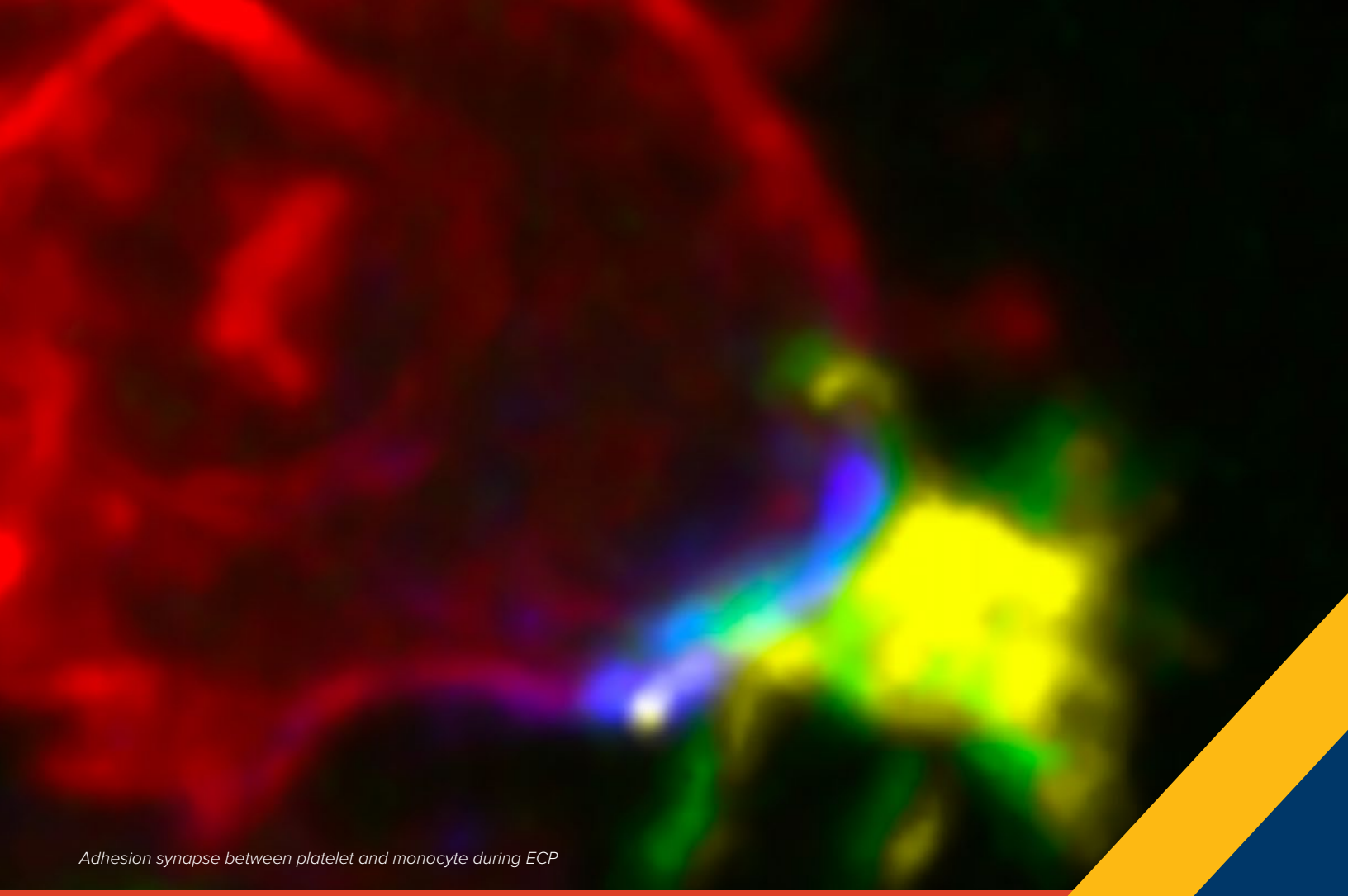

Adhesion synapse between platelet and monocyte during ECP

PROGRAM

ASFA 2019

STATE OF THE SCIENCE CONFERENCE ON
EXTRACORPOREAL PHOTOPHERESIS (ECP)

PORTLAND, OREGON
TUESDAY, MAY 14TH, 2019
Hilton Portland Downtown

2019
ASFA's 40th Annual Meeting

ASFA
American Society for Apheresis

Photo courtesy of Dr. Richard Edelson's lab

CONTINUING EDUCATION CREDIT INFORMATION

ACCREDITATION AND CREDIT DESIGNATION

TARGET AUDIENCE

This activity has been designed to meet the educational needs of physicians, allied health professionals and medical students involved with donor and therapeutic apheresis. The specialties involved include, but are not exclusive of, pathology, hematology, immunology, nephrology, pediatrics, and rheumatology.

STATEMENT OF NEED/PROGRAM OVERVIEW

Participants of the ASFA 2019 State of the Science Conference on Extracorporeal Photopheresis (ECP) will learn about scientific advances with substantial promise for translation into broadened clinical applications, personalized tailoring of the therapy, and more direct monitoring of treatment efficacy.

This groundbreaking, one-day conference, will highlight the most up-to-date, scientifically-based concepts key to the mechanism(s) underlying ECP's antigen-specific immunogenic and tolerogenic efficacy. Field experts will address the potential to test these principles in the treatment of a broad spectrum of immunogenic cancers (including solid tumors, such as melanoma and ovarian carcinoma) and auto-reactive immunologic disorders (including haplotype mismatched stem cell transplants and allogeneic organ transplants). The special capacity of psoralen to augment the immunogenicity and tolerogenicity of ECP-processed cancer cells and of ECP-activated platelets to physiologically induce therapeutic dendritic antigen processing cells (DC) will be elucidated. Development and execution of derived trials will be described. Meeting participants will then partner with the leaders of the American Council on ECP (ACE) in break-out sessions to discuss the planning of the next generation of innovative trials.

CEU

ASFA is approved by the California Board of Registered Nursing, Provider Number 14122, as a provider of continuing nursing education programs. ASFA designates this event for a maximum of 7.5 contact hours.

CMLE

This continuing medical laboratory education activity is recognized by the American Society for Clinical Pathology as meeting the criteria for 7.5 CMLE credit.

ASCP CMLE credits are acceptable to meet the continuing education requirement for the ASCP Board of Registry Certification Maintenance Program.

INSTRUCTIONS FOR CREDIT

The meeting evaluation must be completed in order to claim CME Credit. Please note that physicians should claim only the credit commensurate with the extent of their participation in the activity. CME Certificates will be emailed within 6-8 weeks of the program.

CONTINUING MEDICAL EDUCATION CREDIT INFORMATION

This activity has been planned and implemented in accordance with the accreditation requirements of the Washington State Medical Association through the joint providership of Providence Health Care and the American Society for Apheresis. Providence Health Care is accredited by the WSMA to provide continuing medical education for physicians.

Providence Health Care designates this live activity for a maximum of 7.5 AMA PRA Category 1 Credit(s) ™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity meets the criteria for up to 7.5 hours of Category I CME credit to satisfy the relicensure requirements of the Washington State Medical Quality Assurance Commission.

PROVIDENCE
Health Care

ORGANIZING COMMITTEE

Jennifer Schneiderman, *MD, MS, Northwestern University, Chair of State of Science Conference Organizing Committee*
Joseph Schwartz, *MD, MPH, Columbia University, ASFA President*
YanYun Wu, *MD, PhD, QIA, Bloodworks, ASFA President-Elect*
Jill Adamski, *MD, PhD, Mayo Clinic*
Laura Connelly-Smith, *MBBCh, DM, Seattle Cancer Care Alliance, University of Washington*
Nancy Dunbar, *MD, Dartmouth College*
Richard Edelson, *MD, Yale University*
Jay Raval, *MD, University of New Mexico*
Amber Sanchez, *MD, University of California, San Diego*

TUESDAY, MAY 14, 2019 — *Grand Ballroom I*

7:00 AM – 11:30 AM	**Registration**	***Grand Ballroom Foyer***
7:00 AM – 8:00 AM	**Continental Breakfast**	***Grand Ballroom Foyer***
8:00 AM – 8:15 AM	**Welcome and Introduction**	
	Welcome and Overview of the Day **Jennifer Schneiderman,** *MD, MS, Northwestern University*	
	Welcome from ASFA, Driving the Scientific Future of ECP **Joseph Schwartz,** *MD, MPH, Columbia University* and **YanYun Wu,** *MD, PhD, QIA, Bloodworks*	
8:15 AM – 8:55 AM	**Topic: Antigen Specific Anti-Cancer immunity**	
	Speaker: Richard Edelson, *MD, Yale University*	
8:15 AM – 8:40 AM	**The Pivotal Controllable Role of Dendritic Cells in ECP** This presentation will present an integrated overview of the scientific mechanism underlying the efficacy of Extracorporeal Photochemotherapy (ECP), as currently understood. ECP is unusual among immunotherapies by essentially being a therapeutic partner with the normal physiologic immune system itself. It induces blood monocytes to rapidly, and physiologically, differentiation into dendritic antigen presenting cells (DC), the master-switch of the immune system. Dependent on the target disease, the induced DC are then efficiently loaded with the relevant antigen and directed by ultraviolet A-activated 8-methoxypsoralen to become either immunogenic (as in cutaneous T cell lymphoma), where the antigens are extracted from the patient's malignant cells, or tolerogenic (as in organ transplantation or graft versus host disease), where the antigens are the relevant transplantation antigens. Activated platelets provide the key signal (p-selectin) that directs ECP-processed monocytes into the DC maturational pathway. The important clinical implications of these insights will be discussed.	
8:40 AM – 8:55 AM	Questions & Discussion	

TUESDAY, MAY 14, 2019

Grand Ballroom I

8:55 AM – 9:35 AM **Topic: Antigen Specific Tolerancein Solid Organ Transplantation**

Speaker: Jennifer Schneiderman, *MD, MS, Northwestern University*

8:55 AM – 9:20 AM **Enhancing ECP-Induced Tolerance to Transplanted Allogeneic Donor Tissue**

Patients undergoing solid organ transplantation require life-long intensive immunosuppressive therapy (IST) to reduce the risk of developing immune mediated rejection of the graft. Such IST regimens themselves carry significant risk for infection, secondary malignancies, and direct toxicity to end organs, including the graft. Development of less toxic means to establish immune tolerance is paramount to improving the success of solid organ transplantation. Extracorporeal Photopheresis (ECP) is currently used to prevent and treat graft rejection following solid organ transplantation by treating the transplant recipient's cells. This presentation will review murine models in which the infusion of donor-type, ECP treated cells prior to transplantation leads to antigen specific tolerance and significantly prolongs graft survival through the reduction of cellular infiltration in the graft, dampening of T-cell response, inhibition of the production of donor specific antibodies, and promotion of T-regulatory production. These laboratory models allow for further investigation of mechanistic insights which will ultimately help optimize clinical trials allowing the reduction, and possibly elimination, of modern IST therapy.

9:20 AM – 9:35 AM Questions & Discussion

9:35 AM – 10:15 AM **Topic: Unmet Needs in Allogeneic Hematopoietic Stem Cell Transplant: Where Does ECP Fit?**

Speaker: Francine Foss, *MD, Yale University School of Medicine*

9:35 AM – 10:00 AM **ECP as a Potential Enabler of Haploidentical Stem Cell Transplantation**

Allogeneic transplantation remains the only curative option for many hematologic malignancies, but transplant has been limited by availability of suitable donors and transplant related morbidities such as acute and chronic graft-vs- host disease and infectious complications. Reduced intensity conditioning and the use of haploidentical donors have improved outcomes, but there remains an unmet medical need for less intensive approaches which preserve graft-vs tumor effect without graft-vs host disease or loss of engraftment. Extracorporeal photopheresis has been shown to be an effective therapy in acute and chronic graft-vs-host disease and has reduced incidence of acute GVHD when used as part of a conditioning regimen. Recently, novel immunomodulatory effects of ECP on antigen presenting cells and other effector populations have been more fully elucidated and approaches are being developed to utilize ECP in the haploidentical or mismatched setting to preserve graft-vs tumor effect while reducing the chance for severe acute GVHD.

10:00 AM – 10:15 AM Questions & Discussion

TUESDAY, MAY 14, 2019

Grand Ballroom I

10:15 AM – 10:30 AM	Break	***Grand Ballroom Foyer***
10:30 AM – 11:10 AM	**Topic: How Do Platelets Influence ECP Therapy?**	
	Speaker: Diane Nugent, *MD, University of California, Irvine*	
	10:30 AM – 10:55 AM **Platelet and Dendritic Cell Interactions: Potential Implications for ECP Therapy**	

Over the past decades, the majority of platelet research focused on its role in coagulation and inflammation. It has only been in the last 10 years that investigators have begun to gain insight into its role in immune surveillance and augmentation of our immune response. The small, agile, and programmable platelet is uniquely suited to scan the vascular bed, and in circumstances of vascular disruption by pathogens will signal circulating effector cells to extravasate, or in the case of monocytes , trigger differentiation into antigen presenting dendritic cells, to promote specific antigen targeting. This presentation will focus on recent breakthroughs in understanding how these immune activities are tightly regulated in the platelet and why ECP presents a unique scenario to augment these interactions down pathways of tolerance or to promote tumor kill.

10:55 AM – 11:10 AM	Questions & Discussion
11:10 AM – 12:00 PM	**Topic: How Does Psoralen influence ECP Therapy?**
	Speaker: Lorenzo Galluzzi, *PhD, Cornell University*
11:10 AM – 11:35 AM	**Immunogenic Cell Stress and Death – Key to Unlock the Dual Therapeutic Potential of ECP**

Extracorporeal Photochemotherapy (ECP) is a widely used immunotherapy for cutaneous T cell lymphoma (CTCL) and has been recently reported to be an effective and selective immunotherapy for established experimental melanoma, colorectal and ovarian cancer. In each of these circumstances, the convenient source of immunizing antigens are cancer cells containing cross-linked pyrimidine bases in their DNA, caused by, and composed of ultraviolet-activated psoralen (8MOP/UVA). These antigens are processed by ECP-induced antigen presenting dendritic cells (DCs), which then can initiate effective CD8+ T cell-dependent anticancer responses. A central question, therefore, is: how does 8-MOP so efficiently increase the availability of cancer antigens? We report that ECP causes the loss of cancer cell viability associated with the emission of the 4 main signals that culminate in the immunogenic death of cancer cells. These key signals are: (1) exposure of calreticulin on the plasma membrane; (2) secretion of ATP; (3) high mobility group box 1 (HMGB1); and (4) type I interferon (IFN). Moreover, in a mouse melanoma system, malignant cells killed by ECP in vitro are sufficient to vaccinate syngeneic immunocompetent mice against a challenge with living cancer cells of the same type, and such a protection is lost when cancer cells are depleted of calreticulin or HMGB1, as well as in the presence of an ATP-degrading enzyme or an antibody that blocks type I IFN receptors. Thus, ECP drives bona fide immunogenic cell death (ICD). Importantly, ICD depends on activation of an endoplasmic reticulum (ER) stress response. As ER stress in monocytes has also been linked to the establishment of a strong tolerogenic effects, these findings may also help explain the remarkable bidirectional “Janus” activity of ECP in treatment of CTCL and autoimmune disorders, i.e. as both an immunizing and tolerizing treatment.

Galluzzi L, et al. Nat Rev Immunol 2017. 17(2):97-111.
Cubillos-Ruiz et al. Cell 2015. 161(7):1527-38.

11:35 AM – 11:50 PM	Questions & Discussion
11:50 AM – 12:00 PM	Morning Session Wrap Up

TUESDAY, MAY 14, 2019

Grand Ballroom I

12:00 PM – 1:00 PM	Lunch	***Grand Ballroom Foyer***
1:00 PM – 2:15 PM	**Topic: Cell-Based Medicine: How to Make Cellular Therapy Trials Feasible and Regulatory Perspectives**	

Speaker: Joseph Leventhal, *MD, PhD, Northwestern University*

1:00 PM – 1:30 PM **Approach to Designing and Executing Clinical Trials in Cellular Therapy**

Successful solid organ transplantation currently requires the life-long use of medications to suppress the immune system in order to prevent transplant rejection. Drug-based immunosuppression significantly increases the risk of infection and cancer, as well as being very costly. Development of new therapies to minimize or eliminate entirely the need for anti-rejection drugs is of great interest to the transplant community. Therapeutic cell transfer for the control of the human immune system represents a compelling approach to reduce or eliminate the need for anti-rejection drugs. Establishment of durable hematopoietic chimerism through hematopoietic stem cell transplantation (HSCT) has been shown in preclinical models and patients to lead to donor specific tolerance. However, the application HSCT is limited by the potential toxicity of conditioning regimens, the risk of graft versus host disease (GVHD) and the challenge of HLA mismatching. This presentation will provide a state of the art appraisal of different approaches, currently being evaluated in clinical trials, to achieving tolerance in solid organ transplant recipients using therapeutic cell transfer.

Speaker: Peter Marks, *MD, PhD, Center for Biologics Evaluation and Research, FDA*

1:30 PM – 2:00 PM **Balancing Safety and Innovation for Cell-Based Regenerative Medicine**

Human cells, tissues, and cellular and tissue-based products (HCT/Ps) represent a diverse array of important medical products. Under its regulations at Part 1271, FDA established a regulatory framework for these products to protect the public health employing a risk-based approach making use of Section 361 and Section 351 of the Public Health Service Act (PHSA) and the Federal Food Drug and Cosmetic Act (FDCA). Manufacturers are responsible for self-determining the appropriate regulatory pathway for their products. Most cell and tissues products, numbering in the thousands, are regulated through the Section 361 pathway, which does not require premarket approval. HCT/Ps that are not regulated solely under the Section 361 pathway are also regulated as drugs, devices, and/or biological products under section 351 of the PHSA and/or the FDCA and require premarket approval. With the passage of the 21st Century Cures Act, certain products regulated as biological products under the Section 351 pathway are eligible for designation as regenerative medicine advanced therapies, or RMATs. This designation is available to certain cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products intended to address unmet needs in serious or life-threatening diseases or conditions. RMAT designation provides the same advantages to sponsors as breakthrough therapy designation plus additional benefits. FDA is trying to foster innovation in this area by streamlining regulatory requirements to the extent possible, while still maintaining the statutory requirements for demonstration of safety and efficacy. It is also working to foster improvements in manufacturing of these products through applied scientific research and through the development and implementation of standards. It has also described a collaborative approach to clinical development that is well suited to cell-based medicine products.z

2:00 PM – 2:15 PM Questions & Discussion

TUESDAY, MAY 14, 2019

Grand Ballroom I

2:15 PM – 3:55 PM	**Break-out Sessions**
	Facilitator: YanYun Wu, *MD, PhD, QIA, Bloodworks*
2:15 PM – 2:20 PM	**Discuss Goals of the Breakout Sessions** *(each participant is invited to join two break-out sessions)*

Topics and Facilitators:

- Anti-Tumor Immunization — ***Parlor C***
  - Richard Edelson, *MD*
  - Amber Sanchez, *MD*
- Tolerance in Solid Organ Transplantation — ***Gallerias II***
  - Joseph Leventhal, *MD, PhD*
  - Jennifer Schneiderman, *MD, MS*
  - YanYun Wu, *MD, PhD, QIA*
- Haplo-Identical Hematopoietic Stem Cell Transplantation/Graft Versus Host Disease — ***Gallerias III***
  - Laura Connelly-Smith, *MBBCh, DM*
  - Diane Nugent, *MD*
- Autoimmune Diseases — ***Gallerias II***
  - Jill Adamski, *MD, PhD*
  - Jay Raval, *MD*
- Practical Challenges/How to Monitor ECP Therapy — ***Gallerias I***
  - Nancy Dunbar, *MD*
  - Joseph Schwartz, *MD, MPH*

2:20 PM – 3:05 PM	Break-out Session 1
3:10 PM – 3:55 PM	Break-out Session 2
4:00 PM – 4:45 PM	**Consensus Deliberation** — ***Grand Ballroom I***
	Facilitator: Zbigniew M. Szczepiorkowski, *MD, PhD, Dartmouth University*
4:45 PM – 5:00 PM	**Closing Statements**
	Jennifer Schneiderman, *MD, MS, Northwestern University* and **YanYun Wu,** *MD, PhD, QIA. Bloodworks*

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