Celebrate Survival

Improve survival in the **adjuvant** treatment of stage III colon cancer

Extend survival in **metastatic** colorectal cancer

Eloxatin® (oxaliplatin injection), used in combination with infusional 5-FU/LV, is indicated for

- **Adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor**
- **Treatment of advanced carcinoma of the colon or rectum**

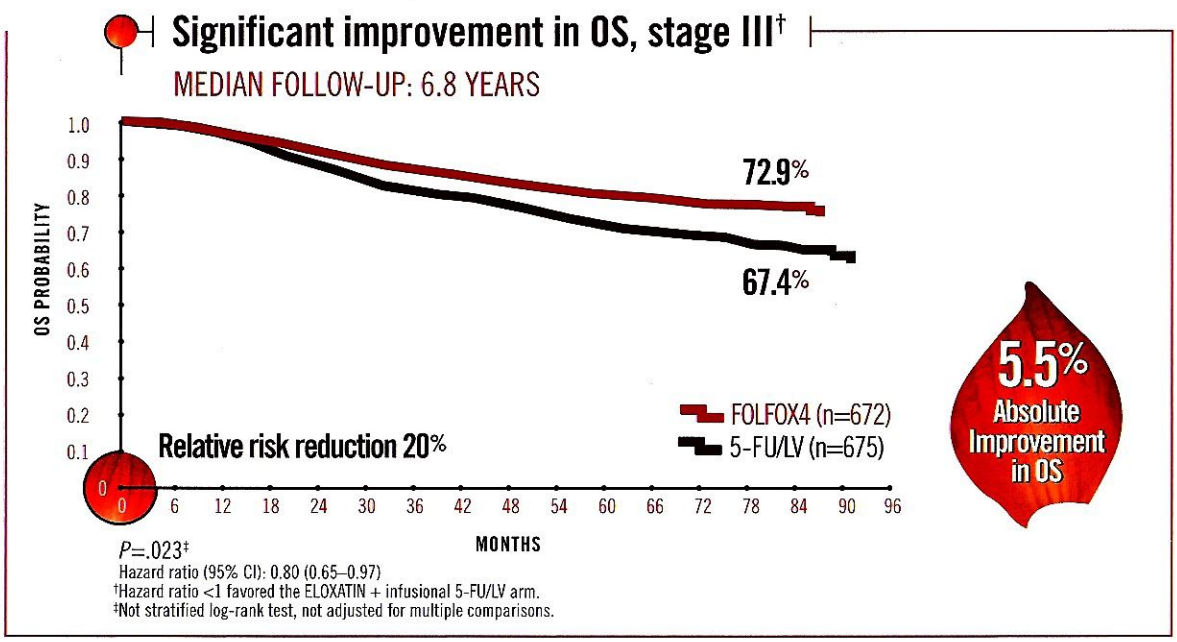
Please see enclosed full prescribing information and important safety information, including Boxed WARNING, on inside back cover.

Eloxatin®
(OXALIPLATIN injection)

Two Settings, One Choice

Survival in Two Settings

Improve overall survival in **stage III colon cancer**[1,2]



- The first chemotherapy in decades to provide additional improvement in OS[2]
- FOLFOX4 is the only combination chemotherapy proven superior to infusional fluoropyrimidine alone for stage III colon cancer[3-5]

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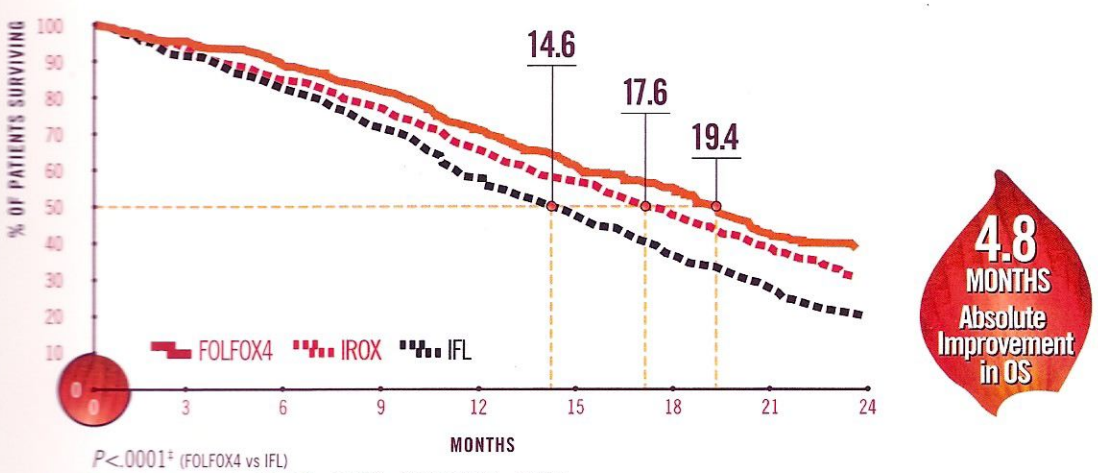
Extend survival in **metastatic CRC**[1]

Significant improvement in OS



P<.0001‡ (FOLFOX4 vs IFL)

‡Log-rank test comparing ELOXATIN + 5-FU/LV with IRINOTECAN + 5-FU/LV.

- FOLFOX4 extended overall survival in 1st-line mCRC patients to 19.4 months[1]

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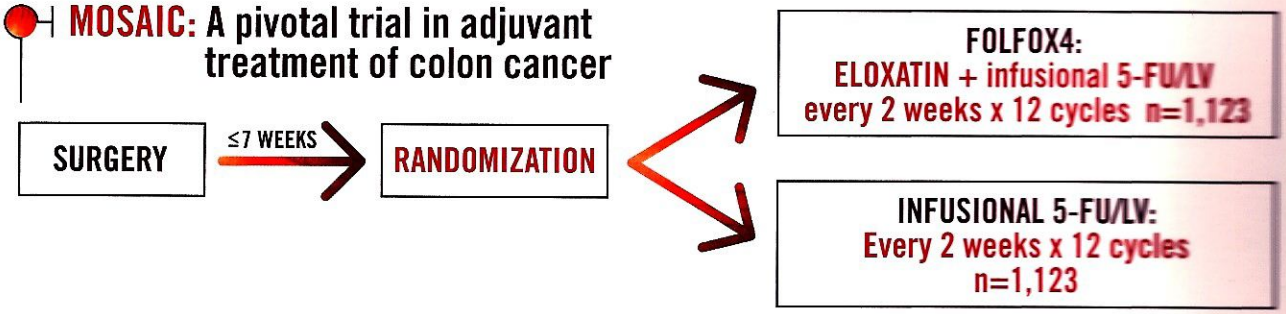
Improve Overall Survival

in the **stage III adjuvant** setting[1,6]

6-year MOSAIC data[1,2]

MOSAIC: A pivotal trial in adjuvant treatment of colon cancer



Study Design:
A Multicenter International Study of Oxaliplatin/5-Fluorouracil/Leucovorin in the Adjuvant Treatment of Colon Cancer. This randomized phase III study compared the efficacy and safety of FOLFOX4 (ELOXATIN + infusional 5-FU/LV q2w) (n=1,123) and 5-FU/LV alone q2w (n=1,123) in stage II or III colon cancer following complete resection of the primary tumor. Primary end point: DFS. Secondary end points: safety, overall survival (OS).

Patient characteristics were well balanced between treatment arms.[1] In both groups, 60% of patients had stage III disease and 40% had stage II disease.[1] Approximately 87% of patients were KPS 80-100 (ECOG 0-1).[1,2,7]

- Absolute improvement at 5 years in DFS was 7.5% for stage III patients, with a median follow-up of 6.4 years (Hazard ratio [95% CI]: 0.78 [0.65–0.93]; *P*=.005)*[1]
- Absolute improvement at 5 years in DFS was 5.9% for stage II and III patients, with a median follow-up of 6.4 years (Hazard ratio [95% CI]: 0.80 [0.68–0.93]; *P*=.003)*[1]
  - No significant improvement in DFS was seen in stage II patients[1]

Median number of FOLFOX4 cycles administered: **11**[1]

- 12 cycles over 6 months was the recommended duration of therapy

2008 NCCN Guidelines[8]

Adjuvant therapy: FOLFOX4 (Category 1)
The only Category 1 recommendation for stage III colon cancer

*Hazard ratio < 1 favored the ELOXATIN + infusional 5-FU/LV arm.

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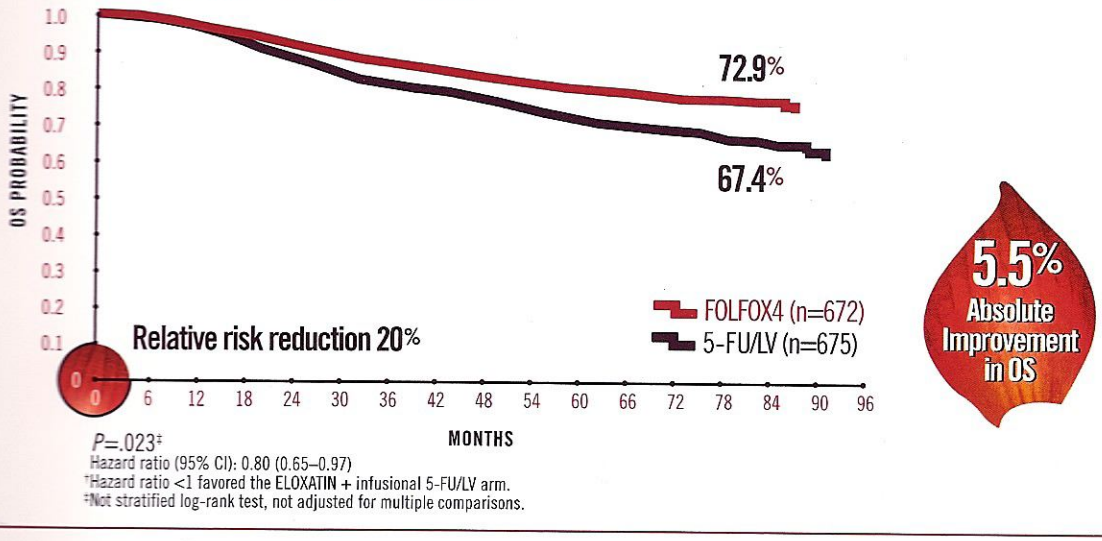
CELEBRATE 6-YEAR DATA

FOLFOX4 improved OS by 5.5% vs 5-FU/LV alone[1,2]

Significant improvement in OS, stage III†

MEDIAN FOLLOW-UP: 6.8 YEARS



P=.023‡

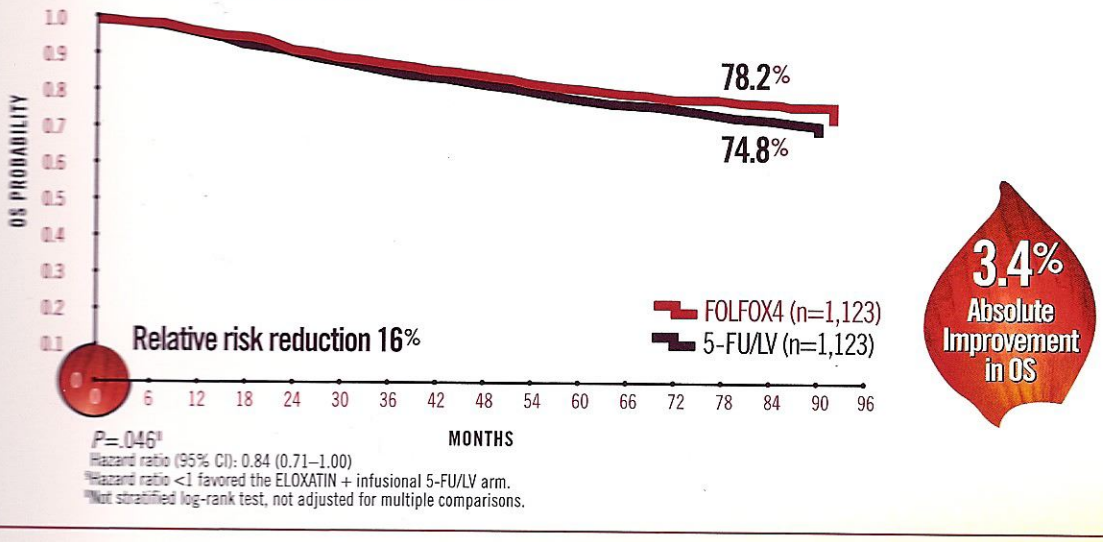
Hazard ratio (95% CI): 0.80 (0.65–0.97)

†Hazard ratio <1 favored the ELOXATIN + infusional 5-FU/LV arm.

‡Not stratified log-rank test, not adjusted for multiple comparisons.

Significant improvement in OS, stages II and III combined§

MEDIAN FOLLOW-UP: 6.8 YEARS



P=.046¶

Hazard ratio (95% CI): 0.84 (0.71–1.00)

†Hazard ratio <1 favored the ELOXATIN + infusional 5-FU/LV arm.

¶Not stratified log-rank test, not adjusted for multiple comparisons.

- No significant OS benefit was seen in stage II patients[1]
- ELOXATIN is not indicated for treatment of stage II colon cancer[1]

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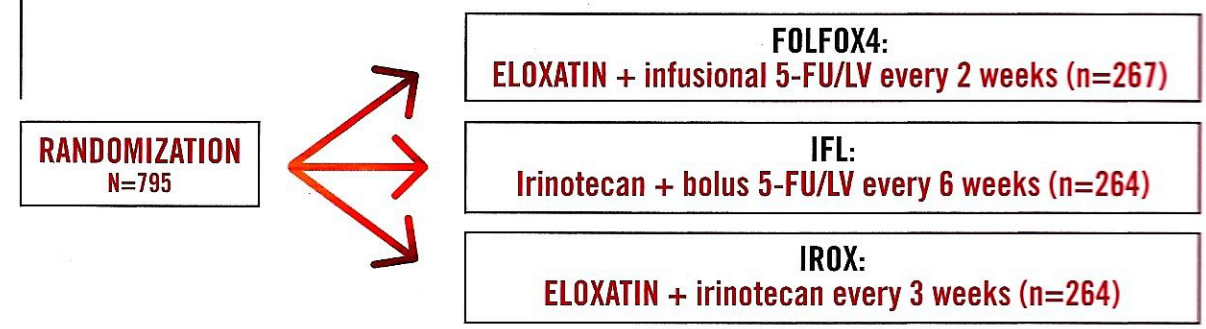
Extend Overall Survival

in 1st-line mCRC

N9741: A pivotal 1st-line mCRC trial[1,9]



Study Design:
A multicenter, open-label, randomized, controlled intergroup study led by the North Central Cancer Treatment Group (NCCTG) comparing the efficacy and safety of FOLFOX4 (ELOXATIN + infusional 5-FU/LV q2w), IFL (irinotecan + bolus 5-FU/LV q6w), and IROX (ELOXATIN + irinotecan q3w) in previously untreated advanced CRC. Primary end point: time to tumor progression (TTP) for FOLFOX4 vs IFL vs IROX. Secondary end points: OS, response rate, safety.

Patient characteristics were well balanced between study arms. 65% to 72% of patients received additional poststudy chemotherapy. 58% of FOLFOX4 patients received an irinotecan-containing regimen. 23% of IFL patients received an ELOXATIN-containing regimen (ELOXATIN was not commercially available during the trial).[1]

Median number of FOLFOX4 cycles administered: **10**[1]

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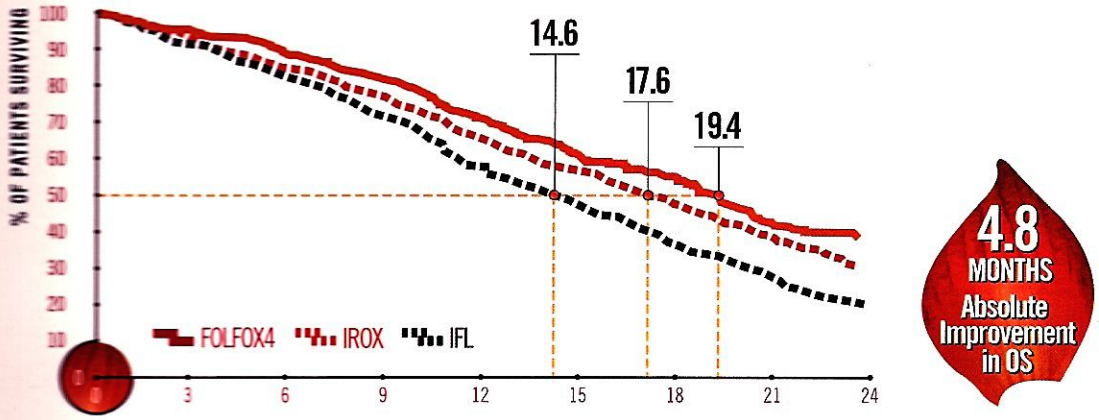
FOLFOX4 extended OS by **4.8 months** vs IFL[1]

Significant improvement in OS



P<.0001* (FOLFOX4 vs IFL)

*Log-rank test comparing ELOXATIN + 5-FU/LV with IRINOTECAN + 5-FU/LV.

- Significantly longer TTP with FOLFOX4 vs IFL: 8.7 months vs 6.9 months (*P*=.0014); 6.5 months with IROX[1]
- Significantly higher RR with FOLFOX4 vs IFL: 45.2% vs 32.5% (*P*=.0080); 34.4% with IROX[1]

N9741: Location of metastases well-balanced between study arms

Localization of metastases (%)	FOLFOX4	IFL	IROX
Colon only	0.7	0.8	0.4
Liver only	39.3	44.3	39.0
Liver + other	41.2	38.6	40.9
Lung only	6.4	3.8	5.3
Other (including lymph nodes)	11.6	11.0	12.9

- **24/795 initially unresectable patients underwent resection**[9,10]
  - **11 FOLFOX4**
  - **11 IROX**
  - **2 IFL**

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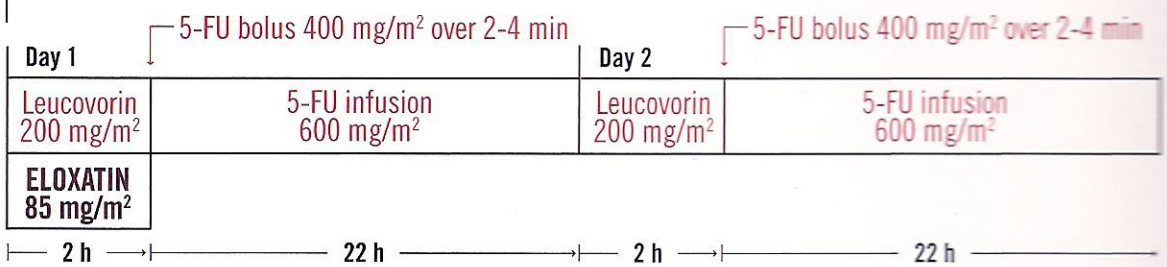
Dosing and Administration

FOLFOX4 2-week cycle*†



Day 1 ELOXATIN 85-mg/m² IV infusion in 250-500 mL of D5W and leucovorin 200-mg/m² IV infusion in D5W, both given over 120 minutes at the same time in separate bags using a Y-line, followed by 5-FU 400-mg/m² IV bolus given over 2-4 minutes, followed by 5-FU 600-mg/m² IV infusion in 500 mL of D5W (recommended) as a 22-hour continuous infusion

Day 2 Leucovorin 200-mg/m² IV infusion over 120 minutes, followed by 5-FU 400-mg/m² IV bolus given over 2-4 minutes, followed by 5-FU 600-mg/m² IV infusion in 500 mL of D5W (recommended) as a 22-hour continuous infusion

ELOXATIN is not administered on Day 2.

*Premedication with antiemetics, including 5-HT_3 blockers with or without dexamethasone, is recommended. Monitoring of white blood cell count with differential, hemoglobin, platelet count, and blood chemistries (including ALT, AST, bilirubin, and creatinine) is recommended before each ELOXATIN cycle.

†ELOXATIN should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.

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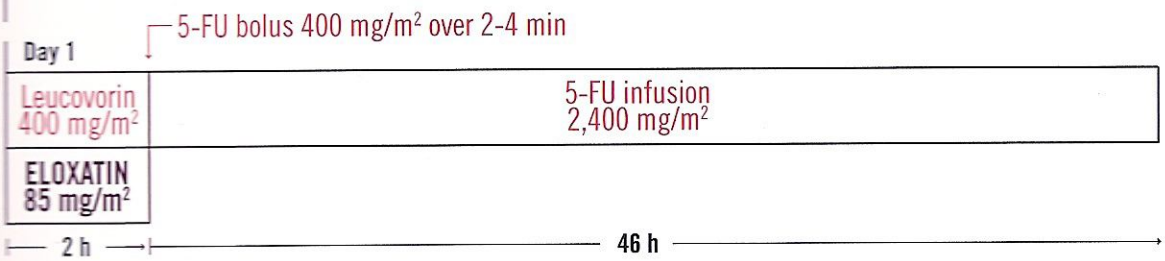
mFOLFOX6 2-week cycle: recommended by the NCCN*†[8]



Day 1 ELOXATIN 85-mg/m² IV infusion in 250-500 mL of D5W and leucovorin 400-mg/m² IV infusion in D5W, both given over 120 minutes at the same time in separate bags using a Y-line, followed by 5-FU 400-mg/m² IV bolus given over 2-4 minutes, followed by 5-FU 1,200-mg/m²/day x 2 days (total 2,400 mg/m² over 46 hours) IV infusion in 500 mL of D5W (recommended) as a 46-hour continuous infusion

- mFOLFOX6 is a convenient option that reduces the patient and nurse time in the office by eliminating the Day 2 visit[1,8]
- Pharmacokinetic analysis shows that fluorouracil exposure is similar for mCRC patients receiving mFOLFOX6 compared with a standard de Gramont regimen[11]
- Based on these results, mFOLFOX6 was the ELOXATIN-containing regimen chosen for the phase III FOCUS trial involving 2,135 patients with mCRC[12]

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Optimize Dosing

Optimize treatment cycles **for efficacy**[1]

In adjuvant therapy:

12 cycles over 6 months was the recommended duration of therapy in the MOSAIC trial

- FOLFOX4 achieved a 25% reduction in recurrence after a median of 11 cycles of therapy (recommended: 12)

In 1st-line mCRC:

10 cycles of FOLFOX4 significantly improved efficacy; treatment is recommended until disease progression or unacceptable toxicity

- In the pivotal mCRC trial N9741, FOLFOX4 therapy extended survival to 19.4 months after a median of 10 cycles

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Dose modifications
for managing grade 2 or 3 persistent neuropathy[1]

	Acute sensory neuropathy	Persistent sensory neuropathy		
	Any grade	Grade 1	Grade 2	Grade 3 or 4
Stage III colon cancer	Prolong ELOXATIN infusion from 2 h to 6 h* (optional)	No dose modification recommended	Consider reducing ELOXATIN dose to 75 mg/m^2*	Consider discontinuing ELOXATIN therapy*
Advanced CRC	Prolong ELOXATIN infusion from 2 h to 6 h* (optional)	No dose modification recommended	Consider reducing ELOXATIN dose to 65 mg/m^2*	Consider discontinuing ELOXATIN therapy*

*The 5-FU/LV doses need not be altered. Prolonging the infusion time for ELOXATIN from 2 hours to 6 hours may mitigate acute toxicities; infusion times for 5-FU/LV do not need to be changed.

- Acute sensory neuropathy: a reversible, primarily peripheral sensory neuropathy that is of early onset, occurring within hours or 1 to 2 days of dosing, that resolves within 14 days, and that frequently recurs with further dosing
- Persistent sensory neuropathy: a primarily peripheral sensory neuropathy lasting >14 days that is usually characterized by paresthesias, dysesthesias, and hypoesthesias, but may also include deficits in proprioception that can interfere with daily activities

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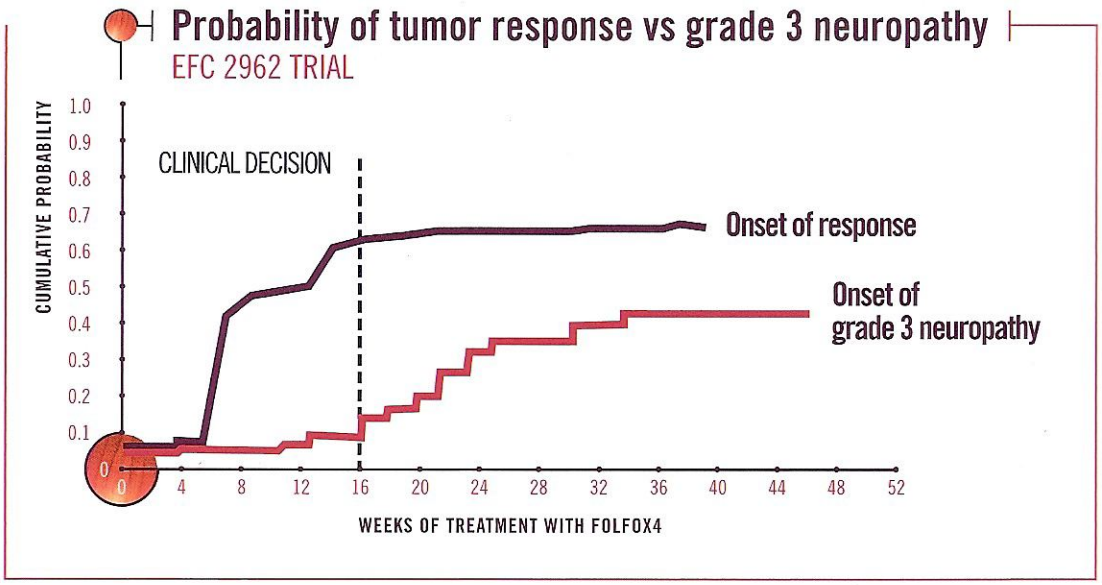
Response Precedes Neuropathy

Predictable tumor response **before onset** of persistent neuropathy[13,14]



Study Design:
A randomized, multicenter, phase III pivotal trial comparing FOLFOX4 (ELOXATIN + infusional 5-FU/LV q2w) (n=209) and 5-FU/LV alone q2w (n=207) in previously untreated mCRC.

Adapted from Haller DG. *Oncology (Williston Park)*. 2000;14(12) (suppl 11):15-20.

- The median number of 2-week cycles administered was 12 in the FOLFOX4 group vs 11 in the 5-FU/LV alone group[13]
- Less than 10% of 1st-line mCRC patients experienced dose-limiting cumulative neuropathy before reaching a total cumulative dose of 850 mg/m^2 (10 or more cycles of treatment)*[13]

* Incidence of grade 3 neurotoxicity among patients receiving FOLFOX4 in the EFC 2962 trial was also 16.3% according to a trial-specific neurotoxicity scale or 18.2% according to the NCI CTC scale.

NCI CTC=National Cancer Institute Common Toxicity Criteria.

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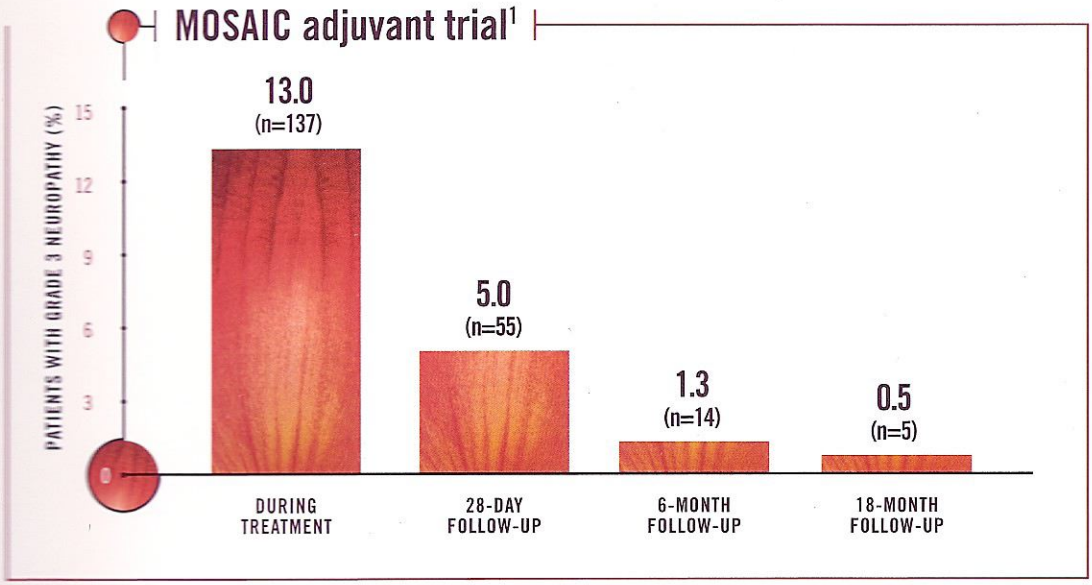
Persistent neuropathy is **generally reversible** over time[1,13,14]



- In the de Gramont 1st-line mCRC trial, the median time to recovery from grade 3 neurotoxicity was 13 weeks after treatment withdrawal[14]
  - Information regarding reversibility of neuropathy was not available for the N9741 1st-line mCRC trial[1]

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Treating Older Patients

Similar **safety and efficacy** in older mCRC patients

In the Goldberg pooled analysis, FOLFOX4 in 1st-line mCRC **was proven safe and effective in older patients**[15]

- Rates of overall adverse events, including grade 3/4 events, were similar across and within arms in different age groups across all studies
- Overall, analysis of the data shows similar toxicity patterns, including grade 3/4 events, in patients ≥70 years of age as younger patients
- The dose intensity did not differ between patients ≥70 at any cycle for any study for either ELOXATIN or infusional FU
- After adjusting for treatment, age was not significantly associated with survival (P=.22)

Similar efficacy and safety results were achieved with FOLFOX4 in older vs younger patients—across multiple 1st-line mCRC trials[1,14]

	de Gramont trial		N9741 trial	
Age	≤65	>65	<65	≥65
n (FOLFOX4 patients only)	134	76	160	99
Response rate (RR)	50.0%	50.0%	40.5%	39.4%
Time to progression (TTP)	*	*	8.1 months	10.1 months
Overall survival (OS)	*	*	19.5 months	19.4 months

*Data broken down by age subset are not available for these parameters.

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Rates of overall adverse events, including grade 3/4 events, were similar across and within arms in different age groups across all pivotal trials[1]

- In pivotal trials of ELOXATIN combination therapy for mCRC, incidences of diarrhea, dehydration, hypokalemia, leukopenia, fatigue, and syncope were higher in patients ≥65 years old
- No adjustment to ELOXATIN starting dose was required in patients ≥65 years old

In the de Gramont trial, elderly patients (>65 years old; n=160/420) did not experience increased toxicity as compared with younger patients, except for grade 3/4 diarrhea[14]

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Safety Profile

In the pivotal trial for adjuvant treatment of stage III colon cancer, **MOSAIC**[1]

- Grade 3 neuropathy was reported in 13% of stage III colon cancer patients
- Peripheral sensory neuropathy (all grades) was reported in 92% of MOSAIC patients

Adverse Event (1% NCI Grade 3/4) (WHO/Pref)	**FOLFOX4** (n=1,108)		**5-FU/LV** (n=1,111)	
	Hematologic Toxicities			
	All Grades (%)	Grades 3/4 (%)	All Grades (%)	Grades 3/4 (%)
Anemia	76	1	67	<1
Thrombocytopenia	77	2	19	<1
Neutropenia	79	41	40	5
	GI Toxicities			
Nausea	74	5	61	2
Diarrhea	56	11	48	7
Vomiting	47	6	24	1
Stomatitis	42	3	40	2
Anorexia	13	1	8	<1

- Febrile neutropenia was reported in only 0.7% of FOLFOX4 patients[1]
- The incidence of infection with grade 3/4 neutropenia was 1.1% among FOLFOX4 patients[1]
- 60-day all-cause mortality was 0.3% with FOLFOX4 vs 0.3% with infusional 5-FU/LV alone[1]

Other toxicities in MOSAIC[1]

Additional NCI grade 3/4 toxicities (≥1%) included allergic reaction, fatigue, abdominal pain, skin disorder, injection site reaction, fever, infection, and overall peripheral sensory neuropathy. Additional adverse experiences (≥5% of all patients but <1% NCI grade 3/4 events) included rhinitis, epistaxis, weight increase, conjunctivitis, headache, dyspnea, pain, lacrimation abnormal, alopecia, constipation, taste perversion, dyspepsia, phosphate alkaline increased, and sensory disturbance.

A ≤1% absolute increase in grade 3/4 hepatic toxicity was observed with FOLFOX4 compared with 5-FU/LV alone. Changes noted on liver biopsies include: peliosis, nodular regenerative hyperplasia or sinusoidal alterations, perisinusoidal fibrosis, and veno-occlusive lesions. Hepatic vascular disorders should be considered and, if appropriate, investigated in case of abnormal liver function test results or portal hypertension not explained by liver metastases.

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In the pivotal 1st-line mCRC trial, **N9741**

- Grade 3/4 neuropathy was reported in 19% of FOLFOX4 patients, 2% of IFL patients, and 7% of IROX patients[1]
- Among patients receiving FOLFOX4, the onset of grade 3 paresthesias occurred after a median of 12 two-week treatment cycles[9]

Adverse Event[1] (WHO/Pref)*	**FOLFOX4 (n=259)**	**IFL (n=256)**	**IROX (n=258)**
	Grades 3/4 (%)	Grades 3/4 (%)	Grades 3/4 (%)
Febrile neutropenia	4	14	11
Neutropenia	53	44	36
Infection–normal ANC	4	1	2
Infection–low ANC	8	11	8
Lymphopenia	2	1	2
Anemia	3	4	3
Leukopenia	20	23	24
Thrombocytopenia	5	2	4
Nausea	6	15	19
Diarrhea	12	29	25
Vomiting	4	13	23
Stomatitis	0	1	1
Anorexia	2	4	5
Constipation	4	2	2
Diarrhea–colostomy	2	7	3
Gastrointestinal NOS	2	2	2

*≥1% NCI grade 3/4 adverse events. ANC=absolute neutrophil count; NOS=not otherwise specified.

- 60-day all-cause mortality was 2.3% with FOLFOX4, vs 5.1% with IFL, and 3.1% with IROX[1]

Other toxicities in N9741

Other adverse events (≥1% NCI grade 3/4 events) reported with ELOXATIN in combination with infusional 5-FU/LV include hypersensitivity, thrombosis, hypotension, fatigue, abdominal pain, myalgia, pain, skin reaction (hand/foot), hyperglycemia, hypokalemia, dehydration, hyponatremia, urinary frequency, cough, dyspnea, and hiccups.[1]

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Patient Support

Sanofi-aventis is committed to patient support

PACT PLUS℠
Providing Access to Cancer Therapy

Phone: **1-800-996-6626** Fax: **1-800-996-6627** Hours: **Monday–Friday 9:00 AM – 8:00 PM ET**
Web site: **www.pactplusonline.com**

- Sanofi-aventis is dedicated to ensuring access to ELOXATIN for every patient. Via the PACT+℠ Program, sanofi-aventis provides medication free of charge for patients who are uninsured and who meet the program eligibility requirements
- PACT+ offers toll-free support Monday through Friday, from 9:00 AM to 8:00 PM Eastern Time, to answer questions about reimbursement
- Patient Assistance Program (PAP)
  - To help uninsured patients who require medical intervention, or patients who have medical coverage and have been denied coverage on appeal (due to lack of medical necessity, and who meet program eligibility criteria)
- Reimbursement Services
  - Benefit verification and prior authorization
  - Claims management
  - Appeals assistance
  - Coding and billing guidance
- Alternative Services
  - Patients who have no insurance, who are underinsured, or who have already received their maximum insurance benefits, may be eligible for alternative services
  - Reimbursement counselors will work with you and your patients to help identify alternative financial and social support services

Refer patients and caregivers to www.ELOXATIN.com for helpful information, including patient education materials.

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References

Indications and Usage

Eloxatin® (oxaliplatin injection), used in combination with infusional 5-FU/LV, is indicated for

- Adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor
- Treatment of advanced carcinoma of the colon or rectum

Clinical Safety Considerations

Anaphylactic-like reactions to ELOXATIN have been reported and may occur within minutes of ELOXATIN administration. Epinephrine, corticosteroids, and antihistamines have been employed to alleviate symptoms of anaphylaxis.

- ELOXATIN should not be administered to patients with a history of known allergy to ELOXATIN or other platinum compounds. Hypersensitivity and anaphylactic/anaphylactoid reactions to ELOXATIN have been reported and were similar in nature and severity to those reported with other platinum compounds (ie, rash, urticaria, erythema, pruritus, and, rarely, bronchospasm and hypotension). These reactions occur within minutes of administration and should be managed with appropriate supportive therapy. Drug-related deaths from this reaction have been reported
- ELOXATIN may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant while receiving ELOXATIN. It is not known whether ELOXATIN or its derivatives are excreted in human milk
- ELOXATIN has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal. The combined incidence of cough and dyspnea was 7.4% (<1% grade 3, no grade 4) in the ELOXATIN plus 5-FU/LV arm compared to 4.5% (no grade 3, 0.1% grade 4) in the 5-FU/LV alone arm in the adjuvant colon cancer study. In this study, one patient died from eosinophilic pneumonia in the ELOXATIN combination arm. The combined incidence of cough, dyspnea, and hypoxia was 43% (7% grade 3 and 4) in the ELOXATIN plus 5-FU/LV arm compared to 32% (5% grade 3 and 4) in the irinotecan plus 5-FU/LV arm in patients with previously untreated colorectal cancer. In case of unexplained respiratory symptoms, ELOXATIN should be discontinued until pulmonary investigation excludes interstitial lung disease or pulmonary fibrosis
- ELOXATIN is associated with two types of primarily peripheral sensory neuropathy: an acute, reversible type of early onset and a persistent type (>14 days). In patients with advanced colorectal cancer, paresthesias occurred in 77% (all grades) and 18% (grade 3/4) of previously untreated patients. In previously treated patients, acute neuropathy occurred in 56% (all grades) and 2% (grade 3/4) of patients; persistent neuropathy occurred in 48% (all grades) and 6% (grade 3/4) of patients. In patients with stage II and III colon cancer, paresthesia was seen in 92% (all grades) and 13% (grade 3/4) of patients; 21% (all grades) and 0.5% (grade 3/4) of patients had residual paresthesia at 18-month follow-up
- Hepatotoxicity, as evidenced in the adjuvant study by increase in transaminases and alkaline phosphatase, was observed more commonly in the ELOXATIN combination arm. The incidence of increased bilirubin was similar on both arms. Changes noted on liver biopsies include: peliosis, nodular regenerative hyperplasia or sinusoidal alterations, perisinusoidal fibrosis, and veno-occlusive lesions. Hepatic vascular disorders should be considered and, if appropriate, investigated in case of abnormal liver function test results or portal hypertension not explained by liver metastases
- Monitoring of white blood cell count with differential, hemoglobin, platelet count, and blood chemistries (including ALT, AST, bilirubin, and creatinine) is recommended before each ELOXATIN cycle
- The safety and effectiveness of ELOXATIN plus 5-FU/LV in patients with renal impairment have not been evaluated. Since the primary route of platinum elimination is renal, this combination should be used with caution in patients with preexisting renal impairment. Clearance of these products may be decreased by coadministration of potentially nephrotoxic compounds, although this has not been specifically studied
- The incidence of diarrhea, dehydration, hypokalemia, leukopenia, fatigue, and syncope was higher in patients ≥65 years old
- Extravasation may result in local pain and inflammation that may be severe and lead to complications, including necrosis. Injection site reaction, including redness, swelling, and pain, has been reported
- There have been reports of prolonged prothrombin time and INR occasionally associated with hemorrhage in patients receiving ELOXATIN plus 5-FU/LV while on anticoagulants. Patients receiving ELOXATIN plus 5-FU/LV and requiring oral anticoagulants may require closer monitoring
- The most common adverse reactions in patients with stage II or III colon cancer receiving adjuvant therapy were peripheral sensory neuropathy, neutropenia, thrombocytopenia, anemia, nausea, increase in transaminases and alkaline phosphatase, diarrhea, emesis, fatigue, and stomatitis. The most common adverse reactions in patients with advanced colorectal cancer were peripheral sensory neuropathy, fatigue, neutropenia, nausea, emesis, and diarrhea

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Two Settings, One Choice

Celebrate Survival

ELOXATIN + infusional 5-FU/LV...

- Significantly improves survival in adjuvant treatment of stage III colon cancer[1]
- Significantly extends survival in mCRC[1]
- Persistent neuropathy is predictable, manageable, and generally reversible[1,13]
- Similar safety and efficacy in older patients[1]
- Optimize dosing to meet your patients' needs[1,8]

Please see enclosed full prescribing information and important safety information, including Boxed WARNING, on inside back cover.

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