Chemotherapy Regimen Extends Life by Nearly Twenty Months for People With Pancreatic Cancer

For immediate release
June 4, 2018

MEDIA CONTACT:
Ashley Yum
571-483-1376
ashley.yum@asco.org

PATIENT AND CAREGIVER INQUIRIES:
Contact Cancer.Net

ASCO Perspective

"Pancreatic cancer is notoriously aggressive and typically has a poor prognosis, so it is a major win to find that a new treatment regimen significantly improves survival for patients with this disease," said ASCO Expert Andrew Epstein, MD.

CHICAGO – In a randomized phase III trial people with surgically removed pancreatic cancer who received mFOLFIRINOX, a chemotherapy regimen containing four different medicines, lived a median of 20 months longer and were cancer-free nine months longer than those who received the current standard of care, gemcitabine (Gemzar®).

The study will be featured in a press briefing today and presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

“For the first time, our trial shows a large benefit from adjuvant FOLFIRINOX chemotherapy over standard chemotherapy with gemcitabine, showing we can help patients with pancreatic cancer live much longer,” said lead study author Thierry Conroy, MD, a medical oncologist and director of the Institut de Cancerologie de Lorraine in Nancy, one of the UNICANCER comprehensive cancer centers in France. “In addition, we were encouraged to see that the results were better than expected when we planned this trial.”

After pancreatic cancer surgery, adjuvant chemotherapy with gemcitabine can substantially
prolong survival compared to surgery alone, as well as increase the number of patients who are cured, meaning patients who are healthy again and will probably not relapse from pancreatic cancer (at 5 years, about 21% with gemcitabine vs. 10% with surgery alone). Gemcitabine has been the standard adjuvant therapy for the past 10 years.

About the Study
The PRODIGE 24/CCTG PA.6 trial enrolled patients with non-metastatic pancreatic ductal adenocarcinoma (PDAC) who had surgery that removed all or nearly all of the tumor (meaning no cancer cells visible to the surgeon after surgery, but microscopic tumoral cells may have remained). PDAC is the most common type of pancreatic cancer and accounts for 90% of all cases. Surgery is possible in only 10-20% of patients with pancreatic cancer overall. In the United States, an estimated 55,400 people will be diagnosed with pancreatic cancer in 2018. ¹

Three to 12 weeks after surgery, 493 patients were randomly assigned in France and in Canada to receive either gemcitabine or mFOLFIRINOX for six months. The mFOLFIRINOX regimen combines four chemotherapy medicines: oxaliplatin (Eloxatin®), leucovorin (folinic acid), irinotecan (Camptosar®), and 5-fluorouracil (Adrucil®). A very similar regimen is already used as an initial treatment for metastatic pancreatic cancer, and this study shows FOLFIRINOX can also benefit patients with earlier-stage disease.

Key Findings
At a median follow-up of 33.6 months, the median length of time without recurrence of pancreatic cancer (disease-free survival) was much longer in the mFOLFIRINOX group than in the gemcitabine group (21.6 months vs. 12.8 months), as was the median overall survival (54.4 months with mFOLFIRINOX vs. 35.0 months with gemcitabine). The benefit of the mFOLFIRINOX is observed in all subgroups of patients. mFOLFIRINOX also markedly extended the time until metastases appeared (median 30.4 months vs. 17.0 months with gemcitabine).

Overall, more patients experienced severe side effects (mainly hematologic) in the mFOLFIRINOX group than in the gemcitabine group (76% vs. 53%), but the side effects were manageable, according to the authors. One treatment-related death occurred in the gemcitabine group, and none in the mFOLFIRINOX group.

The types of side effects also differed between the two groups. The most common side effects of gemcitabine were headache, fever, flu-like symptoms, swelling, and low white blood cell counts. Patients who received mFOLFIRINOX had more diarrhea, nausea, vomiting, and fatigue. There was no difference in the risk of febrile neutropenia (a dangerous complication characterized by fever and low white blood cell counts) between the two groups.
Past medical history of ischemic heart disease represents a risk with either regimen, but particularly mFOLFIRINOX. Patients should be assessed for underlying heart disease before starting this adjuvant treatment, a precaution that is routine for many people with cancer receiving surgery and chemotherapy.

**Next Steps**
The next step will be to explore the timing of chemotherapy. Patients may benefit from receiving chemotherapy before surgery (neoadjuvant chemotherapy) to shrink the tumor, to destroy undetectable micrometastases and increase the chance that the tumor can be completely removed through surgery. Dr. Conroy noted that mFOLFIRINOX appears to be a good candidate for neoadjuvant chemotherapy. Another option is to give half the cycles of chemotherapy before, and the other half after surgery (perioperative chemotherapy.) Ongoing clinical trials are already testing both of these approaches.

This study, sponsored by UNICANCER, Paris, France, received funding from the Institut National du Cancer in France, French national Ligue against cancer, Canadian Cancer society and “7 days in May,” a charity cycling event in Canada.

**Study at a Glance**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Pancreatic Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Phase, Type</strong></td>
<td>Phase III, Randomized</td>
</tr>
<tr>
<td><strong>Patients on Trial</strong></td>
<td>493</td>
</tr>
<tr>
<td><strong>Intervention Tested</strong></td>
<td>Adjuvant mFOLFIRINOX vs. gemcitabine (standard of care)</td>
</tr>
<tr>
<td><strong>Primary Finding</strong></td>
<td>mDFS 21.6 months with mFOLFIRINOX vs. 12.8 months with gemcitabine</td>
</tr>
<tr>
<td><strong>Secondary Finding(s)</strong></td>
<td>mOS 54.4 months with mFOLFIRINOX vs. 35 months with gemcitabine</td>
</tr>
</tbody>
</table>

View the full abstract.

For your readers:

- Guide to Pancreatic Cancer  
  (Cáncer de pancreas )  
- Understanding Chemotherapy  
  (Qué es la quimioterapia )

View the disclosures for the 2018 ASCO Annual Meeting News Planning Team.
ATTRIBUTION TO THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING IS REQUESTED IN ALL COVERAGE.

###


### About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at [www.ASCO.org](http://www.ASCO.org), explore patient education resources at [www.Cancer.Net](http://www.Cancer.Net), and follow us on Facebook, Twitter, LinkedIn, and YouTube.