

# ESMO WORKSHOP

An abstract geometric pattern composed of numerous small triangles in various shades of blue, green, purple, and brown, arranged in a complex, non-repeating pattern that resembles a stylized 'X' or a large arrow pointing downwards and to the right.

**GENDER MEDICINE  
MEETS ONCOLOGY**

**LAUSANNE SWITZERLAND  
30 NOV. – 01 DEC. 2018**

## **Final Programme**

### **Organizing Committee:**

D. Wagner, B. Özdemir, G. P. Dotto

### **Friday, November 30, 2018**

**8.00 - 8.45:** Light refreshments

**8.45:** *Dorothea Wagner, George Coukos*

Welcome

### **Session 1. Gastrointestinal Cancers and the Concept of Gender Medicine**

Chairs: D. Wagner/ M. Ducreux

**9.00 - 09.30:** *Michel Ducreux*, Institut Gustave Roussy, Paris

Clinical impact of sex and gender on biology and treatment of GI cancer

**9.30 - 10.00:** *Sabine Oertelt-Prigione*, Radboud University Medical Center, Nijmegen

What is gender medicine and why do we need it? Current concepts and methods

**10.00 - 10.30:** *Valéry Lemmens*, Netherlands Cancer Registry

Epidemiology of non-sex-related cancers in men and women: impact of biology and behaviour

**10.30 - 11.00** Coffee Break

### **Session 2. Lymphoma, Disease Biology, and Pharmacology**

Chairs: G. P. Dotto, B. Özdemir

**11.00 - 11.30:** *Anne Letsch*, Charité, Berlin

Impact of sex on the biology and treatment of lymphomas

**11.30 - 12.00:** *Gian-Paolo Dotto*, University of Lausanne, Lausanne

Sex differences in hormones, chromosomes and metabolism and their potential impact on malignant tumours

**12.00 - 12.15:** *Arnaud Hocquelet*, CHUV, Lausanne

Sex differences in body composition – how can they be assessed?

**12.15 - 13.00:** *Thierry Buclin, Chantal Csajka, CHUV, Lausanne*

Sex differences in the pharmacology of different classes of anticancer drugs (chemotherapies, tyrosine-kinase inhibitors, antibodies) and possible strategies for dose individualization

**13.00 - 14.15** Lunch

### **Session 3: Melanoma, the Immune System and Gendered Innovations**

Chairs: M. Moehler/ S. Peters

**14.15 - 14.45:** *Sabine Oertelt-Prigione, Radboud University Medical Center, Nijmegen*

Gendered innovations in medicine

**14.45 - 15.15:** *Jacques Fellay, CHUV, Lausanne*

Sex differences in the immune system and immune reactions

**15.15 - 15.45:** *John Haanen, National Cancer Institute, Amsterdam*

Sex differences in melanoma biology and treatment

**15.45 - 16.15:** Coffee Break

### **Session 4: Methodological Aspects**

Chairs: O. Dafni, A. Adjei

**16.15 - 16.45:** *Alex Adjei, Mayo Clinic, Rochester*

Consideration of patients' sex in drug development in oncology

**16.45 - 17.15:** *Ourlia Dafni, University of Athens*

Methodological hurdles in evaluating the impact of sex in oncology clinical trials

**17.15 - 17.45:** *Murielle Mauer, EORTC, Brussels*

Analyses of sex in oncology clinical trials: EORTC experience and position

**19.30:** Welcome cocktail followed by dinner with all participants (Chateau d'Ouchy)

## **Saturday December 01, 2018**

**8.30 - 9.00:** Light refreshments

**9.00 - 12.00** (Coffee Break 10:30 - 10:45): Elaboration of consensus statements with all faculty members

Chairs: *D. Wagner, M. Ducreux, G. P. Dotto, B. Özdemir, M. Moehler, S. Peters, G. Coukos, U. Dafni, A. Adjei*

Discussion of consequences and perspectives with all speakers, organizing committee and participants

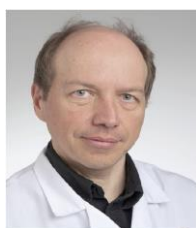
## Faculty



### **Alex Adjei**

Alex A. Adjei is Professor of Oncology and Professor of Pharmacology in the Mayo College of Medicine. He is also a consultant in Medical Oncology at Mayo Clinic. Dr Adjei is Director of the Early Cancer Therapeutics Program across all three Mayo Clinic sites, and leader of the Lung Cancer Program across all three Mayo Clinic sites.

He is the Principal Investigator of the Mayo Phase I and Phase II NCI grants. Dr Adjei has served on a number of National Cancer Institute Committees. He is the Editor-in-Chief of the Journal of Thoracic Oncology. Dr Adjei's research is focused on experimental therapeutics and clinical drug development. He received the first ASCO Drug Development Research Professorship 2012-2017, in recognition of his mentorship and his work in cancer drug development. He has authored 260 publications dealing primarily with preclinical pharmacology and phase I trials as well as novel therapeutics/phase II trials of lung cancer.



### **Thierry Buclin**

Thierry Buclin obtained his MD degree at the University of Lausanne in 1984 and received full clinical training in Internal Medicine, complemented by stages in Neurology and Psychiatry. Since 1991, he has undertaken a specialisation in Clinical Pharmacology under the direction of Jean-Louis Schelling and Jérôme Biollaz. In 1998, he received an

appointment of Senior Lecturer and Researcher at the University of Lausanne, where he participated in the teaching of Clinical Pharmacology to medicine and pharmacy students. In 2004, he was made Privat-Docent for the teaching of a specialized workshop on pharmacokinetic-pharmacodynamic models. In 2008, he benefited from a sabbatical leave in the Centre for Evidence-Based Medicine in Oxford, where he conducted a research project in the clinical epidemiology of therapeutic monitoring. In 2011, he received the chair of Clinical Pharmacology at the University Hospital of Lausanne. He supervises the clinical services offered by his department (consultation, pharmacovigilance, teratovigilance, therapeutic drug monitoring), and he has the responsibility of teaching and specialized training in his discipline. The research projects conducted in his unit pertain to the clinical development of new drugs (phase I trials, PKPD modelling), the optimisation of established treatments through therapeutic concentration monitoring (HIV and other anti-infective agents, new anticancer drugs), and the elaboration of investigational methods in renal and cardiovascular pharmacology. Thierry's particular interests are for methodological aspects of clinical research (study design, data analysis, pharmacometrics, biostatistics, modelling of drug effects), with the aim of translating them into elements supporting the efficient, rational, adapted, safe and monitored use of medicinal drugs. He also works on the societal implications of medicinal drug development and consumption. He is a member of several scientific societies, including the Swiss Society for Clinical Pharmacology and Toxicology, which he chaired 2003-2005 and 2017-2019. Besides his professional involvement, Thierry is fond of mountaineering and ancient music.



### **Chantal Csajka**

Chantal Csajka is Associate Professor of clinical pharmacy at the School of Pharmaceutical Sciences, University of Geneva and Lausanne and Research Unit leader at the Service of Clinical pharmacology, University Hospital of Lausanne (CHUV). She leads the unit of Pharmacometrics that has been very active in the field of modeling and simulation of pharmaceutical drugs to promote optimisation of drug use in various fields of drug therapy and with a special focus on at risk populations.

She has initiated and is co-investigator of several translational research projects on the population pharmacokinetic-pharmacodynamic and pharmacogenetic modeling of drugs in collaboration with local, national and international groups. She is the principal investigator of a study on target anticancer therapies at the CHUV that aims at providing better understanding of factors affecting kinase inhibitors' pharmacokinetics, efficacy and toxicity. Her research is supported by several grants from the Swiss National Research Foundation and other institutions and she is working in close collaboration with experts' groups in the field of analytics, pharmacogenetics, therapeutic drug monitoring, pharmacometrics and pharmacoepidemiology.



### **George Coukos**

Prof. George Coukos is currently leading the Department of Oncology at UNIL-CHUV, as well as the Ludwig Lausanne Branch and the Swiss Cancer Center, Lausanne.

Prof. Coukos is interested in elucidating fundamental mechanisms in the tumor microenvironment (TME) that determine the fate of antitumor immunity, focusing on the study of the deregulation of tumor-infiltrating lymphocytes (TILs). These studies are expected to yield novel pharmacologic approaches to restore antitumor immunity as well as novel methodologies to select and expand TILs for adoptive therapy. He is also involved in the study of the tumor vasculature as a barrier to effective T cell infiltration in many tumors, but also as a potential target for therapy. Prof. Coukos is pursuing T cell engineering approaches as a means to address the deregulation of T cells in the TME, and for redirecting them against relevant tumor targets, including the vasculature, with the ultimate goal of translating basic discovery to the clinic.

Prof. Coukos obtained his MD in 1986 at the University of Modena and his PhD in 1991 at the University of Patras. He completed training in obstetrics and gynecology at the University of Modena in 1991. He did a post-doc at the University of Pennsylvania in Philadelphia in cell biology (1991-1994), and he completed residency training in obstetrics and gynecology (1994-1997) and fellowship training in gynecologic oncology (1997-2000) at the University of Pennsylvania. In 2000, he became Assistant Professor at the University of Pennsylvania. He became Associate Professor in 2006 and Full Professor in 2010. At UPenn, George Coukos founded (2007) and directed the Ovarian Cancer Research Center, and served as Associate Director of the Division of Gynecologic Oncology. He then relocated to Switzerland in 2012, to become Director of the Ludwig Institute for Cancer research Lausanne Branch in 2012, Director of the new Department of Oncology at the University Hospital of Lausanne (CHUV-UNIL) in 2013, and Director of the Swiss Cancer Center Lausanne in 2013.



### **Ourania Dafni**

Urania Dafni (DSc in Biostatistics; Harvard School of Public Health; 1993) is currently Professor of Biostatistics at the University of Athens, Greece, and Professeure Invitée at the University of Lausanne (UNIL), Switzerland. She is the Director of Frontier Science Foundation-Hellas (FSF-H) and Group Statistician for the European Thoracic Oncology Platform (ETOP). She has been the Statistics Editor of the journal Lung Cancer since 2013, a member of the ASCO Scientific Program Committee (2013-16), ASCO ICTW Working Group (2017-20), and the International Biometric Society (IBS) Education Committee (2010-16). She is on the ESMO Open editorial board, and is a member of the ESMO Faculty for the Principles of Clinical Trials and the ESMO Magnitude of Clinical Benefit Scale Working Group (ESMO-MCBS). She has served as faculty in numerous educational workshops organized by ESMO, ESO, ETOP and ASCO ICTW. Prof Dafni has over 25 year experience as a Senior Statistician in Clinical Trials and/or Group Statistician of International Cooperative Groups (ACTG; HECOG; BIG-TransHERA; ETOP; CHUV CTE). Her research interests include surrogate markers, multivariate count data, adaptive trial design and methods accounting for crossover.



### **Gian-Paolo Dotto**

Gian-Paolo Dotto is Professor in the Department of Biochemistry at the University of Lausanne, Switzerland, and Biologist at Massachusetts General Hospital, Boston, Mass. He is founder of the newly established International Cancer Prevention Institute (ICPI) (<http://www.icpi-web.org>).

Prof. Dotto was educated at the University of Turin, Italy, where he received his MD in 1979. He then earned his PhD in bacteriophage genetics at the Rockefeller University, New York, in 1983 and received postdoctoral training at the Whitehead Institute/MIT in Cambridge Mass., in the laboratory of Robert A. Weinberg.

Prof. Dotto joined Yale University, New Haven, Connecticut, as assistant professor of Pathology in 1987. In 1992 moved to Harvard Medical School, as associate professor of Dermatology and, in 2000 he obtained full professorship at Harvard Medical School with a Biologist position at Massachusetts General Hospital, which he still maintains. Since 2002 he has been Professor of Biochemistry at the University of Lausanne. He is member of the European Molecular Biology Organization (2011), the Academia Europaea (2012), the Leopoldina German National Academy of Sciences (2014) and an Overseas Fellow of the Royal Society of Medicine (2018).

Prof. Dotto's main research contributions have been in the field of epithelial tissue homeostasis and carcinogenesis, focusing on field cancerization and on novel integrated approaches to primary and secondary cancer prevention as it relates more specifically, to sex and race differences.



### **Michel Ducreux**

Michel Ducreux, MD, PhD, is head of the Gastrointestinal Unit at Gustave Roussy, and professor of oncology at University of Paris Saclay in France. He trained in medicine, gastroenterology, and gastrointestinal tract oncology at the University of Paris Sud, and holds a masters degree in biological sciences and a PhD in health sciences. He has held positions as assistant physician and professor of oncology at the Gastrointestinal Unit of Gustave Roussy and Paul Brousse Hospital in Villejuif. He became medical affairs director of Gustave

Roussy in January 2011. He is the former chair of the European Organisation for Research and Treatment of Cancer (EORTC) Gastrointestinal Tract Cancer Group, and is the former chair of the Gastrointestinal Group of the French Federation of Anticancer Centers (FNCLCC). He is co-editor for GI oncology of the *European Journal of Cancer*.

Professor Ducreux has published more than 430 scientific articles, with papers for which he was lead author, focussing on the management of metastatic colorectal cancer, locally advanced and metastatic pancreatic carcinoma, biliary tract carcinoma, hepatocellular carcinoma, and treatment of neuroendocrine tumors. Further to this, Professor Ducreux is author to over 150 invited lectures in various national and international congresses.



### **Jacques Fellay**

Jacques Fellay is a medical doctor and researcher, with expertise in human genomics of infectious diseases and strong interest in personalized health. He is the founding Director of the Precision Medicine Unit of the Lausanne University Hospital (CHUV) and he leads a genomics laboratory at the EPFL School of Life Sciences. The aim of his research is to decipher the genetic basis of inter-individual differences in immune responses to infections. His group explores the role of human genetic variation in the host-pathogen battle, in the hope of shedding new light on basic biological mechanisms and of paving the way toward more personalized approaches to medicine.



### **John Haanen**

Dr. John B. Haanen is Chief Scientific Officer immunotherapy (CSO), Consultant medical oncologist of the division of Medical Oncology and Staff Scientist in the Division of Immunology at the Netherlands Cancer Institute in Amsterdam. He is also Professor of Translational Immunotherapy of Cancer at Leiden University Medical Centre, the Netherlands.

Dr. Haanen received his medical degree from the University of Leiden, then completed a PhD on human CD4+ helper T cells at the Department of Immunohematology and the Blood Bank of the Leiden University Medical Centre and the DNAX Research Institute in California, USA.

He then trained in internal medicine at Leiden University Medical Centre and at Bronovo Hospital in The Hague, the Netherlands. He did a postdoctoral fellowship in tumor immunology at the division of immunology, followed by training in medical oncology at the Netherlands Cancer Institute.

His research focuses on the translation of novel immunotherapy strategies into the clinical practice, especially adoptive cell transfer programs and immune checkpoint blockade. His clinical medical oncology practice is focused on melanoma and renal cell carcinoma patients.

Dr. Haanen is a co-founder of the Amsterdam Biotherapeutics Unit and was Chairman of The Dutch Tumor Immunology Working Party for Oncology for many years. He is currently ESMO faculty chair for immunotherapy of cancer.

He serves on various national and international advisory boards and committees, including the editorial board of Current Oncology Reports, Kidney Cancer and ESMO Open.





### **Arnaud Hocquelet**

Research Experience: May 2017 – present, Fellow at Lausanne University Hospital, Service de radiodiagnostic et radiologie interventionnelle, Switzerland; Nov 2015 – present, PhD Student at University of Bordeaux, College of Health Sciences, Bordeaux, France; Jan 2014 – present Radiologist, Centre Hospitalier Universitaire de Bordeaux, Pôle imagerie médicale (Groupe hospitalier Saint-André), Bordeaux, France.

Dr Hocquelet received the 2015 Editor's Award of "the International Journal of Hyperthermia" with article "Radiofrequency ablation versus surgical resection for hepatocellular carcinoma within the Milan criteria: A study of 281 Western patients"; he was the winner of the "Prix de Médecine Emile Aubertin 2015 (prix de these d'université)"; he was awarded Congress of the European Society for Gastrointestinal and Abdominal Radiology 2015: Top20 speaker.

He has a ResearchGate Score of 23.93; 24 publications with 1,196 reads and 113 citations.



### **Valéry Lemmens**

Valery Lemmens is head of the Department of Research and Development of the Comprehensive Cancer Organisation the Netherlands. He is a full professor of cancer surveillance at Erasmus MC University in Rotterdam. His research focusses on gastrointestinal cancer, real world data and quality of care, and has (co-)authored 270 peer-reviewed articles. From 2019 onwards, he will be editor of the European Journal of Cancer.



### **Anne Letsch**

Anne Letsch, MD, achieved her MD from the Medical School at the Free University of Berlin, Germany in 2001, shortly followed by concluding her MD- thesis in the department of Hematology, Oncology and Transfusion Medicine at the University Hospital Benjamin Franklin of the Free University of Berlin on „Detection of T cells in melanoma patients”.

From 2001-2009, Dr. Letsch did her residency in Internal Medicine, followed by a Fellowship at the Department of Hematology, Oncology of the Charité, Campus Benjamin Franklin (CBF), Berlin. She got Board certified in Internal Medicine in 2009 and in Hematology and Oncology and Palliative Care in 2011. In the same year, Dr. Letsch received the title of a Charité Universitätsmedizin Berlin Private Docent (PD) and her Venia legendi in Internal Medicine.

Since 2013 Dr. Letsch is Consultant in the Department of Hematology and Oncology at the Charité CBF and in the Charité Comprehensive Cancer Center (CCCC), and is the leading Consultant of the Palliative Care Unit at the Campus Benjamin Franklin. She is currently in charge of teaching and patient care in the area of medical oncology and palliative care at the Department of Hematology and Oncology at the Charité CBF.

Dr Letsch's clinical work and research interests focus on patient-centered and -oriented care with the aim of developing new concepts for integrating supportive and palliative care in the field of cancer. She is leading the research group for Integrated Supportive and Palliative Cancer Care and her broad clinical experience is of particular relevance in several research cooperations with the intention to enhance patient empowerment, treatment planning, illness processing, coping, awareness of the prognosis, therapeutic decision making, symptom assessment and treatment, and the coordination and improvement of supportive measures, also by using E-health solutions. Further research interests include tumor-related fatigue, tumor immunology

and innovative early clinical studies. In this field she is local PI of early immunotherapy trials and co-PI of several other trials.

She is in the board of the German Society for Palliative Care (DGP) and co-chair of the working groups for „Women in Hematology and Oncology“ and for „Tumorfatigue“ in the German Society for Hematology and Oncology (DGHO). Dr. Letsch is involved in several guideline-programs of the German AWMF network. She has authored several peer-reviewed manuscripts and book chapters.



### **Murielle Mauer**

Murielle Mauer holds a PhD in Pure Mathematics. She was Assistant at the Faculty of Science at the University of Liège from 1995 to 2001 and researcher in the Department of Biostatistics and Data Processing at the University Hospital of Liège from 2001 to 2003. She got a Master degree in Biostatistics at Limburgs Universitair Centrum in 2003.

She got practical experience of the design, conduct and analysis of clinical trials in Bristol-Myers Squibb pharmaceutical company from 2003 to 2006. At EORTC, she worked first as a research fellow in the Quality of Life Unit. Since 2007, she is the Biostatistician in charge of providing statistical support to the EORTC Gastro-intestinal Tract Cancer Group and to the EORTC Elderly Task Force. She has become Lead Statistician at EORTC in 2018 in charge of Methodology and of the EORTC Fellowship Program in Statistics at the EORTC Headquarters, Brussels, Belgium.



### **Markus Moehler**

Prof. Markus Moehler is Head of GI Oncology, Senior Physician at the Johannes-Gutenberg-University Clinic, Mainz, Germany. After studies at Heidelberg and Yeshiva University, New York, and his MD supervised by Nobel Prize laureate Professor zur Hausen, he was postDoc at the German Cancer Research Center, Heidelberg.

He received his Degree of Internal Medicine (2003) and his ESMO Certificate (2003).

In February 2005, he completed his PhD, became Junior Professor as well as Senior Consultant for Gastrointestinal Oncology.

Apart from many German associations (DGVS, DGHO, German Gene therapy group etc), he is an active member of the EORTC, American Society of Clinical Oncology (ASCO), European Society of Medical Oncology (ESMO), Arbeitsgemeinschaft Internistische Onkologie (AIO).

Currently, he is principal investigator (PI) in many national and international studies on novel targeted and immunotherapeutic agents, often with translational biomarker research included.

Together with German Awards, he has received 3 ASCO Merit Awards (2003-2006). During the last 10 years, he has been continuously financing more than 10 fully educated members (post-Docs, MTA, study nurses) in his translational research lab and his clinical study team.



### **Sabine Oertelt-Prigione**

Sabine Oertelt-Prigione, MD MSc PhD, is the strategic chair for gender in primary and transmural care at Radboud University in the Netherlands. Before this she worked at Charité-Universitätsmedizin in Berlin, Germany, at the University of California at Davis, USA, and at the University of Milan, Italy. She is specialized in internal medicine, public health and gender medicine and trained as an organizational consultant. She has published widely on aspects of sex and gender in medicine and gender-sensitive prevention. She is a frequent speaker at national and international conferences, member of numerous professional societies, expert counsel on the matter of sexual harassment prevention to German political institutions and pro-bono advisor for young scientists, non-profits and start-ups.



### **Berna Özdemir**

Berna Özdemir graduated from the Medical School of the University of Bern in 2007. She started as a PhD student in Prof. George Thalmann's lab at the University of Bern, working on the stromal reaction of prostate cancer bone metastasis.

She did her post-doc training with Prof. Raghu Kalluri at Harvard University, Beth Israel Deaconess Medical Center and at the University of Texas, MD Anderson Cancer Center. Her main research interest was genetically engineered mouse models of pancreatic cancer and the contribution of cancer associated fibroblasts to cancer progression. She obtained her MD PhD degree in 2012. Since 2013 she is active as a clinician, currently working as a resident in the Oncology Department of Lausanne University Hospital.

She is interested in elucidating race- and sex-related differences in cancer susceptibility and mortality and the interplay between sex hormones and the immune system. She is the Director of Clinical Activities of the International Cancer Prevention Institute.



### **Solange Peters**

Solange Peters, MD, PhD, is professor and chair of medical oncology as well as the thoracic malignancies programme in the department of oncology at the University Hospital of Lausanne, Switzerland. Professor Peters is currently in charge of teaching and patient care in the area of thoracic malignancies in the department of oncology of Lausanne

University, where she is building a translational program in collaboration with the Swiss Federal Institute of Technology in Lausanne and the Ludwig Institute. Professor Peters' main field of interest is new biomarker discovery and validation in preclinical and clinical settings. She is also strongly involved and interested in immunotherapy and multimodality trial building for locally advanced non-small cell lung cancer.

Professor Peters acts as the local principal investigator (PI) for local and international lung trials opened at Lausanne Cancer Centre, focused on phase I predictive biomarkers and thoracic malignancies immunotherapy, and is a co-PI of several multidisciplinary trials. Additionally, she acts as the scientific coordinator of the European Thoracic Oncology Platform.

Professor Peters has authored numerous peer-reviewed manuscripts and book chapters, and serves as deputy editor of the Journal of Thoracic Oncology, and on the editorial board of several other oncology journals. Professor Peters is active in the educational programs of the European Society for Medical

Oncology (ESMO) and the International Association for the Study of Lung Cancer (IASLC), notably working as the current editor of the ESMO lung cancer clinical practice guidelines. She is the Chair of ESMO Women for Oncology Committee, and she is the youngest ESMO President-elect ever, for a mandate in 2020-2021. She was also a member of the IASLC board of directors, and acts as vice president of the Swiss Group for Clinical Cancer Research lung group.



**Dorothea Wagner**

Senior staff medical oncologist, senior lecturer and head upper gastrointestinal cancer outpatient clinic, Department of Oncology, Lausanne University Hospitals and Clinics, Lausanne, Switzerland

After training and board certification in internal medicine and medical oncology in Germany, she joined the University Hospital of Lausanne in 2008. Since 2014 she has been co-chair of the EORTC GI group gastric cancer task force. Her principal research activities include clinical trials in GI cancers, meta-analyses, and, since 2015, Gender medicine. She is a coordinating investigator of the EORTC-1203 protocol on perioperative treatment of HER-2 positive gastric cancer ("INNOVATION-trial"), a collaboration between EORTC, the Korean Cancer study group and the Dutch Upper GI Cancer group, which is currently ongoing [http://www.eortc.org/research\\_field/clinical-detail/1203/](http://www.eortc.org/research_field/clinical-detail/1203/). Her memberships include the American Society of Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO), the European Organization for the Research and Treatment of Cancer (EORTC), Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung (SAKK) GI-group.

## Acknowledgments

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