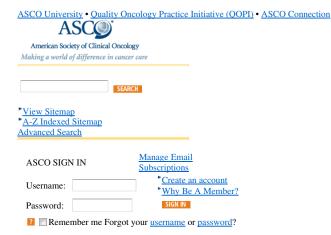
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<u>Research</u> <u>Resources</u> <u>Education &amp;</u> <u>Training</u> <u>Public Policy</u>	A PHASE I AND PHARMACOKINETIC (PK) STUDY OF THE MULTITARGETED ANTIFOL (MTA) LY231514 WITH FOLIC ACID (Meeting abstract).
<ul> <li><u>International</u> <u>Affairs</u></li> <li><u>Grants &amp;</u> <u>Awards</u></li> <li><u>MultiMedia</u></li> </ul>	Sub-category: Other Category:
Press Center	Developmental Therapeutics - Clinical Pharmacology and Immunotherapy Meeting:
	1998 ASCO Annual Meeting Abstract No: 866
	Author(s): L Hammond, M Villalona-Calero, SG Eckhardt, R Drengler, C Aylesworth, T Johnson, M Hidalgo, G Rodriguez, S Diab, P Monroe, D Thornton, Hoff D Vo, E Rowinsky
	Abstract:
	MTA (LY 231514) is a new antifol that inhibits multiple folate-dependent enzymes, including thymidylate synthase, dihydrofolate reductase, and glycinamide ribonucleotide formyl transferase. Initial phase I trials demonstrated major antitumor responses when MTA was given as a 10 min I.V. infusion, however, myelosuppression precluded dose escalation above 500-600 mg/m2. Since preclinical studies indicated that folic acid supplementation increases the eherapeutic index of MTA, the feasibility of administering folic acid 5 mg daily for 5 days starting 2 days before MTA in minimally- and heavily-pretreated pts was evaluated to determine if folic acid supplementation ameliorates the toxif effects of MTA, permitting significant dose-escalation above the recommended phase II dose of MTA alone. Thus far, 21 pts with solid cancers have received 55 courses at the following dose levels: 600, 700, and 800 mg/m2. Drug-related toxicities have included neutropenia, anemia, and thrombocytopenia, which have been more severe in heavily-pretreated pts. Other toxicities (grade 1-2) include rash, somnolence, fatigue, leg edema, and diminished renal function manifested by a decrease in creatinine clearance. One pt taking a non-steroidal anti-inflammatory agent experienced severe toxicities at the 800 mg/m2 dose, which resolved after administration of leucovorin and thymidine. One partial response in a pt with metastatic colon cancer has been observed. PK and vitamin (folic acid) metabolite profiles were done during cycles 1 and 3 at 600 to 800 mg/m2. To date, serum folic acid levels do not appear to be related to toxicity, but homocysteine was significantly elevated in the pt with severe toxicities at the 800 mg/m2 dose. Thus far, heavily-and minimally-pretreated patients have tolerated MTA at 600 and 800 mg/m2 and accrual continues at 700 and 900

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mg/m2, respectively. These results indicate that folic acid supplementation appears to permit MTA dose escalation.

Associated Presentation(s):

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Other Abstracts in this Sub-Category:

1. PHARMACOKINETICS OF IRINOTECAN AND ITS ACTIVE METABOLITE SN-38 IN CHILDREN WITH RECURRENT SOLID TUMORS AFTER PROTRACTED LOW DOSE IV IRINOTECAN (Meeting abstract).

Meeting: <u>1998 ASCO Annual Meeting</u> Abstract No: 715 First Author: <u>Stewart C</u> Category: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy - <u>Other</u> 2. <u>POPULATION PHARMACOKINETIC (PK) MODEL FOR TOPOTECAN (TPT) (Meeting abstract).</u>

Meeting: <u>1998 ASCO Annual Meeting</u> Abstract No: 716 First Author: <u>PB Laub</u> Category: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy - <u>Other</u> 3. <u>CYCLOSPORIN A (CsA) STRONGLY ENHANCES ORAL BIOAVAILABILITY OF PACLITAXEL (pac)</u> <u>IN CANCER PATIENTS (Meeting abstract).</u>

Meeting: <u>1998 ASCO Annual Meeting</u> Abstract No: 717 First Author: <u>JH Schellens</u> Category: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy - <u>Other</u> <u>More...</u>

Abstracts by L Hammond:

1. ILX651 administered daily for five days every 3 weeks (qdx5dq3w) in patients (pts) with inoperable locally advanced or metastatic melanoma:phase II experience

Meeting: 2005 ASCO Annual Meeting Abstract No: 7556 First Author: D. F. McDermott Category: Melanoma/Skin Cancers - Melanoma 2. A phase I pharmacokinetic (PK) trial of XAA296A (Discodermolide) administered every 3 wks to adult patients with advanced solid malignancies.

Meeting: 2004 ASCO Annual Meeting Abstract No: 2025 First Author: <u>A. Mita</u> Category: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy -<u>Pharmacology/Pharmacokinetics</u>
3. <u>A pharmacologic and metabolic study of docetaxel (D) administered on a continuous weekly schedule in</u> patients with advanced solid tumors.

Meeting: 2003 ASCO Annual Meeting Abstract No: 651 First Author: J. D. Rizzo Category: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy -Pharmacology/Pharmacokinetics More...

Presentations by L Hammond:

1. Phase (Ph) I evaluation of the dolastatin analogue synthadotin (SYN-D; ILX651): Pooled data analysis of three alternate schedules in patients (pts) with advanced solid tumors.

Meeting: 2004 ASCO Annual Meeting Presenter: Lisa A. Hammond, MD Session: Developmental Therapeutics: Molecular Therapeutics (General Poster Session) 2. Phase 1 study of pemetrexed (LY231514) with vitamin supplementation in patients with locally advanced or metastatic cancer

Meeting: 2003 ASCO Annual Meeting Presenter: Lisa A Hammond, MD Session: <u>Developmental Therapeutics - Cytotoxic Chemotherapy</u> (General Poster Session) 3. Phase I and pharmacokinetic (PK) trial of sequences of the rebeccamycin analog, NSC 655649, and cisplatin (CDDP)

Meeting: 2002 ASCO Annual Meeting Presenter: Lisa A. Hammond, MD Session: Pharmacology (General Poster Session) More...

Educational Book Manuscripts by L Hammond:

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