## Archived Adverse Events:

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

*Denotes addendum for clarification or resolution.

### 60A02 – Juice Plus

| *Event number* | *Date of Event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| 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 |

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### 71103 – Depsipeptide, metastatic soft-tissue sarcoma

| *Event number* | *Date of Event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| 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 pnemothorax and grade 3 back pain | No |
| 22 | 09/20/06 | Hospitalization due to grad 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 | Yes |

arrhythmia

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# 91105 - Donepezil

| *Event Number* | *Date of event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| **Aug-08** | | | |
| 1 | 8/3/2008 | Hospitalization due to grade 3 confusion and cognitive disturbance | No |
| 2 | 8/15/2008 | Death, Grade 3 confusion and cognitive disturbance | No |
| **Sep-08** | | | |
| 3 | 9/8/2008 | Hospitalization due to grade 3 syncope | No |
| **June-09** | | | |
| 4 | 03/26/09 | Grade 3 insomnia | Probable |
| **Aug-09** | | | |
| 5 | 7/29/09 | Grade 3 insomnia and headaches | Probable |
| **Sept-09** | | | |
| 6 | 7/7/09 | Grade 3 mood alteration | No |
| **Oct-09** | | | |
| 7 | 7/22/09 | Hospitalization due to surgery | No |
| 8 | 9/25/09 | Hospitalization due to seizure | No |
| 9 | 10/2/09 | Death due to pulmonary embolus | No |
| 10 | 10/22/09 | Hospitalization due to grade 4 aspiration and grade 3 somnolence | Possible |
| **Nov-09** | | | |
| 11 | 11/01/09 | Death due to aspiration and infection | No |
| **Mar-10** | | | |
| 12 | 03/07/10 | Grade 3 vomiting and diarrhea | No |
| **May-10** | | | |
| 13 | 03/26/10 | Pain, Nausea, Vomiting, Infection - Grade 3, Lower gait walking - Grade 1 | No |
| **June-10** | | | |
| 14 | 04/27/10 | Hospitalization due to grade 3 nausea | No |
| 15 | 05/30/10 | Grade 3 muscule pain | No |
| **Sept-10** | | | |
| 16 | 06/18/10 | Grade 3 syncope event | No |
| 17 | 07/20/10 | Grade 3 pain | No |
| **March-12** | | | |
| 18 | 03/21/12 | Hospitalization due to grade 3 hernia | No |

**97102 – Oxandrin / Megace**

| *Event Number* | *Date of Event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| 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 | |
| 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 grade 3 hydration (*different patient from one in SAE #25; similar circumstances) | No |
| 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 hemoptyais | 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 |

| | | | |
|---|---|---|---|
| | | function and grade 4 acidosis | |
| 77 | 09/20/06 | 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 |

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# 97202 - CoQ10, Fatigue, Breast cancer

| *Event Number* | *Date of Event* | *Main Event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| 1 | 10/18/2004 | Hospitalization for grade 4 febrile neutropenia | No |
| 2 | 11/25/2004 | Hospitalization for grade 3 febrile neutropenia | No |
| 3 | 2/17/2005 | Hospitalization following laparoscopy with bilateral salpingo-oophorectomy; diverticulitis | No |
| 4 | 3/15/2005 | Hospitalization for nausea/vomiting, febrile neutropenia, hypovolemia and dehydration | No |
| 5 | 3/22/2005 | Hospitalization for chemotherapy-induced pancytopenia, febrile neutropenia | No |
| 6 | 3/29/2005 | Hospitalization for grade 3 febrile neutropenia and diarrhea | No |
| 7 | 7/15/2005 | Hospitalization for chemotherapy-induced neutropenia with nausea/vomiting, and diarrhea | No |
| 8 | 8/15/2005 | Hospitalization for chills and fever | No |
| 9 | 10/11/2005 | Hospitalization for cellulites, fever, chills | No |
| 10 | 10/20/2005 | Hospitalization for neutropenic fever | No |
| 11 | 11/21/2005 | Patient seen in clinic for vomiting, dehydration, pain; grade 4 leucopenia, grade 4 neutropenia | No |
| 12 | 12/5/2005 | Hospitalization for dehydration, nausea | No |
| 13 | 12/12/2005 | Hospitalization for shortness of breath; grade 4 vascular event | No |
| 14 | 12/13/2005 | Hospitalization for grade 4 infection | No |
| 15 | 12/15/2005 | Hospitalization for syncopal episode | No |
| 16 | 12/19/2005 | Labs revealed grade 4 decreased ANC | No |
| 17 | 12/21/2005 | Hospitalization for fatigue and syncope | No |
| 18 | 12/24/2005 | Hospitalization for dehydration, fatigue, nausea, vomiting | No |
| 19 | 1/2/2006 | Hospitalization for grade 3 diarrhea | No |
| 20 | 1/5/2006 | Hospitalization for thrombus | No |
| 21 | 1/16/2006 | Hospitalization for grade 1 fever and possible sepsis | No |
| 22 | 2/27/2006 | Hospitalization for grade 2 nausea, vomiting, and dehydration. | No |
| 23 | 3/27/2006 | Hospitalization for grade 3 catheter infection, nausea/vomiting, and headache | No |
| 24 | 4/4/2006 | Hospitalization for grade 2 DVT | No |
| 25 | 2/20/2006 | Hospitalization for dehydration, possible hypotension, tachycardia, swelling | No |
| 26 | 5/16/2006 | Hospitalization for grade 3 constipation | No |

| | | | |
|---|---|---|---|
| **Jun-06** | | | |
| 27 | 4/22/2006 | Hospitalization for grade 2 hematuria and hydonephroasis | No |
| **Aug-06** | | | |
| 28 | 8/18/2006 | Hospitalization due to grade 3 shortness of breath and syncope | No |
| **Oct-06** | | | |
| 29 | 10/17/2006 | Hospitalization due to grade 4 neutropenia | No |
| **Nov-06** | | | |
| 30 | 11/9/2006 | Hospitalization due to grade 3 diarrhea and dehydration | No |
| 31 | 11/14/2006 | Hospitalization due to grade 3 anemia and neutropenia | No |
| **Jan-07** | | | |
| 32 | 12/6/2006 | Hospitalization due to grade 3 diarrhea and neutropenia | No |
| **Feb-07** | | | |
| 33 | 12/8/2006 | Hospitalization due to infection | No |
| 34 | 1/31/2007 | Hospitalization due to grade 3 neutropenia | No |
| 35 | 2/4/2007 | Hospitalization due to grade 3 infection, fever and hydration | No |
| **Mar-07** | | | |
| 36 | 3/1/2007 | Hospitalization due to grade 3 dehydration and diarrhea | No |
| **May-07** | | | |
| 37 | 3/30/2007 | Hospitalization due to grade 4 neutropenia and grade 3 dehydration | No |
| **Jun-07** | | | |
| 38 | 5/10/2007 | Hospitalization due to grade 2 dizziness and weakness, grade 3 fever, infection, leukocytes and neutropenia. | No |
| **July-07** | | | |
| 39 | 7/24/2007 | Hospitalization due to grade 3 dehydration | No |
| **Aug-07** | | | |
| 40 | 8/11/2007 | Hospitalization due to grade 2 muscle weakness | No |
| 41 | 11/22/2005 | Hospitalization due to appendicitis | No |
| **Sep-07** | | | |
| 42 | 4/24/2007 | Hospitalization due to grade 3 cellulitis | No |
| 43 | 5/31/2007 | Hospitalization due grade 4 WBC and grade 4 ANC | No |
| 44 | 7/31/2007 | Hospitalization due to grade 3 neutropenic fever and grade 3 hypotensive | No |
| 45 | 8/18/2007 | Hospitalization due to grade 3 neutropenia and grade 3 colon infection | No |
| **Oct-07** | | | |
| 46 | 9/29/2007 | Hospitalization due to grade 3 post-op liver resection ileus and grade 2 UTI | No |
| **Nov-07** | | | |
| 47 | 09/08/07 | Hospitalization due to grade 3 vomiting, pain and infection | No |
| **Sep-08** | | | |
| 48 | 8/31/2008 | Hospitalization due to grade 2 fever | No |
| **Nov-08** | | | |
| 49 | 11/7/2008 | Hospitalization due to grade 4 neutropenia and grade 3 | No |

| | | | |
|---|---|---|---|
| | | dehydration | |
| **Dec-08** | | | |
| 50 | 12/19/2008 | Hospitalization due to grade 3 neutropenia | No |
| **Feb-09** | | | |
| 51 | 1/5/2009 | Hospitalization due to grade 3 vomiting, diarrhea and dehydration | No |
| **Aug-09** | | | |
| 52 | 2/20/2009 | Grade 4 neutropenia | No |
| 53 | 7/15/2009 | Cardiomyopathy | No |
| **Sept-09** | | | |
| 54 | 8/17/2009 | Hospitalization due to grade 3 mood alteration-anxiety | No |

# 98308 COLD-fX

| Event Number | *Date of event* | *Main event* | *Related to study drug?* |
|---|---|---|---|
| **Dec-08** | | | |
| 1 | 12/3/2008 | Hospitalization due to grade 3 abdominal pain | No |
| 2 | 12/25/2008 | Hospitalization due to grade 3 pneumonia | No |
| **Jan-09** | | | |
| 3 | 1/2/2009 | Hospitalized due to grade 4 dyspnea and grade 3 diastolic dysfunction | No |
| 4 | 1/4/2009 | Grade 3 stomach pain and grade 3 vomiting | No |
| 5 | 1/5/2009 | Hospitalization due to grade 3 pain | No |
| 6 | 1/12/2009 | Grade 3 hypertension | No |
| 7 | 1/12/2009 | Hospitalization due to grade 3 dyspnea | No |
| 8* | 1/16/2009 | Hospitalization due to grade 3 hemorrhage, pain and dyspnea<br>(amended: grade 3 infection) | No |
| **Feb-09** | | | |
| 9 | 11/18/2008 | Hospitalization due to transurethral hypertrophy | No |
| 10 | 12/29/2008 | Grade 3 urinary frequency | Possibly |
| 11 | 1/20/2009 | Grade 3 hyperglycemia | No |
| 12 | 1/20/2009 | Hospitalization due to grade 3 cardiac ischemia/infarction | No |
| 13 | 1/27/2009 | Grade 3 hemolysis | Possibly |
| 14 | 2/3/2009 | Hospitalization due to spleen abscess | No |
| 15 | 2/4/2009 | Prostate biopsy revealing low risk prostate cancer | No |
| 16 | 2/11/2009 | Hospitalization due to grade 3 dyspnea and low heart rate | No |
| **Mar-09** | | | |
| 17 | 1/12/2009 | Hospitalization due to knee surgery | No |
| 18 | 1/23/2009 | Hospitalization due to grade 3 chest pain | No |
| 19 | 2/25/2009 | Hospitalization due to grade 2 chest pain | No |

| | | | |
|---|---|---|---|
| 20* | 3/16/2009 | Hospitalization due to grade 4 seizures<br>Addendum: Death due to encephalitis | No |
| **Apr-09** | | | |
| 21 | 4/15/2009 | Hospitalization due to grade 3 syncope and lightheadedness | No |
| **May-09** | | | |
| 22 | 4/21/09 | Grade 3 thrombosis | Unlikely |
| 23 | 5/1/09 | Grade 3 hyperglycemia | No |
| 24 | 5/4/09 | Hospitalization due to grade 3 infection and ulceration | No |
| **June-09** | | | |
| 25 | 5/8/09 | Grade 3 pain, headache | No |
| **July-09** | | | |
| 26 | 3/26/09 | Grade 4 chest pain | Unlikely |
| 27 | 4/27/09 | Grade 3 bronchospasm, wheezing, and dyspnea | Unlikely |
| **Aug-09** | | | |
| 28 | 3/9/09 | Grade 3 glucose | No |
| 29 | 3/18/09 | New cancer diagnosis | No |
| 30 | 4/8/09 | Hospitalization due to planned lobectomy | No |
| **Sept-09** | | | |
| 31 | 12/22/08 | Hospitalization due to grade 2 colitis and grade 3 diarrhea | No |
| **Oct-09** | | | |
| 32 | 3/6/09 | Grade 3 rash | No |
| 33 | 4/24/09 | Grade 3 URI | No |
| 34 | 5/16/09 | Hospitalization due to grade 4 hypercalcemia | No |
| **Nov-09** | | | |
| 35 | 3/18/09 | Grade 3 knee pain | No |
| **Dec-09** | | | |
| 36 | 2/1/09 | Grade 3 brusitis | No |
| 37 | 4/30/09 | Grade 3 abdominal pain and joint pain | No |
| 38 | 5/28/09 | Grade 3 back pain | No |
| **Dec-10** | | | |
| 39 | 2/24/09 | Grade 3 Serum Glucose | No |

# 97405 – Soy/Effexor

| *Event Number* | *Date of event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| **Nov-07** | | | |
| 1 | 10/12/2007 | Hospitalization due to grade 4 abdominal pain | No |
| 2 | 12/19/2007 | Hospitalization due to grade 3 infection | No |
| **Jun-08** | | | |
| 3 | 11/5/2007 | Hospitalization due to grade 3 pain and GU obstruction | No |

| | | | |
|---|---|---|---|
| **Aug-08** | | | |
| 4 | 1/8/2008 | Hospitalization due to knee replacement | No |
| **May-09** | | | |
| 5 | 4/16/09 | Grade 3 anxiety, fatigue and pain | No |
| **Aug-09** | | | |
| 6 | 7/30/09 | Hospitalization due to grade 3 pain | No |
| 7 | 9/02/07 | Hospitalization due to grade 3 pain | No |
| **Jan-10** | | | |
| 8 | 11/3/09 | Grade 3 chest pain | No |
| 9 | 11/27/09 | Grade 3 erectile dysfunction | Possible |
| **Mar-10** | | | |
| 10 | 02/05/10 | Hospitialization due to grade 3 back and knee pain | No |
| 11 | 03/19/10 | Grade 1 Nausea, Grade 2 drenching sweats, Grade 2 fatigue and Grade 2 dizziness | Probable |
| **April -10** | | | |
| 12 | 02/15/10 | Grade 3 Pain | No |
| 13 | 04/17/10 | Grade 3 Cystitis | No |
| **May-10** | | | |
| 14 | 03/02/10 | Grade 3 Insomia | Possible |
| 15 | 03/02/10 | Grade 3 Erectile Dysfunction | Possible |
| 16 | 04/30/10 | Infection | No |
| **June-10** | | | |
| 17 | 05/12/10 | Grade 3 Pain | Unlikely |
| 18 | 05/20/10 | Hospitalization due to grade 3 pain | No |
| **July-10** | | | |
| 19 | 04/30/10 | Grade 2 urticaria | Probably |

# 97106 - ArginMax

| *Event Number* | *Date of event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| **Jan-08** | | | |
| 1 | 11/29/2007 | Grade 3 stomach pain | No |
| 2 | 3/17/2008 | Hospitalization due to grade 3 Vulva abscess | No |
| **Aug-08** | | | |
| 3 | 8/15/2008 | Grade 3 hyperglycemia | No |
| **May-09** | | | |
| 4 | 1/21/08 | Grade 3 night sweats and insomnia | Possible |
| **April-10** | | | |
| 5 | 01/01/10 | Grade 3 Infection | No |

# 97309 Yoga

| *Event number* | *Date of event* | *Main event* | *Related to study drug?* |
|---|---|---|---|
| **Mar-10** | | | |
| 1 | 03/11/2010 | Hospitalization due to grade 3 neutropenic fever | No |
| **Sept-10** | | | |
| 2 | 08/27/2010 | Hospitalization due to grade 4 neutropenic fever and grade 3 acute kidney injury | No |
| 3 | 09/04/2010 | Hospitalization due to grade 3 Congestive Heart Failure | No |

# 97211 Cognitive Dysfunction

| *Event Number* | *Date of event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| **February - 13** | | | |
| 1 | 02/01/13 | Hospitalization due to grade 4 E Coli bacteremia | No |
| **March - 13** | | | |
| 2 | 02/20/13 | Hospitalization due to grade 3 chest pain | No |
| **August - 13** | | | |
| 3 | 07/13/13 | Hospitalization due to grade 3 chest pain | No |

| | | | |
|---|---|---|---|
| **September -13** | | | |
| 4 | 5/9/13 | Hospitalization due to coronary stent cath lab procedure | No |

# 97509 Armodafinil

| *Event number* | *Date of event* | *Main event* | *Related to study drug?* |
|---|---|---|---|
| **Sept-10** | | | |
| 1 | 09/11/2010 | Hospitalization due to grade 4 agitation | No |
| **Nov-10** | | | |
| 2 | 11/19/2010 | Hospitalization due to grade 3 anemia and hematuria | No |
| **Dec-10** | | | |
| 3 | 11/14/2010 | Hospitalization due to grade 3 diarrhea, nausea, vomiting, dehydration and grade 2 pain | No |
| **Feb-11** | | | |
| 4 | 12/01/10 | Hypertension Grade 3, Sinus Tachycardia Grade 2 | No |
| 5 | 12/07/10 | Grade 3 Chest Pain, Grade 3 Headache, Grade 2 Nausea, Grade 3 Photophobia | Possibly |
| 6 | 01/01/11 | Hospitalization due to Fever Grade 1, Productive Cough Grade 2, Dyspnea Grade 1, Plenral Effusion Grade 2 | No |
| **Mar-11** | | | |
| 7 | 01/11/11 | Hospitalization due to Grade 2 headache, siezure and fatigue. | Possibly |
| **April-11** | | | |
| 8 | 03/30/11 | Grade 3 ALT and grade 1 AST | No |
| **May-11** | | | |
| 9 | 03/21/11 | Hospitalization due to grade 3 muscle weakness and grade 2 lethargy | No |
| 10 | 04/12/11 | Grade 4 fatigue | No |
| 11 | 04/22/11 | Grade 5 due to tumor progression | No |
| **June-11** | | | |
| 12 | 05/31/11 | Grade 5 due to tumor progression | No |
| **July-11** | | | |
| 13 | 06/27/11 | Grade 5 due to disease | No |
| **Nov-11** | | | |
| 14 | 11/02/11 | Hospitalization due to grade 3 infection | No |
| 15 | 11/05/11 | Hospitalization due to grade 3 dizziness and grade 2 impaired mobility | No |
| **Dec-11** | | | |
| 16 | 12/08/11 | Hospitalization due to grade 3 stroke and grade 1 rash | No |
| **Jan-12** | | | |
| 17 | 10/05/11 | Hospitalized due to grade 4 febrile neutropenia | No |
| 18 | 12/20/11 | Death due to grade 3 delirium, UTI and pneumonia | No |
| **October-12** | | | |
| 19 | 09/25/12 | Hospitalization due to grade 3 chest pain and grade 4 acute coronary syndrome | No |
| **November -12** | | | |

| | | | |
|---|---|---|---|
| 20 | 10/30/12 | Hospitalization due to grade 3 pulmonary embolus | No |
| **December -12** | | | |
| 21 | 12/03/12 | Hospitalization due to grade 3 fall | No |
| 22 | 12/09/12 | Hospitalization due to grade 2 mucosal infection | No |

# 97609 Biomarkers

These AEs are posted for infomational purposes only.

| *Event Number* | *Date of event* | *Main event (brief description)* | *Related to study?* |
|---|---|---|---|
| **February - 13** | | | |
| 1 | 01/21/13 | Death due to advanced disease | No |
| **March - 13** | | | |
| 2 | 03/01/13 | Hospitalization due to grade 4 neoplasm, benign, malignant and upsecificed meningioma | No |
| 3 | 03/11/13 | Bleeding at treatment site | No |
| **April - 13** | | | |
| 4 | 06/22/12 | Hospitalization due to grade 3 cognitive function | No |
| 5 | 97609 AE 5 was submitted and posted in error. The Grade 4 toxicity was a Grade 4 from the ONS Case Report Form not the CTC. | | |
| 6 | 01/27/13 | Death. Unrelated to study. | **No** |
| 7 | 04/09/13 | Hospitalization due to grade 3 mitral valve | No |
| **May - 13** | | | |
| 8 | 02/16/13 | Hospitalization due to grade 3 dizziness and grade 2 weakness | No |
| 9 | 02/20/13 | Death due to grade 4 sepsis and colitis. Death unrelated to study. | **No** |
| **June -13** | | | |
| 10 | 11/12/12 | Hospitalization due to grade 3 headache | No |
| 11 | 03/26/13 | Hospitalization due to grade 3 lethargy and acute renal failure | No |
| 12 | 05/01/13 | Hospitalization due to grade 3 chest pain and shortness of breath | No |
| 13 | 6/14/13 | Hospitalization due to shortness of breath | No |

98110

| *Event Number* | *Date of event* | *Main event (brief description)* | *Related to study drug?* |
|---|---|---|---|
| **May - 11** | | | |
| 1 | 3/22/11 | Grade 3 rash | Unlikely |

| | | | |
|---|---|---|---|
| **Sept - 11** | | | |
| 2 | 7/6/11 | Hospitalization due to grade 2 chest pain | Unrelated |
| 3 | 9/10/11 | Hospitalization due to grade 2 respiratory disorder | Unrelated |

*Denotes addendum for clarification or resolution.