

Meeting Abstract: 2015 Gastrointestinal Cancers Symposium

FREE ACCESS Cancers of the Colon, Rectum, and Anus January 20, 2015



Phase I/II trial of IMMU-132 (isactuzumab govitecan), an anti-Trop-2-SN-38 antibody drug conjugate (ADC): Results in patients with metastatic gastrointestinal (GI) cancers.

Authors: [Alexander Starodub](#), [Allyson J. Ocean](#), [Wells A. Messersmith](#), [Vincent J. Picozzi](#), [Michael J. Guarino](#), [Sajeve Samuel Thomas](#), [Aditya Bardia](#), ... [SHOW ALL](#) ..., and [David M. Goldenberg](#) | [AUTHORS INFO & AFFILIATIONS](#)

J Clin Oncol 33, 703(2015) | [Volume 33, Number 3, suppl](#)
DOI: 10.1200/jco.2015.33.3_suppl.703



Abstract

703

Background: Trop-2 is a tumor-associated glycoprotein highly expressed in many epithelial cancers. Elevated expression has been linked to more aggressive disease and a poorer prognosis. IMMU-132 is an ADC comprising a humanized mAb binding to Trop-2 and conjugated to SN-38 (drug: Ab ratio = 7.6), the active metabolite of irinotecan. After finding potent activity in human tumor xenografts, a phase I/II trial was undertaken (NCT01631552). **Methods:** Pts with relapsed/refractory metastatic cancers were enrolled, starting at a dose of 8 mg/kg given on days 1 and 8 of a 3-week cycle. Dose levels of 8 and 10 mg/kg were chosen for phase II (N=47). **Results:** Sixty pts with advanced GI cancers were enrolled in phase I/II. Neutropenia was the principal dose-limiting toxicity, with fatigue, diarrhea, nausea, and vomiting as other reported toxicities. In the phase II pts with median prior therapies of 3 (range 1-



ASCO Career Center

ASCO Career Center

Employed Hem Onc | UNC Community Hospital | Regional Cancer Center | NC

North Carolina | Competitive Salary and Benefits Package



Highlights: - Established team of physicians and APPs. 4-day work week, minimal after-hours phone call only. - Accredited Comprehensive Cancer Cent...

Employer: Jackson Physician Search
[Apply for this job](#)

Hematology/Oncology near Fort Collins, CO | 4 Day Week | 30k Annually for Loans

Wyoming | Competitive Salary and Benefits Package



A thriving 200-bed regional medical center just 40 minutes from Fort Collins, CO is seeking a BE/BC Hematology/Oncology physician to join their tea...

Recommended Articles

DEVELOPMENTAL THERAPEUTICS—CLINICAL PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS | MAY 2015

Therapy of advanced metastatic lung cancer with an anti-Trop-2-SN-38 antibody-drug conjugate (ADC), sacituzumab govitecan (IMMU-132): Phase I/II clinical experience.

DEVELOPMENTAL THERAPEUTICS—IMMUNOTHERAPY | MAY 2014

Characterization of an anti-Trop-2-SN-38 antibody-drug conjugate (IMMU-132) with potent activity against solid cancers.

LUNG CANCER—NON-SMALL CELL METASTATIC | MAY 2016

Therapy of metastatic, non-small cell lung cancer (mNSCLC) with the anti-Trop-2-SN-38 antibody-drug conjugate (ADC), sacituzumab govitecan (IMMU-132).

7), the following moderate/severe drug-related toxicities occurred: neutropenia (Gr 3, 18.8%; Gr 4, 10.4%); fatigue (Gr 3, 14.6%; Gr 4, 0%), anemia (Gr 3, 10.4%; Gr 4, 0%); diarrhea (Gr 3, 4.2%; Gr 4, 0%). Of 29 CRC pts (10 mg/kg [N=9], 8 mg/kg [N=20]), 1 had a PR and 14 had SD as the best response by RECIST, with a time to progression (TTP) of 11.5+ months (mo) for the PR (65% shrinkage) and a median of 4.8+ mo for the SD pts (5 ongoing). This is a disease control rate (DCR) of 51.7%. Thirteen CRC pts had KRAS mutations, 7 with SD (median TTP = 4.4+ mo [range, 2.8-7.8 mo; 3 ongoing]). Of 15 pts with pancreatic ca, 8 had SD as best RECIST response (median TTP = 3.4 mo); DCR=53.3%. Among 11 pts with esophageal ca, 7 had CT assessments with 1 PR (TTP, 6.9+ mo), and 4 SD (TTP, 4.0+, 5.0, 6.0, and 6.9 mo) as best response; DCR=62.5%. Of 5 gastric ca pts, only 3 had post-baseline CT assessments, all with SD (1 with 19% target lesion reduction and an ongoing TTP of 6.7+ mo). **Conclusions:** IMMU-132 is a novel anti-

cancer therapeutic, conjugating a topoisomerase I inhibitor to an internalizing, cancer-selective mAb. This ADC can be given safely and repeatedly over many months to heavily pretreated patients. Encouraging activity in pts with several metastatic gastrointestinal tumors has been observed.

[Clinical trial information: NCT01631552.](#)

This is an ASCO Meeting Abstract from the 2015 Gastrointestinal Cancers Symposium. This abstract does not include a full text component.

Therapy of gastrointestinal malignancies with an anti-Trop-2-SN-38 antibody drug conjugate (ADC) (sacituzumab govitecan): Phase I/II clinical experience.

IMMU-132, an SN-38 antibody-drug conjugate (ADC) targeting Trop-2, as a novel platform for the therapy of diverse metastatic solid cancers: Clinical results.

JOURNALS

Journal of Clinical
Oncology
JCO Oncology Practice
JCO Global Oncology
JCO Clinical Cancer
Informatics
JCO Precision
Oncology
JCO Oncology
Advances

ASCO

About ASCO
Press Center
Meetings & Education
Contact Us

PUBLICATIONS

ASCO Educational Book
ASCO Daily News
ASCO Connection
The ASCO Post
ASCO Podcasts

ASCO WEBSITES

asco.org
ASCO Career Center
Conquer Cancer

CONTENT

Journal Podcasts
Topics
Meeting Abstracts
ASCO Guidelines

INFORMATION

Author Center
Subscriber Center
Permissions
Reprints
Advertise
E-Alerts
View My Profile
About ASCO Journals

FOLLOW US

JCO_ASCO
JCOOP_ASCO
JCOGO_ASCO
JCOPO_ASCO
JCOCCI_ASCO
JCOOA_ASCO

American Society of Clinical Oncology
2318 Mill Road, Suite 800, Alexandria, VA 22314
© 2026 American Society of Clinical Oncology

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Cookies](#)