

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 60 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☒ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
		PRIVACY						JUN	2023		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 Other Serious Criteria: Med sig
 Headache [Headache]
 Insomnia [Insomnia]
 Low blood pressure [Blood pressure decreased]
 Sour stomach [Dyspepsia]
 Dizzy spells [Dizziness]
 Fire in the mouth [Oral discomfort]
 Thirst [Thirst]
 Swelling in her ankles [Joint swelling]
 Constipation [Constipation]

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet #2) MORPHINE (MORPHINE) Unknown (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☒ YES ☐ NO ☐ NA
15. DAILY DOSE(S) #1) 150 mg, bid (every 12 hours) #2) UNK UNK, unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral #2) Unknown	
17. INDICATION(S) FOR USE #1) Breast cancer (Breast cancer) #2) Bone pain (Bone pain) (Continued on Additional Information Page)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA
18. THERAPY DATES(from/to) #1) 26-MAY-2023 / Unknown #2) Unknown	19. THERAPY DURATION #1) Unknown #2) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) MODIFICAL [ONDANSETRON HYDROCHLORIDE] (ONDANSETRON H #2) PROBIOTICS NOS (PROBIOTICS NOS) Unknown ; Unknown #3) LANZOPRAL [LAN SOPRAZOLE] (LAN SOPRAZOLE) Unknown ; Unknown #4) OTILONIUM BROMIDE (OTILONIUM BROMIDE) Tablet ; Unknown (Continued on Additional Information Page)							
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) <table border="1"> <thead> <tr> <th>From/To Dates</th> <th>Type of History / Notes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Unknown</td> <td>Medical Condition</td> <td>Irritable bowel syndrome (Irritable bowel syndrome)</td> </tr> </tbody> </table>		From/To Dates	Type of History / Notes	Description	Unknown	Medical Condition	Irritable bowel syndrome (Irritable bowel syndrome)
From/To Dates	Type of History / Notes	Description					
Unknown	Medical Condition	Irritable bowel syndrome (Irritable bowel syndrome)					

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Eli Lilly Interamerica Inc (AR Branch) Tronador 4890 - Piso 12 Buenos Aires, Capital Federal CP: 1430 ARGENTINA Phone: 54 1145464000		26. REMARKS
	24b. MFR CONTROL NO. GT202307001766	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 19-AUG-2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:	
DATE OF THIS REPORT 29-AUG-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 6	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

low defenses (immunosuppression) [Immunosuppression]
 could not walk very well [Gait disturbance]
 Abdominal pain [Abdominal pain]
 Pneumonia [Pneumonia]
 Colic/ Abdominal pain [Abdominal pain]
 Low hemoglobin [Haemoglobin decreased]
 Dry mouth [Dry mouth]
 Metallic taste [Dysgeusia]
 Anemic [Anaemia]
 Weakness/Does not allow her to get out of bed/lack of energy [Asthenia]
 Tiredness/Does not allow her to get out of bed [Fatigue]
 Low platelets [Platelet count decreased]
 Nausea [Nausea]
 Lack of appetite [Decreased appetite]
 Diarrhea/ aggravated diarrhea [Diarrhoea]
 Anemia (second episode); red blood cell reduced [Anaemia]
 Bone metastasis [Malignant neoplasm progression]
 Head pain [Headache]
 Ribcage pain / pain in her ribs [Musculoskeletal chest pain]
 Nasal congestion [Nasal congestion]
 Ear pain/ Ear was hurting [Ear pain]
 Pain in left shoulder [Arthralgia]
 Pain in her flank [Flank pain]
 Right leg pain/ leg pain / walking hurts [Pain in extremity]
 Colic [Abdominal pain]
 Headache [Headache]
 Bone pain [Bone pain]
 Dehydration [Dehydration]
 Flu [Influenza]
 Pain in legs [Pain in extremity]
 Difficulty moving due to pain / difficult to move her right leg / cannot move her leg very well [Mobility decreased]
 swelling in her right leg [Peripheral swelling]
 constipated / difficult for her to go to the toilet [Constipation]
 going to the toilet painfully [Proctalgia]
 lot of pain in lower stomach [Abdominal pain upper]
 gassing [Flatulence]
 Presents temperature fever [Pyrexia]
 Headache [Headache]
 only drinks liquids and has to go to the toilet very quickly [Micturition urgency]
 Fatigued and tired; exhausted and very tired [Fatigue]
 Nausea [Nausea]
 Poor appetite [Decreased appetite]
 Diarrhea; lot of diarrhea [Diarrhoea]
 Feel weak [Asthenia]
 Excessive fatigue (3rd episode) [Fatigue]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) through a business partner, with additional information from the initial reporter, concerned a 60-year-old (at initial time of report) female patient of an unknown ethnicity.

Medical history included irritable bowel syndrome. Concomitant medications included lansoprazole as gastric protector, ondansetron hydrochloride, otilonium bromide and unspecified probiotics; all for unknown indication of use.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice a day, orally, for the treatment of breast cancer, beginning on 26-May-2023. Additionally, she received iron (unknown manufacturer), for the treatment of low platelets, low hemoglobin, and anemia; formulation, dose, frequency, route of administration and start date were not provided. Furthermore, she received morphine (unknown manufacturer) every 12 hours, for the treatment of bone pain, pain when walking with the right leg and pain in the left shoulder; formulation, dose, frequency, route of administration, and therapy start date were not reported. On 15-Jun-2023, after three weeks of starting abemaciclib therapy, she experienced colic and abdominal pain, weakness, tiredness, and thirst. The events of asthenia and fatigue were considered as serious by the reporter due to disability reasons because they did not allow her to get out of bed (bedridden) and at the same time were considered serious by the reporter due to medically significant reasons. She received clonixin lysinate/pargeverine as a corrective treatment for colic. Since approximately 16-Jun-2023, she experienced nausea, lack of appetite, diarrheal stools, and headache. The treating physician considered the headache, abdominal pain, nausea, and diarrhea as related to abemaciclib therapy. Also, in the week of 16-Jun-2023, she underwent a radiotherapy treatment on both hips, with femur and left shoulder and due to the event, her diarrhea was aggravated. On 29-Jun-2023, she was prescribed with otilonium bromide, which

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

started on 30-Jun-2023 as a corrective treatment for colic and it helped. Also, since 30-Jun-2023, she experienced metallic taste, four diarrheal stools daily and colic. On 08-Jul-2023, she had swelling in her ankles and diuretic was provided as a corrective treatment on an unknown date, and she was recovered on 21-Jul-2023. She experienced low platelets, low hemoglobin, she was anemic (neither results, units nor reference values were provided for none of them), so she was prescribed erythropoietin, twice a week, and iron as corrective treatments. On an unknown date, iron was discontinued because she had heartburn (sour stomach) when taking it. She also had constipation. Physician prescribed lactulose as a corrective treatment and indicated that the constipation was due to the morphine being administered. On 19-Sep-2023, a blood transfusion was carried out due to low platelets, low hemoglobin, and anemia. These events were considered as serious by the company due to their medical significance. On 20-Sep-2023, she felt fatigued and tired, and abemaciclib therapy was discontinued for eight days, as per medical advice. Since 10-Nov-2023, she had pain in her legs for which was performed unspecified tests to rule out thrombosis, but the results came out well. As of 17-Nov-2023, she had been experiencing ribcage pain, headache, ear pain, and abdominal pain on unknown dates. Her doctor prescribed erythropoietin and lansoprazole as a gastric protector. On 29-Dec-2023, she experienced pain in her flank and pain in her right leg due to which, she had morphine and then it was discontinued and switched to buprenorphine, and if she still was in pain she also took paracetamol, since the pain increased from 4 to 6 out of 10. On 11-Jan-2024, she had a control lab indicated anemia and low defenses (immunosuppression) (values, units and range was not provided), due to which, the physician recommended her that for 10 consecutive days she would take abemaciclib only once a day and then evaluated, so on an unspecified date, in Jan-2024, abemaciclib therapy was resumed at decreased dose of 150 mg, daily. She also was very fatigued and tired. The events of first episode of headache, constipation, insomnia, first and second episodes of abdominal pain, dysgeusia, blood pressure decreased, dizziness, dyspepsia, oral discomfort, thirst, first episode of nausea, decreased appetite and diarrhea, joint swelling, second episode of anemia and immunosuppression, were considered serious by the reporter due to medically significant reasons. In Feb-2024, she would have a scintigraphy and had requested a nutrition consult. Also, in Feb-2024, there was no 150 mg dose, so she took two tablets of 100 mg dose. Approximately in Mar-2024, she had nausea, poor appetite, colic, diarrhea, and headache. On 15-Mar-2024, she received 150 mg twice daily dose. She experienced lot of bone pain. In Apr-2024, she continued to be sick. As of 15-Apr-2024, she continued with diarrhea, but it was more abundant in the morning; thus, tried to change her eating habits. Her treating physician instructed her to discontinue abemaciclib every two weeks and restart again. On 29-May-2024, she was in poor health because she woke up with nasal congestion, headache and felt weak, for this reason she tried to stay awake but did not manage to feel well. She had done her breakfast with oatmeal and granola but could not eat lunch because she was very nauseous. When she took the drug abemaciclib, she got stomach pain like colic and sometimes nausea and the nausea was sporadic. On an unknown date, she had a pain in her left shoulder and had bone metastases. The event malignant neoplasm progression was considered serious by the company due to its medical significance. On an unknown date, she changed the dose of the abemaciclib one tablet a day, due to diarrhea problems for which she received loperamide as a corrective treatment, but she still had it and went to the bathroom less often. She experienced flu due to which her ear was hurting. Additionally, she was dehydrated and continued with hemoglobin very low and diarrhea. Since Apr-2024, she had difficulty moving her right leg due to pain. All the events initially considered medically significant were also considered serious by the reporter due to disability criteria. On an unknown date, by decreasing dairy consumption the diarrhea settled down a little, thus, she asked the doctor (after had regularized her diarrhea by avoiding dairy products) if she could go back to taking 300 mg of abemaciclib daily because her diarrhea was under control, but the doctor told her to continue with 150 mg. One day she ate a loaf of bread and cream cheese with jelly for dinner and got diarrhea. On an unknown date, she was constipated being difficult for her to go to the toilet as she found it painful. As corrective treatment for constipation she took lactulose at night before going to bed. She told her doctor not to give her fiber because was fine with the lactulose, so was not currently taking fiber. On an unknown date, she underwent a bone scintigraphy with contrast medium (no results provided). The bone scintigraphy study was made in case someone could help her with physiotherapy. On the same date the bone scintigraphy was performed, after eating a croissant with panela cheese and mushrooms for breakfast, her stomach was very upset (referring to diarrhea) with a lot of pain in her lower stomach; it first started in the pit of her stomach, and thought it was gas and started gassing thinking she was going to the bathroom and then she got really sick (referring to diarrhea). She did not know if it was the dairy or the contrast medium. Moreover, since she only drank liquids, she had to go to the toilet very quickly but did not drink as many liquids because of the pain in her right leg. On an unknown date she continued taking morphine as corrective treatment because it was still difficult to move her right leg and walking hurt due to pain in right leg. Morphine helped taking away the pain that she could move more so as not to stay in bed. Not only she could not move her leg very well, but also could not walk very well, thus, was with a walker. The event of walking difficulty was considered serious by the reporter due to disability and medically significant reasons. On an unknown date, she felt pain in her ribs again when cooking an egg and did not finish it. On an unknown date, metastasis was stagnant, as all her organs were fine. On an unknown date while taking abemaciclib 300 mg daily, her hemoglobin reached 9, then while taking one tablet of abemaciclib 150 mg daily, her hemoglobin was at 10.3; and in May-2024, her hemoglobin was 10.9 which was quite good (no units or reference range provided for either result). As per information was on 04-Jul-2024, from eight months, she was feeling exhausted and very tired, the physician who checked her prescribed erythropoietin as her red blood cells were reduced (unit, value and reference ranges were not provided) that made her exhausted and tired. Three months ago (from time of reporting), she felt very bad as she was more exhausted and with a lot of diarrhea her dose was changed to 150 mg daily. She continued with erythropoietin as corrective treatment for low hemoglobin and anemia. On 02-Oct-2024, at 04:00 in the morning, she had fever, due to which she presented a great headache on the right side and could not even stand at the right side because it hurt her. Since Feb-2025 she had experienced excessive fatigue. On 11-Aug-2025, she had been hospitalized for pneumonia. As a corrective treatment for the events of bone pain, pain when walking with her right leg and pain in her left shoulder, she received tramadol hydrochloride/DE ketoprofen, also she received caffeine/paracetamol for ear pain while information regarding further corrective treatments was not provided. Outcome of the events abdominal pain (3rd episode), headache (3rd episode), nausea (2nd episode), decreased appetite (2nd episode), arthralgia, asthenia, hemoglobin decreased, anemia (1st and 2nd episodes), platelet count decreased, immunosuppression, flank pain, pain in extremity (2nd episode), fatigue (2nd and 3rd episode), nasal congestion, malignant neoplasm progression, influenza, peripheral swelling, diarrhea (2nd episode), dehydration, bone pain, mobility decreased fever, and walking difficulty was not recovered; for constipation (2nd episode), anal pain, stomachache, flatulence, urinary urgency, and headache (onset 02-Oct-2024) was unknown; and for remaining events was recovering. Abemaciclib therapy was resumed and

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

continued at 150 mg daily, morphine was restarted and ongoing and iron therapy status after discontinuation was not provided. This case was received per business alliance and therefore, follow-up will not be pursued. If additional information is received, the case will be updated accordingly.

The reporting consumer related the events of colic pain, nausea and Fatigue (3rd episode) with abemaciclib therapy while did not provide a relatedness assessment between the remaining events and abemaciclib therapy. The reporting consumer did not provide a relatedness assessment between the events and morphine therapy. The reporting consumer related the event of heartburn (sour stomach) to iron therapy and did not provide a relatedness assessment between the remaining events and iron therapy.

Update 12-Jul-2023: Additional information received on 04-Jul-2023 and 05-Jul-2023 from the initial consumer reporter via a business partner which upgraded the case to serious. Added morphine as concomitant medication, serious event of asthenia and fatigue and non-serious events of thirst and dysgeusia. Updated dosage, frequency of use and start date of abemaciclib, and narrative with new information.

Update 07-Aug-2023: Additional information received on 28-Jul-2023 from the initial consumer reporter via a business partner. Added four non-serious events of low platelets, low hemoglobin, anemia and constipation. Updated narrative with new information.

Update 09-Aug-2023: Additional information received on 02-Aug-2023 from the initial consumer reporter via a business partner. Added one suspect drug as iron and updated morphine from concomitant to suspect and seven non-serious events of ankle swelling, heartburn, blood pressure decreased, dizzy spells, insomnia, dry mouth and oral mucosal burning sensation. Updated narrative with new information.

Update 26-Sep-2023: Additional information was received from the initial reporter via a business partner on 20-Sep-2023. Added one non-serious event of fatigue (second episode). Updated outcome of all the events, except for low hemoglobin, anemic, and low platelets, from not recovered to recovering; abemaciclib action taken from no change to drug discontinued; the seriousness criteria of the events low platelets, low hemoglobin, and anemia, was updated from non-serious to serious due to the type of treatment received, and narrative accordingly with new information. Upon review of previous information, added lansoprazole as concomitant medication.

Update 22-Nov-2023: Additional information was received from the initial reporter via a business partner and PSP on 17-Nov-2023. Report type was updated to PSP. Added new non-serious events of ribcage pain, headache, ear pain, and abdominal pain. Updated indication for lansoprazole and erythropoietin. Narrative and relevant fields were updated accordingly.

Update 18-Jan-2024: Additional information was received from the initial reporter via PSP through a business partner on 12-Jan-2024. Added four non-serious events of flank pain, pain in leg, anemia and immunosuppression, a new lab test; new dosage regimen for abemaciclib; buprenorphine and paracetamol as product treatments. Morphine therapy status was changed from unknown to drug discontinued. Narrative was updated accordingly.

Edit 24-Jan-2024: Upon internal review of information received on 12-Jan-2024. Added the date of follow-up information received from the update statement of 18-Jan-2024.

Update 12-Apr-2024: Additional information was received from the initial reporter via a PSP through a business partner on 05-Apr-2024. Added five non-serious events of nausea (2nd episode), decreased appetite (2nd episode), abdominal pain (3rd episode), diarrhea (2nd episode) and headache (3rd episode); start date of abemaciclib 150 mg, daily and buprenorphine; and acetaminophen concentration and units. Updated narrative and relevant fields accordingly.

Update 18-Apr-2024: Additional information received on 15-Apr-2024 from the initial reporter via a PSP through a business partner. Added another non-serious event of pain in extremity with different onset date and omeprazole as concomitant medication. Updated outcome of second episode of diarrhea from unknown to not recovered; the following events as serious due to medical significance: first episode of headache, constipation, insomnia, first and second episodes of abdominal pain, dysgeusia, blood pressure decreased, dizziness, dyspepsia, oral discomfort, thirst, first episode of nausea, decreased appetite and diarrhea, joint swelling, second episode of anemia and immunosuppression; and narrative accordingly.

Update 06-Jun-2024: Additional information was received from the reporter via PSP on 30-May-2024. Added two treatment drug, one concomitant drug, start date of events ribcage pain, ear pain, one serious event of malignant neoplasm progression and three new non serious event of nasal congestion, asthenia and arthralgia. Updated the start date of non-serious event fatigue from 20-Sep-2023 to 10-Sep-2023. Updated the indication of co suspect drug morphine from unknown to bone pain, pain in extremity and arthralgia, treatment received from unknown to yes for event diarrhea and as reported causality of non-serious events colic and nausea from not reported to yes. Accordingly updated narrative with new information.

Update 13-Jun-2024: Additional information was received from the initial reporter via a PSP on 31-May-2024. Added two new dosage regimens for abemaciclib therapy; one treatment drug; irritable bowel syndrome as medical history; and three non-serious events of bone pain, Influenza, and dehydration. Updated narrative and relevant fields accordingly.

Update 20-Jun-2024: Additional information was received from initial consumer reporter via PSP on 14-Jun-2024. Added two new non-serious events of mobility decreased and peripheral swelling. Updated outcome of the event influenza from unknown to not recovered and narrative with new information.

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Update 05-Jul-2024: Additional information was received on 28-Jun-2024 from the initial reporter via PSP of a business partner. Both reports received on 28-Jun-2024 were processed at the same time. Added disability as another seriousness criteria for all events initially considered medically significant by the reporter, medical significance as another seriousness criteria for asthenia and fatigue; non-serious events of constipation, anal pain, stomachache, flatulence, urinary urgency; bone scintigraphy study, another dosage regime for co-suspect morphine, onset date of mobility decreased, serious event of gait disturbance and another hemoglobin test results. Upon internal review of previous information, it was added start date of fourth regimen and a fifth regimen of abemaciclib. Updated description as reported of mobility decreased, pain in extremity (1st episode) and musculoskeletal chest pain; status of morphine and narrative accordingly with new information.

Update 12-Jul-2024: Additional information was received from initial consumer reporter via PSP on 04-Jul-2024. Added one laboratory test of red blood cell and one dosage regimen of 150 mg with lot number as D689937 to abemaciclib. Updated description as reported for the event serious of anemia, and for one-serious events of fatigue and diarrhea, corresponding fields and narrative with new information.

Update 10-Oct-2024: Additional information was received from initial consumer reporter via PSP on 02-Oct-2024. Added one dosage regimen with batch number 0689937, two non-serious events of pyrexia and headache. Updated the narrative with new information.

Update 21-May-2025: Additional information was received from initial consumer reporter via PSP on 12-May-2025. Added a non-serious event of fatigue (3rd episode). Updated narrative with new information.

Update 29-Aug-2025: Additional information was received from initial consumer reporter via PSP on 19-Aug-2025. Added one serious event of pneumonia via hospitalization as seriousness criteria. Updated the narrative with the new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement		
		low		
2	11-JAN-2024	Blood test		
		Anemia and low defenses (immunosuppression)		
3		Bone scan		
		No results provided.		
4		Haemoglobin	9	
		No units or reference range provided.		
5		Haemoglobin	10.3	
		No units or reference range provided.		
6		Haemoglobin	10.9	
		quite good		
		No units or reference range provided.		
7	15-JUN-2023	Haemoglobin		
		Low (Value, unit and reference range not provided)		
8		Laboratory test		
		Thrombosis ruled out, results came out well (additional information not provided).		
9	15-JUN-2023	Platelet count		

ADDITIONAL INFORMATION**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
Low (Value, unit and reference range not provided)				

10

Red blood cell count

Reduced (Value, unit and reference range not provided)

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	JAN-2024 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #3	100 mg, bid; Oral	Breast cancer (Breast cancer)	FEB-2024 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #4	150 mg, bid; Oral	Breast cancer (Breast cancer)	15-MAR-2024 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #5	150 mg, daily; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D689937; Exp.Dt. MAY-2026}; Regimen #6	150 mg, daily; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # 0689937; Exp.Dt. MAY-2026}; Regimen #7	150 mg, daily; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown
#2) MORPHINE (MORPHINE) Unknown; Regimen #1	UNK UNK, unknown; Unknown	Bone pain (Bone pain) Shoulder pain (Arthralgia) Leg pain (Pain in extremity)	Unknown; Unknown
#2) MORPHINE (MORPHINE) Unknown; Regimen #2	UNK UNK, unknown; Unknown	Bone pain (Bone pain) Shoulder pain (Arthralgia) Leg pain (Pain in extremity)	Ongoing; Unknown
#3) IRON (IRON) Unknown; Regimen #1	UNK, unknown; Unknown	low hemoglobin (Haemoglobin decreased) low platelets (Platelet count decreased) anemic (Anaemia)	Unknown; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#1) MODIFICAL [ONDANSETRON HYDROCHLORIDE] (ONDANSETRON HYDROCHLORIDE) Unknown, 8 mg; Unknown