

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**ADVISORY COMMITTEE: ONCOLOGIC DRUGS ADVISORY  
COMMITTEE**

**DATE OF MEETING: 06/23/97**

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**SLIDES**

## PERIPHERAL NEUROPATHY BMS-174

	Number of Patients (%) (n=29)
CTC Grade I	15 (52)
Grade II	4 (14)
Grade III	3 (10)
Grade Unknown	1 (3)

- Thirteen patients reported PNS prior to TAXOL
- 15/23 with PNS received concomitantly didanosine, zalcitabine and/or stavudine

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## PROTEASE INHIBITOR BMS-281

	Number of Patients (%) (n=56)
Protease inhibitors at any time	20 (38)
started at course: median	11
range	1 - 22
Protease inhibitors in ACTG responders	18 / 33 (55)
initiated prior to response	3
initiated after date of response	15

Similar rates of myelosuppression were observed

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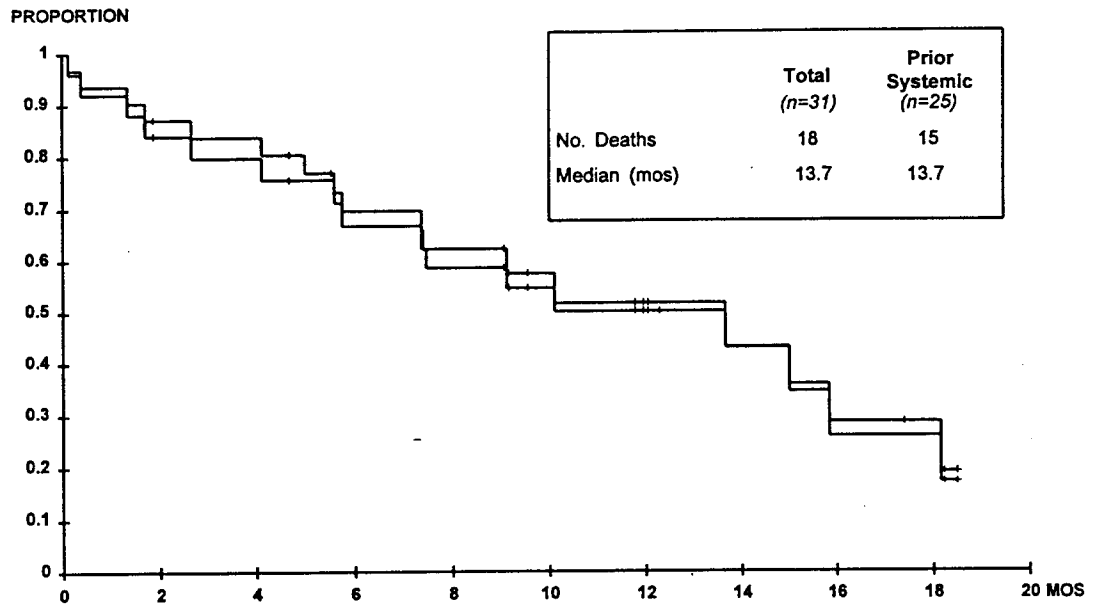
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# VISCERAL DISEASE SURVIVAL - PRIOR THERAPY



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## FEVER/FEBRILE NEUTROPENIA, ALL

	BMS - 174	BMS - 281	Total	Prior Systemic
	<i>(n = 29)</i>	<i>(n = 56)</i>	<i>(n = 85)</i>	<i>(n = 59)</i>
Percent of patients with fever	97	66	76	78
febrile neutropenia	55	9	25	24
	<i>(n = 336)</i>	<i>(n = 605)</i>	<i>(n = 941)</i>	<i>(n = 691)</i>
Percent of courses with fever	41	15	24	23
febrile neutropenia	10	1	5	4

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## FEVER/FEBRILE NEUTROPENIA: SOLID TUMORS VS KS

	Solid Tumors		KS	
	135/3 (n = 190)	175/3 (n = 181)	Total (n = 85)	Prior Systemic (n = 59)
Percent of patients with				
fever	36	38	76	78
febrile neutropenia	3	4	25	24
Percent of courses with	(n = 987)	(n = 957)	(n = 941)	(n = 691)
fever	10	11	24	23
febrile neutropenia	1	1	5	4

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## PNS / ARTHRALGIA/MYALGIA, ALL

	Percent of Patients			
	BMS-174 (n=29)	BMS-281 (n=56)	Total (n=85)	Prior Systemic (n=59)
Peripheral neuropathy				
any grade	79	46	58	61
grade III - IV	10	2	5	3
Arthralgia/myalgia				
any grade	93	48	64	63
grade III - IV	14	16	15	14

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## PNS / ARTHRALGIA/MYALGIA: SOLID TUMORS VS KS

	Percent of Patients			KS Prior Systemic (n=59)
	Solid Tumors 135/3 (n=190)	175/3 (n=181)	Total (n=85)	
Peripheral neuropathy				
any grade	48	64	58	61
grade III -IV	2	4	5	3
Arthralgia/myalgia				
any grade	56	54	64	63
grade III - IV	7	12	15	14

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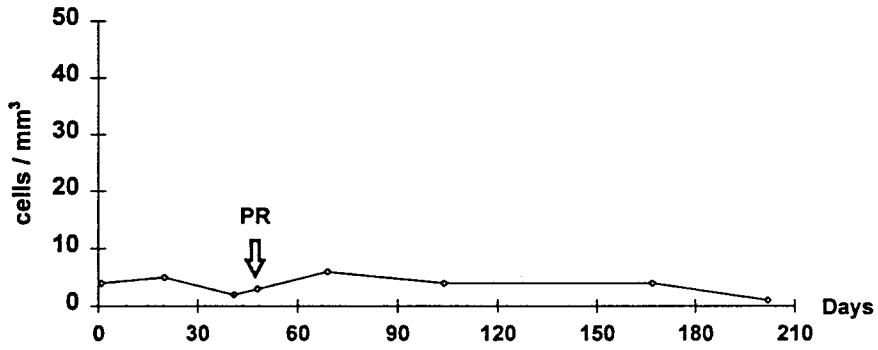
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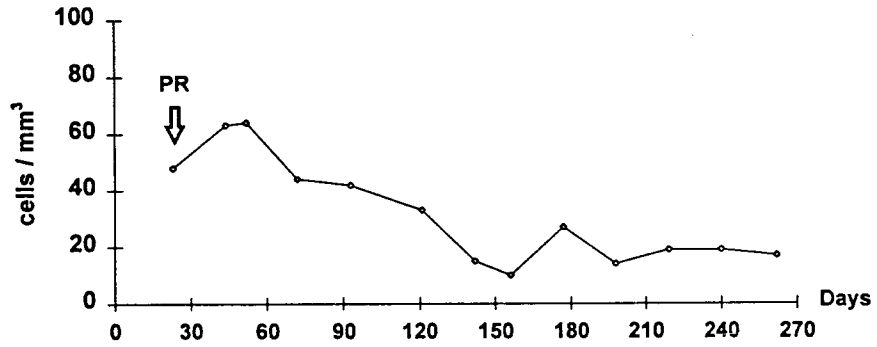
**CD4 CELL COUNT**  
**CA139-174 Subject 001-001**



**Text Name: TAXCD4.ppt**  
**Slide No. 1**

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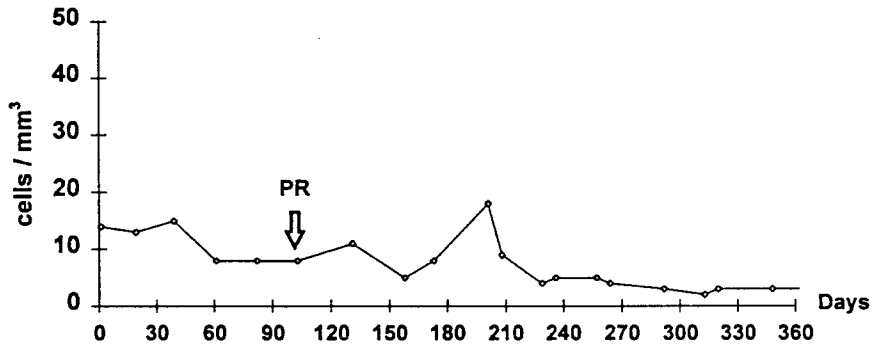
**CD4 CELL COUNT**  
**CA139-174 Subject 001-002**



**Text Name: TAXCD4.ppt**  
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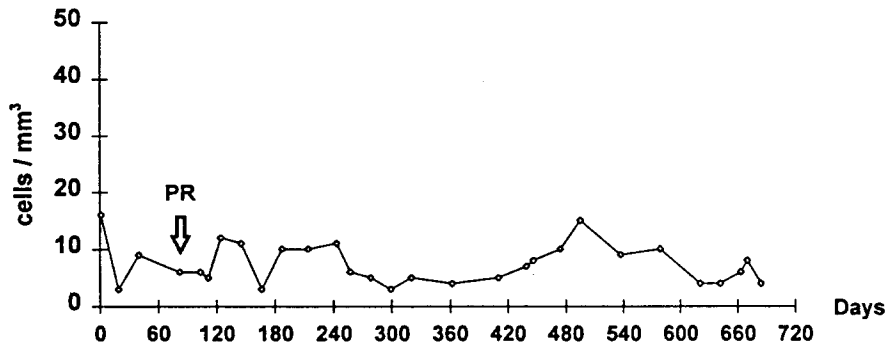
**CD4 CELL COUNT**  
**CA139-174 Subject 001-005**



**Text Name: TAXCD4.ppt**  
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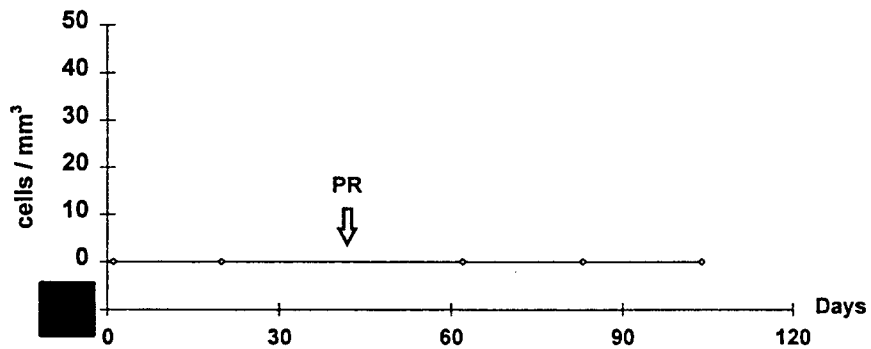
**CD4 CELL COUNT**  
**CA139-174 Subject 001-006**



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**CD4 CELL COUNT**  
**CA139-174 Subject 001-007**



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