and beyond. – *Immunotherapy*. 2012 Aug; 4(8):761-72.
19. **Kandalraft L.E.**, Powell D.J. Jr., Coukos G. A phase I clinical trial of adoptive transfer of folate receptor-alpha redirected autologous T cells for recurrent ovarian cancer. – *J Transl Med*. 2012 Aug 3; 10:157.
20. **Kandalraft L.E.**, Powell D.J. Jr., Chiang C.L., Tanyi J., Kim S., Bosch M., Montone K., Mick R., Levine B.L., Torigian D.A., June C.H., Coukos G. Autologous lysate-pulsed dendritic cell vaccination followed by adoptive transfer of vaccine-primed ex vivo co-stimulated T cells in recurrent ovarian cancer. – *Oncoimmunology*. 2013 Jan 1; 2(1):e22664.
21. **Kandalraft L.E.**, Chiang C.L., Tanyi J., Motz G., Balint K., Mick R., Coukos G. A Phase I vaccine trial using dendritic cells pulsed with autologous oxidized lysate for recurrent ovarian cancer. – *J Transl Med*. 2013 Jun 18; 11:149.
22. **Kandalraft L.E.**, Chiang C.L., Tanyi J., Hagemann A.R., Motz G.T., Svoronos N., Montone K., Mantia-Smaldone G.M., Smith L., Nisenbaum H.L., Levine B.L., Kalos M., Czerniecki B.J., Torigian D.A., Powell D.J. Jr., Mick R., Coukos G. A dendritic cell vaccine pulsed with autologous hypochlorous acid-oxidized ovarian cancer lysate primes effective broad antitumor immunity: from bench to bedside. – *Clin Cancer Res*. 2013 Sep 1; 19(17):4801-15.
23. **Kandalraft L.E.**, Balint K., Berek J., Coukos G. What is the future of immunotherapy in ovarian cancer? In: *Controversies in the management of gynecological cancers*. Ledermann J.A., Creutzberg C.L., Quinn M.A., editors. Ney York: Springer; 2013, pp. 323–337.
24. Zsiros E., Tanyi J., Balint K., **Kandalraft L.E.** Immunotherapy for ovarian cancer: recent advances and perspectives. – *Curr Opin Oncol*. 2014 Sep; 26(5):492-500.
25. Chiang C.L., Balint K., Coukos G., **Kandalraft L.E.** Potential approaches for more successful dendritic cell-based immunotherapy. – *Expert Opin Biol Ther*. 2015 Apr; 15(4):569-82.
26. Zsiros E., Duttagupta P., Dangaj D., Li H., Frank R., Garrabrant T., Hagemann I.S., Levine B.L., June C.H., Zhang L., Wang E., Marincola F.M., Bedognetti D., Powell D.J. Jr., Tanyi J., Feldman M.D., **Kandalraft L.E.**, Coukos G. The Ovarian Cancer Chemokine Landscape Is Conducive to Homing of Vaccine-Primed and CD3/CD28-Costimulated T Cells Prepared for Adoptive Therapy. – *Clin Cancer Res*. 2015 Jun 15; 21(12):2840-50.

27. Chiang C.L., Coukos G., **Kandalraft L.E.** Whole Tumor Antigen Vaccines: Where Are We? – **Vaccines (Basel)**. 2015 Apr 23; 3(2):344-72.
28. Ophir E., Bobisse S., Coukos G., Harari A., **Kandalraft L.E.** Personalized approaches to active immunotherapy in cancer. – **Biochim Biophys Acta**. 2016 Jan; 1865(1):72-82.
29. Yan X., Hu Z., Feng Y., Hu X., Yuan J., Zhao S.D., Zhang Y., Yang L., Shan W., He Q., Fan L., **Kandalraft L.E.**, Tanyi J.L., Li C., Yuan C.X., Zhang D., Yuan H., Hua K., Lu Y., Katsaros D., Huang Q., Montone K., Fan Y., Coukos G., Boyd J., Sood A.K., Rebbeck T., Mills G.B., Dang C.V., Zhang L. Comprehensive Genomic Characterization of Long Non-coding RNAs across Human Cancers. – **Cancer Cell**. 2015 Oct 12; 28(4):529-540.
30. Zsiros E., Dangaj D., June C.H., **Kandalraft L.E.**, Coukos G. Ovarian cancer chemokines may not be a significant barrier during whole tumor antigen dendritic-cell vaccine and adoptive T-cell immunotherapy. – **Oncoimmunology**. 2015 Oct 19; 5(5):e1062210.
31. Ray-Coquard I., Oaknin A., **Kandalraft L.E.** New targeted therapies and development. In: **100 key questions on ovarian cancer**. Poveda A., editor. Barcelona: Permanyer; 2016.
32. Martin Lluesma S., Wolfer A., Harari A., **Kandalraft L.E.** Cancer Vaccines in Ovarian Cancer: How Can We Improve? – **Biomedicines**. 2016 May 3; 4(2). pii: E10.
33. Coukos G., Tanyi J., **Kandalraft L.E.** Opportunities in immunotherapy of ovarian cancer. – **Ann Oncol**. 2016 Apr; 27 Suppl 1:i11-i15.
34. Graciotti M., Berti C., Klok H.A., **Kandalraft L.E.** The era of bioengineering: how will this affect the next generation of cancer immunotherapy? – **J Transl Med**. 2017 Jun 19; 15(1):142.
35. Bassani-Sternberg M., Chong C., Guillaume P., Solleder M., Pak H., Gannon P.O., **Kandalraft L.E.**, Coukos G., Gfeller D. Deciphering HLA-I motifs across HLA peptidomes improves neo-antigen predictions and identifies allosteric regulating HLA specificity. – **PLoS Comput Biol**. 2017 Aug 23; 13(8):e1005725.
36. Guo Y, Hu J, Wang Y, Peng X, Min J, Wang J, Matthaiou E, Cheng Y, Sun K, Tong X, Fan Y, Zhang PJ, **Kandalraft L. E.**, Irving M, Coukos G, Li C. Tumour endothelial marker 1/endothelialin-mediated targeting of human sarcoma. – **Eur J Cancer**. 2018 Jan 2;90:111-121.
37. Graciotti M, Mookerjee A, **Kandalraft L.E.** A cancer vaccine with dendritic cells differentiated with GM-CSF and IFN $\alpha$  and pulsed with a squaric acid treated cell lysate improves T cell priming and tumor growth control in a mouse model – **Bioimpacts**. 2018;8(3):211-221. Epub 2018 Jun 10. Correction: Bioimpacts. 2019;9(1):65.
38. Herrera FG, Valerio M, Berthold D, Tawadros T, Meuwly JY, Vallet V, Baumgaertner P, Thierry AC, De Bari B, Jichlinski P, **Kandalraft L.**, Coukos G, Harari A, Bourhis J. 50 Gy Stereotactic Body Radiation Therapy to the Dominant Intra-Prostatic Nodule: Results from a Phase Ia/b Trial - **Int J Radiat Oncol Biol Phys**. 2019 Feb 1;103(2):320-334
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115. Michele Graciotti, **Lana E. Kandalajt**. Cancer preventive vaccines: navigating challenges and embracing hopes. *Nat Rev Drug Discov*. 2024 Dec 2. doi: 10.1038/s41573-024-01081-

#### Invited lectures and international conferences

1. Autologous Whole-Tumor Antigen Combinatorial Immuno-therapy for Recurrent Ovarian Cancer-TRC3. **Pittsburg, US** February 2011
2. Combinatorial Immunotherapy Approaches in Ovarian Cancer- COGI, **Chicago, US**. June 2012
3. Combinatorial Immunotherapy Approaches in Ovarian Cancer- Gynecologic Oncology Fellowship Program at University of Pennsylvania, **Philadelphia, US**- October 2012
4. Autologous Whole-Tumor Antigen Combinatorial Immunotherapy for Recurrent Ovarian Cancer-AACR
5. Special Conference Tumor Immunology: Multidisciplinary Science Driving Basic and Clinical Advances-**US**, December 2012
6. Personalized Vaccines for Ovarian Cancer- Cancer Support Community Conference, **Philadelphia, US**, Jan 2013
7. Whole Tumor Antigen Vaccine Approaches- CRRWH Conference Series- **Philadelphia, US**, April-2013
8. Autologous Whole-Tumor Antigen Combinatorial Immunotherapy for Recurrent Ovarian Cancer-AACR-April Miami, US, 2013 (Press Conference Invitation)
9. Immunotherapy in Ovarian Cancer- Delaware Ovarian Cancer Foundation, **Delaware, US** June 2013
10. Combinatorial Immunotherapy Using Whole Tumor Antigen: Evidence from Phase I Trials-AACR Special Conference on Advances in Ovarian Cancer Research: From Concept to Clinic, **Washington DC, US** September 2013
11. Developing Personalized Vaccines to Treat Ovarian and Other cancers Affecting Women- Women in Science Second Annual Lecture, **Montreux, Switzerland**, October 2013
12. Collaborative Clinical Studies on Immunotherapies to Treat Ovarian Cancer- Clinical Trials of Dendritic Cell Therapies for Cancer: Biotech's Bumpy Road to the Market- The New York Academy of Sciences, **NY, US**. Oct 2013.
13. Combinatorial Immunotherapy and Anti-angiogenic Approaches in Ovarian Cancer- Immunotherapy Of Cancer Conference, **Munich, Germany**, March 2014
14. Immunotherapy of Gynecologic Cancers- XI. Gynecological Discourse, Salzburg, Austria, December 2014
15. Ovarian Immunology- Advanced Ovarian Cancer Optimal Therapy. Update ESMO International Symposium, **Valencia, Spain**, March 2015
16. Ovarian Cancer - ESMO Preceptorship on Immunotherapy of cancer, **Prague, Czech Republic**, October 2015
17. Immunotherapy of Gynecologic Cancers- Cancer Cross Links, **Lund, Sweden**, October, 2015
18. Immunotherapy of Ovarian Cancer: challenges and opportunities - 4th GINOVA meeting (Journée scientifique du Groupe Coopératif GINOVA (Groupe d'Innovation et de recherche sur les Néoplasmes OVAriens). **Nantes, France**, December 2015
19. Present and future of immunotherapy strategies in gynecological cancers. EORTC GCG, **Madrid, Spain**, April 2016
20. Cellular Immunotherapy for Ovarian Cancer. EORTC GCG, **Lausanne, Switzerland**, September 2016
21. Immunotherapy in Ovarian Cancer – Personalised medicine in gynaecological cancers. ESMO Congress, **Copenhagen, Denmark**, October 2016.
22. Immunotherapy in Ovarian Cancer. 16th Biennial Meeting of the IGCS 2016, **Lisbon, Portugal**, October 2016.
23. Adoptive T-cell transfer – ESMO Preceptorship on Immuno-Oncology, **Zurich, Switzerland**, November 2016
24. Ovarian Cancer – ESMO Preceptorship on Immuno-Oncology, **Zurich, Switzerland**, November 2016

25. My vision on how to cure ovarian cancer through innovative personalised immunotherapy approaches –3rd Annual OvaCure Innovation Summit, **Geneva, Switzerland**, November 2016.
26. Immune checkpoints inhibitors – New targets in gynaecological cancers, ESMO Asia 2016, **Singapore, Asia**, December 2016.
27. Immuno-Oncology: new possibilities to treat hardly treatable types of cancer –Science Media Meeting, **Zurich, Switzerland**, March 2017.
28. Modulation of endothelial cells for T Cell recruitment – 4th ImmunoTherapy of Cancer Conference (ITOC-4), **Prague, Czech Republic**, March 2017.
29. Combinatorial Immunotherapy Approaches in Ovarian Cancer – Cambridge Healthtech Institute’s Combination Immunotherapy **London, UK**, March 2017.
30. Immunotherapy for Ovarian Cancer: Recent Advances and Perspectives – Ovarian Cancer Conference, **Warsaw, Poland**, May 2017.
31. Different Vaccine Approaches: Advantages and Challenges – OvaCure Innovation Summit, **Copenhagen, Denmark**, September 2017.
32. The Immunotherapy Story – ESGO 2017, **Vienna, Austria**, November 2017
33. Using Tumors for Therapy- Personalized whole tumor antigen vaccination in ovarian cancer – Distinguished Clinicians in oncology – CHUV, **Lausanne, Switzerland** December 2017
34. Whole Tumor Antigen Vaccines in Ovarian Cancer - ESMO Immuno-Oncology Congress 2017, **Geneva, Switzerland**, December 2017
35. Personalized Whole Tumour Antigen Vaccines in Ovarian Cancer: Using Tumors for Therapy – ITOC5, **Berlin, Germany**, March 2018
36. Les innovations en médecine de précision en vue – 20ème Congrès Suisse des soins en oncologie, **Geneva, Switzerland**, March 2018
37. Using Tumors for Therapy: Personalized Whole Tumor Antigen Vaccination in Ovarian Cancer – Cancer Vaccine Summit 2018, **Prague, Czeck Republic**, April 2018
38. Cancer Vaccines – ESMO Preceptorship on Immuno-Oncology, **Lugano, Switzerland**, May 2018
39. Dendritic Cell Vaccines in Ovarian cancer – 15th International Symposium on Dendritic Cells, **Aachen, Germany**, June 2018
40. Mobilizing antitumor immunity: Lessons from ovarian cancer – KWF’s working party Dutch Tumor Immunology Meeting (KWF-DTIM), **Amsterdam, Netherlands**, June 2018
41. Development of Vaccines in Ovarian Cancer Immunotherapy – FIGO 2018 Congress, **Rio de Janeiro, Brazil**. October 2018
42. Hope for late-stage ovarian cancer: Development of a personalized dendritic cell vaccine – 3rd Immuno Oncology Profiling Conference - 19th World Vaccine Congress Europe, **Lisbon, Portugal**, October 2018
43. Optimizing immune checkpoint inhibitor therapy in ovarian cancer – ESMO Immuno-Oncology Congress 2018, **Geneva, Switzerland**, December 2018
44. Personalized/Neoantigen Vaccines – 2019 ASCO-SITC Clinical Immuno-Oncology Symposium, **San Francisco, California**, March 2019
45. T cell therapy in oncology : state of the art & perspectives – GORTEC Meeting, **Lille, France**, June 2019
46. Personalized Whole Tumour Antigen Vaccines in Ovarian Cancer: Using Tumors for Therapy – DC-based immunotherapy in cancer and autoimmune diseases (Miltenyi Biotech), **Barcelona, Spain**, July 2019
47. Personalized Whole Tumour Antigen Vaccines in Ovarian Cancer: Using Tumors for Therapy – HHMT 14th International Forum on Ovarian Cancer, **Surrey, United-Kingdom**, September 2019
48. Personalized Whole Tumour Antigen Vaccines in Ovarian Cancer: Using Tumors for Therapy – AACR Special Conference: Advances in Ovarian Cancer Research, **Georgia, USA**, September 2019
49. Transforming Immunologically Cold Cancers into Hot Cancers with Vaccines and Act – IGCS Annual Meeting 2019, **Rio de Janeiro, Brazil**, September 2019
50. Rationale For, and an Orientation To, Immunotherapy – ESMO 2019 Congress, **Barcelona, Spain**, September 2019
51. Hope for Late-Stage Ovarian Cancer: Development of a Personalized Dendritic Cell Vaccine – World Vaccine Europe 2019, **Barcelona, Spain**, October 2019



52. Immunotherapy in Gynae-Oncology: Why and How? – ESGO 2019, **Athens, Greece**, November 2019
53. Personalized Cancer Vaccines: Lessons Learnt from Ovarian Cancer – The Third Combined Gulf Cancer Conference, **Kingdom of Bahrain**, December 2019
54. The future of Immunotherapies in the Treatment of Gynecological Malignancies – The Third Combined Gulf Cancer Conference, **Kingdom of Bahrain**, December 2019
55. Personalized Cancer Vaccines in Ovarian Cancer – ESMO Immuno-Oncology Congress, **Geneva, Switzerland**, December 2019
56. Immuno-Oncology in Gynecological cancers: an overview- NSGO Symposium, **Oslo, Norway**, March 2020
57. Principles of cellular immunotherapies in gynecologic oncology– 1st International Congress of Gynecological Oncology, **Bucharest, Romania**, July 2020 (Webex)
58. Enhancing Cellular Immune Responses in Gynecologic Cancers- ASCO educational virtual Program, July 2020
59. Tipping the hand of Immunotherapy in Ovarian Cancer- Update in gynecologic tumors: Shaping the future, **Barcelona, Spain** November 2020
60. Immunotherapy – the basics, Annual meeting Nordic Society of Gynecologic Oncology, **Oslo, Norway**, November 2020
61. Cancer Vaccines for Ovarian Cancer: challenges and opportunities - 7th GINOVA meeting (Journée scientifique du Groupe Coopératif GINOVA (Groupe d’Innovation et de recherche sur les Néoplasmes OVAriens). **Nantes. France**, November 2020
62. Anticancer Vaccines - NSGO-CTU Satellite Symposium. **Copenhagen, Denmark**, November 2021
63. Ovarian cancer, panel speaker - I UPDATE in gynecologic tumors: shaping the future. **Madrid, Spain**, November 2021.
64. Personalized Whole tumor Lysate Vaccines in the New Era of Neo-Antigens. VIB conference ‘Immuno-Oncology. **Leuven, Belgium**, June 2022
65. Cancer vaccines based on whole-tumor-lysate or neoepitopes with validated HLA-binding outperform those with predicted HLA-binding affinity - ESMO Immuno-Oncology Congress 2022, **Geneva, Switzerland**
66. Novel Immunotherapeutics: Perspectives on Checkpoints, Bispecifics, and Vaccines in Development, ASCO annual meeting, **Chicago, USA**, June 2023
67. A tale of tribulations and trials: developing a cell therapy program in Europe. Champalimaud Foundation Workshop, **Lisbon, Portugal**, April 2024
68. Plenary Lecture Invitation for NYAS Symposium: Frontiers in Cancer Immunotherapy, **NY, USA** May 2024
69. Cancer Vaccines, ESMO, **Madrid, Spain**, Sept 2024

## Annex 1

### **The Center for Experimental Therapeutics:**

The CTE, established in 2013, is a hospital-based clinical research service of the Department of Oncology, whose mission is to support clinical trials and patient-oriented research. The CTE is led by Prof Lana Kandalaft, who built the CTE from the ground up was recruited from the University of Pennsylvania in 2013.

The CTE today comprises units that work together as one organization to support integrated research from bench to bedside, and back, operating according to a stringent Quality Management System. To carry out its mission, the CTE consists of five primary platforms and offices: a) The Quality and Monitoring Office, responsible for quality control, quality assurance, and pharmacovigilance; b) The Clinical Research Office, which includes clinical study development, data management, and regulatory affairs; c) The Translational and Clinical Platform, which comprises a unit of clinical investigation, with staff dedicated to running and coordinating clinical studies in collaboration with the clinical services, a biobank and a translational laboratory of high dimensional tissue imaging; and d) the Manufacturing Platform, which includes the Tech Transfer Unit; The GMP Cell Manufacturing Facility (CMF) platform; and the Peptide and Tetramer Facility (PTF). A Vector & Viral Facility has been planned and the project has started.

The CTE has played a pivotal role in establishing a robust infrastructure for supporting phase I innovative clinical studies, including cell therapy and non-cell therapy studies, which have featured numerous PIs from all Department of Oncology services, including clinical trials and translational studies.

### **The CTE manufacturing environment**

#### **The CTE manufacturing environment includes several units:**

- a) **Technology transfer unit:** The technology transfer unit is the starting point of the product manufacturing. This unit is dedicated to bringing a process from development to manufacturing. The common steps for tech transfer are but not limited to: small scale study; large scale study; selection of materials in conformance to cGMP regulations; selection of process equipment in conformance to cGMP regulations; set up and validation of analytical methods needed to characterize a GMP product; preparing all documentation needed to submit the IMPD (investigational medicinal product dossier); transferring the process to a cGMP production facility; creating all the documentation needed to support the manufacture of the product (Change control, SOP, Master batch records... etc); training technician and production scientists. All these activities are performed in a semi-regulated environment with materials and equipment that mimic closely the final production processes.
- b) **Cellular manufacturing facility:** The cellular manufacturing facility (CMF) is the core production area for all cell based cGMP products. This facility is composed of the following areas: A production area of 90 cm<sup>2</sup> dedicated to non- genetically modified organisms (GMO); a small non-GMO production area for media preparation (24 cm<sup>2</sup>); a second large area of 109 cm<sup>2</sup> dedicated to GMO production. The manufacturing areas are configured in modules organized in open working bays, which can flexibly accommodate multiple processes and more than one patients. These production areas are environmentally controlled in class D. All open product operation occur in class A isolators.
- c) **Peptide and tetramer core facility:** The PTCF is a platform dedicated to the production of high quality grade peptides, used for research or clinical purposes; since June 2023, PTCF is qualified by Swissmedic to produce cGMP grade peptides, to be used in GMP products. The PTCF also produce tetramers which are used for research.

- d) Quality assurance and quality control: Quality assurance is an office responsible for the compliance to regulation of the overall processes in order to certify the cGMP products. CMF and PTCF are regularly inspected by the regulatory authority (Swissmedic) and are granted certificates to deliver ATMP products. Quality control is a cGMP compliant laboratory that is responsible for analyzing all critical attributes of a specific product to release. It includes sterility analysis, Elisa methods, FACS methods, endotoxin measurement and more, depending on the product release requirements.

#### Office of clinical research – study preparation and regulatory application support

The Clinical Research Bureau consists of the following units: a) Clinical Development Unit; b) Regulatory Affairs Unit; c) Pharmacovigilance Unit; d) Clinical Data Management Unit; and e) Biostatistics Unit. This Office is in charge of submitting clinical studies to the competent authorities. Its team ensures that the files submitted to the authorities comply with the applicable regulations (Regulatory Affairs Unit). These dossiers include: clinical protocols, investigator brochures and pharmaceutical quality dossier (PQD, which is equivalent to the US Investigator New Drug (IND) application; prepared by the Clinical Development Unit), reports of serious adverse events and notification of safety and protection measures (e.g. SAE, SUSARs, annual safety report; prepared by the Pharmacovigilance Unit). In particular, the Office drafts patient information and consent forms, so that patients can participate in a study protocol in a free and informed manner (Clinical Development Unit), as well as redacting the electronic case report forms (eCRFs) that collects all relevant data from patients participating in the clinical trial (Clinical Data Management Unit & Biostatistics Unit). This Bureau also contributes to the writing of scientific publications or reports.

#### Clinical platform - clinical study management:

The Clinical and Translational Platform is responsible for the operational implementation and execution of all clinical studies conducted at the DO (Clinical Investigation Unit), from the initial feasibility analysis (Clinical Operations Unit) to the activation of the study, execution, close-out and archiving, whether the study sponsor is local (CHUV), external academic centers or pharmaceutical companies. When the CHUV is the sponsor, its teams actively participate in writing the operational parts of the clinical protocol (clinical, biological, radiological assessments, etc.) in close collaboration with the medical and nursing teams of the Oncology Department (Clinical Operations Unit). At the core of these activities, the Biobank acts as a central platform for all tissue specimens for Translational Research from the various clinical studies (blood, serum, plasma, PBMCs, etc) by ensuring their appropriate processing, storage and shipment when and how appropriate. It also can provide samples for various research groups. This platform also carries out analytical activities for translational studies linked to the immunotherapy clinical studies. Notably, the Immune Landscape Laboratory conducts cutting-edge analysis of tissue samples (multiplex imaging as well as spatial omics). The Clinical and Translational Platform consists of the following units: a) Clinical Operations Unit; b) Clinical Investigation Unit; c) Biobank; d) Coordination and Data Unit; and e) the Immune Landscape Laboratory.