

Table 4: Most Frequently Observed Adverse Events (>5% in All Vidaza)* Continued

Preferred Term**	All Vidaza‡ (N=220)	Observation† (N=92)
At least 1 TEAE	219 (99.5)	89 (96.7)
Lymphadenopathy	21 (9.5)	3 (3.3)
Herpes simplex	20 (9.1)	5 (5.4)
Hematoma	19 (8.6)	0
Night sweats	19 (8.6)	3 (3.3)
Rales	19 (8.6)	8 (8.7)
Tachycardia	19 (8.6)	6 (6.5)
Wheezing	19 (8.6)	2 (2.2)
Cellulitis	18 (8.2)	4 (4.3)
Dysuria	18 (8.2)	2 (2.2)
Breath sounds decreased	17 (7.7)	1 (1.1)
Lethargy	17 (7.7)	2 (2.2)
Oral mucosal petechiae	17 (7.7)	3 (3.3)
Stomatitis	17 (7.7)	0
Urinary tract infection	17 (7.7)	5 (5.4)
Peripheral swelling	16 (7.3)	5 (5.4)
Dyspepsia	15 (6.8)	4 (4.3)
Hemorrhoids	15 (6.8)	1 (1.1)
Hypotension	15 (6.8)	2 (2.2)
Injection site pruritus	15 (6.8)	0
Transfusion reaction	15 (6.8)	0
Pleural effusion	14 (6.4)	6 (6.5)
Abdominal distension	13 (5.9)	4 (4.3)
Muscle cramps	13 (5.9)	3 (3.3)
Post procedural hemorrhage	13 (5.9)	1 (1.1)
Postnasal drip	13 (5.9)	3 (3.3)
Rhonchi	13 (5.9)	2 (2.2)

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At least 1 TEAE	219 (99.5)	89 (96.7)
Syncope	13 (5.9)	5 (5.4)
Urticaria	13 (5.9)	1 (1.1)
Anemia aggravated	12 (5.5)	5 (5.4)
Loose stools	12 (5.5)	0
Nasal congestion	12 (5.5)	1 (1.1)
Atelectasis	11 (5.0)	2 (2.2)
Chest wall pain	11 (5.0)	0
Dry skin	11 (5.0)	1 (1.1)
Dysphagia	11 (5.0)	2 (2.2)
Dyspnea exacerbated	11 (5.0)	3 (3.3)
Hypoesthesia	11 (5.0)	1 (1.1)
Injection site granuloma	11 (5.0)	0
Injection site pigmentation changes	11 (5.0)	0
Injection site swelling	11 (5.0)	0
Mouth hemorrhage	11 (5.0)	1 (1.1)
Post procedural pain	11 (5.0)	2 (2.2)
Sinusitis	11 (5.0)	3 (3.3)
Skin nodule	11 (5.0)	1 (1.1)
Tongue ulceration	11 (5.0)	2 (2.2)

* Mean Vidaza exposure = 11.4 months. Mean time in observation arm = 6.1 months.
 ** Multiple reports of the same preferred terms for a patient are only counted once within each treatment group.
 † Includes events from observation period only; excludes any events after crossover to Vidaza.
 ‡ Includes events from all patients exposed to Vidaza, including patients after crossing over from observation.

Nausea, vomiting, diarrhea, and constipation all tended to increase in incidence with increasing doses of Vidaza. Nausea, vomiting, injection site erythema, constipation, rigors, petechiae, injection site pain, dizziness, injection site bruising, anxiety, hypokalemia, insomnia, epistaxis, and rales tended to be more pronounced during the first 1-2 cycles of SC Vidaza treatment compared with later cycles of treatment. There did not appear to be any adverse events that increased in frequency over the course of treatment. There did not appear to be any relevant differences in adverse events by gender.

In clinical studies of either SC or IV Vidaza, the following serious treatment-related adverse events occurring at a rate of <5% (not described in Table 4) were reported:

Blood and lymphatic system disorders: agranulocytosis, bone marrow depression, splenomegaly.

Cardiac disorders: atrial fibrillation, cardiac failure, cardiac failure congestive, cardio-respiratory arrest, congestive cardiomyopathy.

Gastrointestinal disorders: diverticulitis, gastrointestinal hemorrhage, melena, perirectal abscess.

General disorders and administration site conditions: catheter site hemorrhage, general physical health deterioration, systemic inflammatory response syndrome.

Hepatobiliary disorders: cholecystitis

Immune system disorders: anaphylactic shock, hypersensitivity.

Infections and infestations: abscess limb, bacterial infection, blastomycosis, injection site infection, Klebsiella sepsis, pharyngitis streptococcal, pneumonia Klebsiella, sepsis, Staphylococcal bacteremia, Staphylococcal infection, toxoplasmosis.

Metabolism and nutrition disorders: dehydration.

Musculoskeletal and connective tissue disorders: bone pain aggravated, muscle weakness, neck pain.

Neoplasms benign, malignant and unspecified: leukemia cutis.

Nervous system disorders: convulsions, intracranial hemorrhage.

Psychiatric disorders: confusion.

Renal and urinary disorders: hematuria, loin pain, renal failure.

Respiratory, thoracic and mediastinal disorders: hemoptysis, lung infiltration, pneumonitis, respiratory distress.

Skin and subcutaneous tissue disorders: pyoderma gangrenosum, rash pruritic, skin induration.

Surgical and medical procedures: cholecystectomy.

Vascular disorders: orthostatic hypotension.

Manufactured for: Pharmion Corporation
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Manufactured by: Ben Venue Laboratories, Inc.
Bedford, OH 44146

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chemotherapy regimen in the adjuvant setting, we now have a treatment that may be able to benefit more women with early stage breast cancer," said Dennis Slamon, MD, Chairman of the BCIRG Scientific Committee and Director of Clinical and Translational Research at UCLA's Jonsson Comprehensive Cancer Center. "With this approval, Taxotere® takes a leading role in the treatment of women with node-positive, early stage breast cancer."

About the BCIRG 001/TAX 316 Study

The primary endpoint of this multi-center study was to compare the disease-free survival after treatment with Taxotere® in combination with doxorubicin (Adriamycin) and cyclophosphamide (Cytoxan), (TAC), to a standard regimen of 5-fluorouracil, doxorubicin and cyclophosphamide, (FAC). The nearly five-year follow-up results of the study were presented at the San Antonio Breast Cancer Symposium on December 5, 2003.

The study enrolled 1,491 pre- and post-menopausal women with node-positive, early stage breast cancer from 112 sites in 20 countries between June 1997 and June 1999.

Women were randomized to receive either TAC or FAC in the adjuvant setting.

Follow-up data (55 months) of women on the study did not identify unexpected safety concerns and confirmed the results already presented at the time of the first interim analysis (33 months). Specifically, the TAC regimen was associated with a higher rate of febrile neutropenia (low white blood cell count that can lead to infections) compared with FAC (24.7 percent versus 2.5 percent). However, incidence of severe infection were similar (3.9 percent versus 2.2 percent) and there were no treatment-related deaths due to infection in the study. Patients in the study were not treated with primary prophylactic G-CSF (granulocyte colony-stimulating factor), but G-CSF was required for subsequent cycles following the first episode of febrile neutropenia and/or infection.

Other severe adverse events occurring in 5 percent or more of patients treated with TAC included neutropenia, nausea, stomatitis and asthenia, and with FAC included neutropenia, nausea, vomiting and asthenia.

More than 90 percent of patients in both treatment groups received all six cycles of treatment.

For more information about Aventis and Taxotere®, please visit: www.aventis-us.com. **OA**

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as "The Tour de Harrison" and frequently send out electronic progress updates with the same name to family and friends.

According to Leslie, "One of the keys to keeping a child positive is to use imagery exercises. With Harrison, we focus on pedaling a bike to the top of a mountain. Every night he gets to the top of the mountain and he wins."

Current Protocol

Harrison's recovery process consists of a two-year protocol and at press time, he was at week 20, 18% through the "Tour de Harrison," preparing to move into seven days of cranial radiation as a preventative measure to ensure cancer cells do not invade the central nervous system.

The greatest concern for most seven-year-old boys is playing sports with their friends, but through Harrison's adversity, he has had the opportunity to gain a greater perspective on life and has learned at an early age to live life to the fullest. Although Harrison has a difficult battle ahead of him, he is fortunate to have a strong support network of friends, family and healthcare professionals to carry him to the Arc de Triomphe! **OA**