

Archived Adverse Events: [60A02](#) | [71103](#) | [97102](#)

Included in the list below are all adverse events (AEs) and serious adverse events (SAEs) from the Wake Forest site and all participating site members for closed studies. Sites should submit AEs/SAEs from other sites as well as those that occur locally, according to the policies and procedures of their IRB. For questions regarding this website, or to request a copy of a particular MedWatch AE/SAE form, please contact Sarah C. Hahne at (336) 716-5992

60A02 – Juice Plus

<i>Event number</i>	<i>Date of Event</i>	<i>Main event (brief description)</i>	<i>Related to study drug?</i>
1	10/25/04	Hospitalization for grade 4 pain due to neuropathy and grade 3 dehydration	No
2	06/16/05	ER presentation with grade 2 versus possible grade 4 mood alteration	No
3	07/26/05	Hospitalization for grade 3 pain and headache	No
4	10/17/05	Hospitalization for chills, cough, fever	No
5	12/07/05	Death at home during sleep.	No
6	12/11/05	Hospitalization for grade 3 ataxia; patient fell and had head injury	No
7	01/12/06	Hospitalized for grade 2 anorexia and grade 3 fatigue	No

[Back to top](#)

71103 – Depsipeptide, metastatic soft-tissue sarcoma

<i>Event number</i>	<i>Date of Event</i>	<i>Main event (brief description)</i>	<i>Related to study drug?</i>
1	01/28/05	Hospitalization for prolongation of QTC	Yes
2	04/16/05	Hospitalization for dehydration and infection	No
3	04/26/05	Hospitalization for prolongation of QTC	Yes
4	04/27/05	Hospitalization for grade 2 pain, fever, and grade 3 dehydration	No
5	05/03/05	Death from disease progression.	No
6	08/15/05	Hospitalization for grade 3 nausea, vomiting, dehydration, and grade 2 fever	No
7	08/23/05	Hospitalization for grade 4 dyspnea, hypoxia and pleural effusion	No
8	08/29/05	Hospitalization for grade 3 back and right thigh pain	No
9	9/15/05	Hospitalization for pain, hypoxia, dyspnea	No
10	10/11/05	Hospitalization for lower back pain	No
11	02/10/06	Asymptomatic prolongation of QT/QTC as demonstrated on EKG; grade 3	Yes

12	03/08/06	Hospitalization for grade 4 constipation, grade 3 nausea/vomiting, anemia, and grade 2 shortness of breath	No
13	03/25/06	Hospitalization for grade 3 dehydration, nausea and vomiting	No
14	03/28/06	Hospitalization for weakness	No
15	04/04/06	Death due to disease progression	No
July 2006			
16	06/23/06	Hospitalization due to grade 3 dehydration	No
17	07/06/06	Hospitalization due to grade 3 dehydration, anorexia, fatigue, edema and grade 4 potassium	No
18	07/11/06	Death due to disease progression	No
August 2006			
19	07/21/06	Asymptomatic prolongations of QT/QTc as demonstrated on EKG, grade 3	Yes
20	07/28/06	Grade 3 cardiac arrhythmia	Yes
October 2006			
21	09/8/06	Hospitalization due to grade 2 dyspnea and pneumothorax and grade 3 back pain	No
22	09/20/06	Hospitalization due to grade 2 dyspnea	No
23	09/19/06	Hospitalization due to grade 3 hip pain and vision	No
24	09/24/06	Hospitalized for grade 3 chest pain and dyspnea	No
25	09/23/06	Hospitalization due to grade 3 abdominal pain, vomiting and nausea	No
November 2006			
26	09/23/06	Hospitalization due to grade 3 abdominal pain, vomiting and nausea	No
27	10/20/06	Hospitalization due to grade 4 abdominal pain, grade 3 vomiting and dehydration	No
January 2007			
28	11/03/06	Hospitalization due to grade 3 abdominal pain, diarrhea, grade 2 N & V	No
29	12/01/06	Hospitalization due to grade 2 edema and UTI	No
30	12/10/06	Death due to disease progression	No
February 2007			
31	02/06/07	Hospitalization due to grade 4 secondary malignancy	No
May 2007			
32	04/20/07	Hospitalization due to grade 3 pain	No
August 2007			
33	08/08/07	Hospitalization due to grade 3 cardiac arrhythmia	Yes

[Back to top](#)

97102 – Oxandrin/Megace

<i>Event Number</i>	<i>Date of Event</i>	<i>Main event (brief description)</i>	<i>Related to study drug?</i>
1	06/25/04	Elevated liver functions	Yes
2	07/22/04	Hospitalization for grade 3 abdominal pain	No
3	08/11/04	Hospitalization for grade 3 shortness of breath	No
4	08/16/04	Grade 4 leucopenia	No
5	08/19/04	Hospitalization for grade 4 shortness of breath	No
6	08/25/04	Hospitalization for aspiration following accidental removal of feeding tube	No
7	10/20/04	Hospitalization for grade 3 neutropenic fever	No
8	11/16/04	Hospitalization for insertion of feeding tube, anorexia, and teeth extractions	No
9	11/20/04	Hospitalization for intractable nausea, vomiting, failure to thrive, dehydration	No
10	12/10/04	Hospitalization for two bleeding ulcers	No
11	12/23/04	Hospitalization for bilateral pulmonary emboli	No
12	12/09/04	Hospitalization for grade 3 dehydration	No
13	01/07/05	Hospitalization for culture neg sepsis syndrome	No
14	02/01/05	Hospitalization for peptic ulcer	No
15	02/19/05	Death due to fatal arrhythmia	No
16	03/16/05	Death due to disease progression	No
17	03/20/05	Hospitalization for surgical revision of transverse loop colostomy	No
18	03/23/05	Hospitalization for grade 3 dehydration	No
19	03/31/05	Hospitalization for small bowel obstruction	No
20	04/13/05	Death due to disease progression	No
21	04/20/05	Hospitalization for failure to thrive, grade 3 dehydration, possible narcotic withdrawal	No
22	04/29/05	Hospitalization for grade 3 dehydration and anemia	No
23	04/30/05	Hospitalization for evaluation of small bowel obstruction	No
24	06/04/05	Hospitalization for grade 3 shortness of breath and grade 1 fever	No
25	06/10/05	Hospitalization for pneumonia	No
26	06/28/05	Hospitalization for grade 3 pain control and grade 3 hydration	No
27	06/28/05	Hospitalization for pain control and	No

		grade 3 hydration (*different patient from one in SAE #25; similar circumstances)	
28	07/01/05	Death reported by patient's daughter	No
29	07/02/05	Death due to disease progression	No
30	07/05/05	Death due to disease progression	No
31	07/24/05	Death following hospitalization for GI bleed, dehydration, shortness of breath	No
32	08/05/05	Hospitalization for grade 3 nausea and vomiting, pain control	No
33	8/10/05	Hospitalization for grade 3 abdominal pain, nausea/vomiting, dehydration, anorexia, constipation, generalized muscle weakness	No
34	9/20/05	Hospitalization for infection of port-a-cath	No
35	9/26/05	Hospitalization for shortness of breath, back pain, hypoxia	No
36	10/8/05	Hospitalization for fever, hypotension, hypoxia, possible pneumonia	No
37	10/15/05	Hospitalization for chest pain	No
38	10/18/05	Mobile apical thrombus demonstrated on ECG	No
39	10/25/05	Hospitalization due to diarrhea	No
40	10/27/05	Hospitalization for nausea/vomiting	No
41	11/4/05	Hospitalization for upper GI bleed	No
42	11/15/05	Hospitalization for leukocytosis, anemia, tachycardia, hyperglycemia	No
43	11/20/05	Hospitalization for neutropenic fever, tonsillar abscess, pneumonia	No
44	11/29/05	Death	No
45	12/01/05	Hospitalization for weight loss, weakness, dehydration, intractable throat pain	No
46	12/20/05	Hospitalization for intractable pain, vomiting, weakness	No
47	12/25/05	Hospitalization for back and epigastric pain, vomiting	No
48	1/04/06	Hospitalization for dehydration, hypotension, neutropenia, possible infection	No
49	02/01/06	Hospitalization for cellulitis	No
50	04/10/06	Hospitalization for grade 3 shortness of breath	No
51	04/10/06	Hospitalization for grade 3 cellulitis	No
52	04/18/06	Grade 5 – Death due to disease progression	No

53	04/21/06	Grade 5 – Death due to disease progression	No
54	05/16/06	Hospitalization for confusion, dizziness, and mood alteration due to brain mets	No
55	05/14/06	Hospitalization for grade 3 abdominal pain	No
June 2006			
56	06/05/06	Hospitalization for grade 3 hemoptysis	No
57	06/07/06	Hospitalization for grade 3 nausea and vomiting	No
58	02/10/06	Hospitalization for dehydration, anorexia, weight loss, fatigue, dysphasia	No
59	06/06/06	Hospitalization for grade 2 abdominal pain	No
60	06/18/06	Hospitalization for grade 3 shortness of breath	No
July 2006			
61	06/22/06	Hospitalization for grade 3 pain	No
62	07/07/06	Hospitalization due to grade 3 dyspnea and grade 3 tachycardia	No
63	07/13/06	Hospitalization due to acute renal failure	No
64	07/16/06	Hospitalization due to grade 3 febrile neutropenia	No
65	07/24/06	Hospitalization due to A-Fib (grade 3)	No
August 2006			
66	04/05/06	Hospitalization due to grade 3 shortness of breath and grade 2 fatigue	Yes
67	7/16/06	Grade 5- Death due to MI	No
68	08/12/06	Hospitalization due to seizure	No
September 2006			
69	06/08/06	Hospitalization due to grade 4 liver enzyme elevation	Yes
70	08/12/06	Hospitalization due to seizures and grade 3 confusion; death due to disease	No
71	08/28/06	Hospitalization due to grade 3 dehydration	No
72	08/29/06	Death due to SIADH	No
73	09/05/06	Hospitalized for grade 3 anemia	No
74	09/12/06	Hospitalization due to grade 3 A-fibrillation	No
75	09/25/06	Hospitalization due to grade 3 hypoxia	No
October 2006			
76	09/05/06	Hospitalization due to grade 3 renal	No

77	09/20/06	function and grade 4 acidosis Grade 4 pulmonary emboli	Yes
78	09/25/06	Death due to pulmonary edema, pneumonitis and pneumonia	No
79	10/24/06	Hospitalization due to grade 3 constipation	No
November 2006			
80	10/06/06	Death	No
81	10/11/06	Hospitalization due to grade 3 cellulitis	No
82	11/12/06	Hospitalization due to grade 3 anemia and fatigue	No
January 2007			
83	01/19/07	Hospitalization due to grade 3 dehydration and pancytopenia	No
February 2007			
84	01/22/07	Death- Exact etiology unknowns	No
85	02/09/07	Hospitalization due to grade 4 sepsis and grade 2 confusion	No
86	02/13/07	Death due to grade 5 sepsis.	No
87	02/13/07	Hospitalization due to grade 3 hypoxia	No
March 2007			
88	03/13/07	Hospitalization due to grade 3 anemia and renal failure, dehydration	No
89	03/08/07	Hospitalization due to grade 3 dyspnea and hypoxia	No
April 2007			
90	03/19/07	Hospitalization due to grade 3 DVT	No
91	03/30/07	Hospitalization due to grade 3 edema and grade 3 pain	No
92	04/12/07	Hospitalization due to grade 4 pain and edema	No
May 2007			
93	05/02/07	Hospitalization due to grade 4 neutropenia and grade 3 dehydration	No
June 2007			
94	06/16/07	Hospitalization due to grade 3 syncope and grade 2 anemia.	No
95	06-19-07	Hospitalization due to grade 3 abdominal pain, grade 3 diarrhea and grade 3 weakness.	No
July 2007			
96	05/23/07	Hospitalization due to grade 3 Ascites and grade 2 Anemia.	No
97	05/26/07	Hospitalization due to grade 2 transient Ischemic attack and grade 3 Ascites.	No
98	06/09/07	Death due to disease progression.	No

99

07/03/07

Hospitalization due to grade 3
altered mental status and grade 3
MRSA bronchitis

No

[Back to top](#)