





AD

ADVERTISEMENT

Journal of Clinical Oncology®

An American Society of Clinical Oncology Journal

 [Log In](#)  [Submit](#)  [E-Alerts](#)  [Subscribe](#)

[OpenAthens/Shibboleth »](#)

ACCESS PROVIDED BY NOVARTIS ONCOLOGY

MENU

[Journal of Clinical Oncology](#) > [List of Issues](#) > [Volume 34, Issue 4 suppl](#) >

Article Tools

CANCERS OF THE PANCREAS, SMALL BOWEL, AND HEPATOBILIARY TRACT

A randomized, open-label phase II study of nanoliposomal irinotecan (nal-IRI)-containing regimens versus nab-paclitaxel plus gemcitabine in patients with previously

OPTIONS & TOOLS

[Export Citation](#)

[Track Citation](#)

[Add To Favorites](#)

[Rights & Permissions](#)

ADVERTISEMENT

untreated metastatic pancreatic adenocarcinoma (mPAC).



[Andrew Dean](#) , [Li-Tzong Chen](#) , [Ramesh K. Ramanathan](#) , [Sarah Blanchette](#) , [Bruce Belanger](#) , [Deyaa AdibElieil Bayever](#)

St. John of God Hospital, Subiaco, Australia; National Health Research Institutes, National Institute of Cancer Research, Taipei, Taiwan; Mayo Clinic Cancer Center, Scottsdale, AZ; Merrimack, Cambridge, MA; Baxalta, Cambridge, MA

[Show Less](#)

[Abstract Disclosures](#)

Abstract

TPS482

Background: Two combination chemotherapy regimens have emerged as standard of care options for first-line treatment of mPAC: 5-fluorouracil (5-FU)/leucovorin (LV) + irinotecan + oxaliplatin (FOLFIRINOX), and nab-paclitaxel + gemcitabine. Nal-IRI (MM-398) is a nanoliposomal formulation of irinotecan. In a randomized phase 3 study (NAPOLI-1), of patients with mPAC who had been previously treated with gemcitabine-based therapy, nal-IRI + 5-FU/LV demonstrated its safety and significant clinical activity, increasing overall survival (OS) and progression-free survival (PFS) relative to 5-FU/LV. The goal of this current study is to determine the preliminary safety and

COMPANION ARTICLES

No companion articles

ARTICLE CITATION

DOI:
10.1200/jco.2016.34.4_suppl.tps482
Journal of Clinical Oncology 34,
no. 4_suppl

Published online February 01,
2016.

ADVERTISEMENT

WE RECOMMEND

Reply to M. Uccello et al
Sharlene Gill, *J Clin Oncol*, 2017

Second-Line Combination Therapies
in Pancreatic Cancer: Where Are We
Now?
Mario Uccello et al., *J Clin Oncol*, 2017

Current and Evolving Therapies for
Metastatic Pancreatic Cancer: Are We
Stuck With Cytotoxic Chemotherapy?
Gauri R Varadhachary et al., *JCO
Oncology Practice*, 2016

Reply to A. Wang-Gillam et al
Davendra P.S. Sohal et al., *J Clin
Oncol*, 2016

PANCREOX: A Randomized Phase III
Study of Fluorouracil/Leucovorin
With or Without Oxaliplatin for

efficacy of nal-IRI+ + 5-FU/LV with or without oxaliplatin as compared to nab-paclitaxel + gemcitabine in previously untreated patients with mPAC. **Methods:** This open-label, phase 2 comparative study will be conducted in two parts. Part 1 is a safety run-in of a nal-IRI+5-FU/LV + oxaliplatin regimen. The safety run-in will enroll small cohorts of patients following a traditional 3 + 3 dose escalation design to confirm the target dose of oxaliplatin (n = ~6-18). The primary objective of Part 1 is the safety and tolerability of nal-IRI + 5FU/LV + oxaliplatin. Part 2 is a randomized, efficacy study of a nal-IRI + 5-FU/LV + oxaliplatin regimen (Arm 1), the nal-IRI + 5-FU/LV combination that previously demonstrated efficacy in the NAPOLI-1 trial (Arm 2), versus a nab-paclitaxel + gemcitabine control arm (Arm 3) (n = ~156-168). The primary objective of Part 2 is to assess the efficacy of nal-IRI-containing regimens in first-line mPAC patients compared to nab-paclitaxel + gemcitabine using the progression-free survival (PFS) rate at 24 weeks as the primary endpoint. Secondary of part 1 is a PK study and Part 2 secondary endpoints will include OS, PFS, objective response rate (per RECIST, v1.1), decrease in CA19-9 levels and quality of life assessments. Clinical trial information: NCT02551991.

© 2016 by American Society of Clinical Oncology

Second-Line Advanced Pancreatic Cancer in Patients Who Have Received Gemcitabine-Based Chemotherapy

Sharlene Gill et al., J Clin Oncol, 2016

Second-line treatment in patients with pancreatic ductal adenocarcinoma: A meta-analysis

Mohamad Bassam Sonbol et al., Cancer, 2017

Recent advances in immunotherapy for pancreatic cancer

Jeffrey Chi, Journal of Cancer Metastasis and Treatment-OAE Publishing, 2020

The efficacy of irinotecan, paclitaxel, and oxaliplatin (IPO) in relapsed germ cell tumours with high-dose chemotherapy as consolidation: a non-cisplatin-based induction approach


Waleed Badreldin et al., BJU International, 2014

Current management and future directions in metastatic pancreatic adenocarcinoma

Anna M. Varghese et al., Cancer, 2016

Poorer Cardiovascular Health Linked to Earlier Age at Menarche

Cardiology Advisor, 2020

Powered by TREND 

I consent to the use of Google Analytics and related cookies across the TrendMD network (widget, website, blog). [Learn more](#)

WHAT'S POPULAR

Most Read Most Cited

[Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer: ASCO Clinical Practice Guideline Update](#)
Key et al.

[Prognostic Index for Acute- and Lymphoma-Type Adult T-Cell Leukemia/Lymphoma](#)
Katsuya et al.

[Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Clinical Practice Guideline](#)
Brahmer et al.

[Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2-, Node-Positive, High-Risk, Early Breast Cancer \(monarchE\)](#)
Johnston et al.

[Updated Analysis From KEYNOTE-189: Pembrolizumab or Placebo Plus Pemetrexed and Platinum for Previously Untreated Metastatic Nonsquamous Non-Small-Cell Lung Cancer](#)
Gadgeel et al.



QUICK LINKS

Content

- Newest Articles
- Archive
- Meeting Abstracts

Journal Information

- About
- Editorial Roster
- Contact Us
- Permissions

Resources

- Authors
- Reviewers
- Subscribers
- Institutions
- Advertisers

Submit Your Manuscript

Subscribe to this Journal



ASCO FAMILY OF SITES

Journals

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

Publications

- ASCO Educational Book
- ASCO Daily News
- ASCO Connection
- The ASCO Post
- JCO OP DAIS

Education

- ASCO eLearning
- ASCO Meetings
- Cancer.Net

Other Sites

- ASCO.org
- ASCO Author Services
- ASCO Career Center
- CancerLinQ
- Conquer Cancer Foundation
- TAPUR Study



American Society of Clinical Oncology
2318 Mill Road, Suite 800, Alexandria, VA 22314
© 2021 American Society of Clinical Oncology



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