About This CME/CE Activity

RATIONALE AND PURPOSE

The complexities of organ transplantation involve many different metabolic pathways and clinical considerations. This issue of *The Immunology Report* covers a variety of topics related to the ongoing therapeutic revolution in organ transplantation, beginning with our current understanding of antibody-mediated rejection and the hazard it represents to long-term renal transplant survival. These reports stress the great strides scientists have made in understanding organ rejection and in developing novel diagnostics and therapeutics to prevent this process and maintaining the health and well-being of transplant patients and their grafts for prolonged periods. Conventional immunosuppressants remain the backbone of therapy following organ transplant, but novel immunosuppressants recently approved by the US Food and Drug Administration (FDA) or currently in development are producing great optimism for continued success in the field. Follow-up is especially important during long-term drug therapy after transplant; an examination of Risk Evaluation and Mitigation Strategies (REMS) imposed by the FDA to detect serious postmarketing safety problems covers the grueling processes that influence regulatory approval and continued scrutiny of new therapeutics. Finally, both short- and long-term follow-up after surgery is a critical facet of organ transplantation; primary care approaches to preventing infection, treating hypertension and diabetes, and screening transplant recipients for malignancy ultimately lead to better outcomes and save patients' lives. The articles within are based upon presentations delivered during the 2012 American Transplant Congress, held June 2–6, 2012, in Boston, Massachusetts.

The articles in this issue, written from the academic perspective of physicians in training at leading medical centers, summarize the import of these new findings and place them into clinical context. This activity has been developed and approved by a planning committee of nationally recognized thought leaders to meet a perceived educational need to provide immunologists, transplant specialists, and other healthcare professionals with the latest knowledge and tools to help them perform their medical roles.

LEARNING OBJECTIVES

After studying this issue of *The Immunology Report,* participants in this educational activity should be able to:

- Describe antibody-mediated rejection, its early detection and diagnosis, and current trends in its management in patients at risk.
- Compare and contrast the advantages and disadvantages of conventional and novel immunosuppressants for preventing graft rejection.
- Outline the background and clinical implications of the FDA's development of REMS to minimize the risks of drug therapy.
- Summarize the key issues involved in long-term care of transplant patients in regard to avoiding infection, maintaining cardiovascular health, managing diabetes, and cancer prevention and screening.

TARGET AUDIENCE

Immunologists and other physicians significantly involved in organ transplantation, transplant nurses, transplant coordinators, pharmacists, and transplant case managers should find participation in this educational activity valuable.

ACCREDITATION AND CREDIT DESIGNATION

Physicians: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the University of Cincinnati and Direct One Communications, Inc. The University of Cincinnati is accredited by the ACCME to provide continuing medical education for physicians.

The University of Cincinnati designates this Enduring Material Activity for a maximum of 2.0 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Transplant nurses and coordinators: The American Board for Transplant Certification (ABTC) has approved the International Transplant Nurses Society (ITNS) as a provider of CEU/ABTC credits from its organization. This CNE activity, sponsored by the International Transplant Nurses Society, has been approved by the ABTC for 2.0 Category 1 CEPTCs (Program Reference No. 3000-347).

Pharmacists: Northeastern University Bouvé College of Health Sciences School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. This activity is approved for 2.0 credit hours (0.20 CEU). The ACPE activity number is 0027-9999-12-053-H01-P, the initial release date is September 14, 2012, and the expiration date is September 14, 2015.

Case managers: This activity is approved by the Commission for Case Manager Certification for 2.0 clock hours through December 31, 2012.

CREDIT AVAILABILITY

Activity release date: September 14, 2012
Expiration date: September 15, 2013

METHOD OF PARTICIPATION

This Enduring Material Activity is available in print and online at **www.ImmunologyReport.com** and consists of an introduction, four articles, a postactivity assessment, and an evaluation. Estimated time to complete the activity is 2.0 hours.

To receive credit, participants must read the CME/CE information on these two pages, including the learning objectives and disclosure statements, as well as the full content of this monograph, and then complete the post test and evaluation form

online at www.ImmunologyReport.com. Upon successful completion of the post test (80% correct) and evaluation form, a CME/CE certificate of participation will be awarded automatically. The certificate may be printed directly from the Web site or e-mailed and printed later.

There are no fees for participating in or receiving credit for this activity.

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FACULTY DISCLOSURES

All faculty members (or anyone else in a position to control content, such as activity planners) are required to complete a Disclosure of Commercial Interest and Resolution form and to cooperate with identified methods for resolving conflict of interest prior to participating in the activity. The University of Cincinnati requires disclosure to the learners of all relevant financial relationships and adheres strictly to the ACCME Standards for Commercial Support.

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Jared Brandenberger, MD, Acting Instructor and Senior Fellow in Transplant Surgery, University of Washington Medical Center, Seattle, Washington, has nothing to disclose.

Rick Ricer, MD, has nothing to disclose.

Susan P. Tyler, MEd, CMP, CCMEP, has nothing to disclose.

Anita Young, EdD, RPh, has nothing to disclose.

Jacqueline Keenan and **Edwin S. Geffner**, of Direct One Communications, Inc., have nothing to disclose.

DISCLAIMER

This activity is an independent educational activity under the direction of the University of Cincinnati. The activity was planned and implemented in accordance with the Essential Areas and Policies of the ACCME, the Ethical Opinions/Guidelines of the American Medical Association, the US Food and Drug Administration, the Office of Inspector General of the US Department of Health and Human Services, and the Pharmaceutical Research and Manufacturers of America Code on Interactions With Healthcare Professionals, thus assuring the highest degree of independence, fair balance, scientific rigor, and objectivity.

However, the planning committee, faculty, University of Cincinnati, ITNS, Northeastern University Bouvé College of Health Sciences School of Pharmacy, Astellas Pharma US, Inc., and Direct One Communications, Inc. shall in no way be liable for the currency of information or for any errors, omissions, or inaccuracies in this activity. Participants in this activity are encouraged to refer to primary references or full prescribing information resources.

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Discussions concerning drugs, dosages, and procedures may reflect the clinical experience of the planning committee, may be derived from the professional literature or other sources, or may suggest uses that are investigational and not approved labeling or indications.

In this issue of *The Immunology Report,* Dr. Gray describes the off-label use of bortezomib to treat antibody-mediated rejection and acute cellular rejection with minimal toxicity. Dr. Weems mentions the use of tofacitinib, diannexin, QPI-1002, ASKP1240, TOL101, and sotrastaurin to prevent graft rejection; none of these drugs has been approved by the FDA for any indication.

CONTACT INFORMATION

We would like to hear your comments regarding this or other educational activities produced by Direct One Communications, Inc. In addition, suggestions for future activities are welcome. Contact us at:

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