

The Medical Letter[®]

on Drugs and Therapeutics

Objective Drug Reviews Since 1959

Volume 57

June 22, 2015

ISSUE No.

1471

IN THIS ISSUE

Addendum: Nivolumab (*Opdivo*) for Metastatic Melanoma and Metastatic NSCLC p 94

Important Copyright Message

FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. and international copyright laws. Forwarding, copying or any distribution of this material is prohibited.

Sharing a password with a non-subscriber or otherwise making the contents of this site available to third parties is strictly prohibited.

By accessing and reading the attached content I agree to comply with U.S. and international copyright laws and these terms and conditions of The Medical Letter, Inc.

For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)
or call customer service at: 800-211-2769

The Medical Letter®

on Drugs and Therapeutics

Objective Drug Reviews Since 1959

Volume 57 (Issue 1471)

June 22, 2015
Take CME Exams

Addendum: Nivolumab (*Opdivo*) for Metastatic Melanoma and Metastatic NSCLC

After our article on nivolumab (*Opdivo* – BMS) for treatment of metastatic melanoma and metastatic squamous non-small cell lung cancer (NSCLC) was published in the most recent issue of *The Medical Letter* (June 8, 2015),¹ some new data became available supporting the efficacy of the drug in previously untreated melanoma and previously treated nonsquamous NSCLC.

MELANOMA – In a double-blind trial, 945 patients with previously untreated, unresectable stage III or IV melanoma were randomized to receive ipilimumab, nivolumab, or combination therapy with ipilimumab and nivolumab. Progression-free survival, a primary endpoint, improved by 43% with nivolumab (median 6.9 months) and by 58% with combination therapy (median 11.5 months), compared to ipilimumab (median 2.9 months). In patients with tumors that expressed the programmed death ligand 1 (PD-L1) on $\geq 5\%$ of cells, median progression-free survival was similar in the nivolumab and combination groups (both 14.0 months); in those with tumors that expressed PD-L1 on $< 5\%$ of cells, it was 5.3 months with nivolumab alone and 11.2 months with both drugs. Rates of complete or partial response were 19.0% with ipilimumab, 43.7% with nivolumab, and 57.6% with combination therapy. At least one severe (grade 3-4) drug-related adverse effect occurred in 27.3% of patients receiving ipilimumab, 16.3% of those receiving nivolumab, and 55.0% of those receiving both drugs.²

NONSQUAMOUS NSCLC – In an open-label trial (available only as an abstract), 582 patients with advanced nonsquamous NSCLC that had progressed during or after treatment with a platinum doublet-based regimen (and, if appropriate, a kinase inhibitor) were randomized to receive nivolumab or docetaxel until disease progression or unacceptable toxicity occurred. Nivolumab significantly improved overall survival, the primary endpoint, by 27% compared to docetaxel (median 12.2 vs 9.4 months). Survival rates in the two groups were similar in patients with tumors expressing PD-L1 on $< 1\%$ of cells, but in patients with tumors expressing PD-L1 on $\geq 1\%$, $\geq 5\%$, and $\geq 10\%$ of cells, nivolumab improved overall survival by 41%, 57%, and 60%, respectively, compared to docetaxel. Patients receiving nivolumab were significantly more likely to have an objective response (19.2% vs 12.4%). Severe (grade 3+) drug-related adverse effects occurred in 10.5% of patients receiving nivolumab and in 53.7% of those receiving docetaxel.³ ■

1. Nivolumab (Opdivo) for metastatic melanoma and metastatic NSCLC. *Med Lett Drugs Ther* 2015; 57:85.
2. J Larkin et al. Combined nivolumab and ipilimumab or monotherapy in untreated melanoma. *N Engl J Med* 2015 May 31 (epub).
3. L Paz-Ares et al. Phase III, randomized trial (CheckMate 057) of nivolumab (NIVO) versus docetaxel (DOC) in advanced non-squamous cell (non-SQ) non-small cell lung cancer (NSCLC). *J Clin Oncol* 2015; 33 (suppl; abstr LBA109). Available at: abstracts.asco.org/156/AbstView_156_154634.html. Accessed June 11, 2015.

EDITOR IN CHIEF: Mark Abramowicz, M.D.; **EXECUTIVE EDITOR:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School; **EDITOR:** Jean-Marie Pflomm, Pharm.D.; **ASSISTANT EDITORS, DRUG INFORMATION:** Susan M. Daron, Pharm.D., Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D.; **CONSULTING EDITORS:** Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.; **SENIOR ASSOCIATE EDITOR:** Amy Faucard

CONTRIBUTING EDITORS: Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Albert Einstein College of Medicine; Jane P. Gagliardi, M.D., M.H.S., F.A.C.P., Duke University School of Medicine; Jules Hirsch, M.D., Rockefeller University; David N. Juurlink, BPhM, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Hans Meinertz, M.D., University Hospital, Copenhagen; Franco M. Muggia, M.D., New York University Medical Center; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; F. Estelle R. Simons, M.D., University of Manitoba; Neal H. Steigbigel, M.D., New York University School of Medicine; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

MANAGING EDITOR: Susie Wong; **ASSISTANT MANAGING EDITOR:** Liz Donohue; **EDITORIAL ASSISTANT:** Cheryl Brown

EXECUTIVE DIRECTOR OF SALES: Gene Carbona; **FULLFILLMENT & SYSTEMS MANAGER:** Cristine Romatowski; **DIRECTOR OF MARKETING COMMUNICATIONS:** Joanne F. Valentino; **VICE PRESIDENT AND PUBLISHER:** Yosef Wissner-Levy

Founded in 1959 by
Arthur Kallet and Harold Aaron, M.D.

Copyright and Disclaimer: The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. is supported solely by subscription fees and accepts no advertising, grants, or donations. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The editors do not warrant that all the material in this publication is accurate and complete in every respect. The editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

Subscription Services

Address:
The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:
Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:
To reproduce any portion of this issue,
please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):
1 year - \$98; 2 years - \$189;
3 years - \$279. \$49 per year
for students, interns, residents, and
fellows in the US and Canada.
Reprints - \$12 each.

Site License Inquiries:
E-mail: info@medicalletter.org
Call: 800-211-2769 ext. 315
Special rates available for bulk
subscriptions.

Copyright 2015. ISSN 1523-2859