ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 10/21/2014

ClinicalTrials.gov ID: NCT00448279

Study Identification

Unique Protocol ID:	ML18742
Brief Title:	THOR Study: A Study of Continued Herceptin (Trastuzumab) in Combination With Second Line Chemotherapy in Patients With HER2 Positive Metastatic Breast Cancer.
Official Title:	A Randomized, Open-label Study to Compare Progression-free Survival in Patients With HER2 Positive Metastatic Breast Cancer Who Continue or Discontinue Herceptin in Combination With 2nd Line Chemotherapy, Having Progressed on 1st Line Chemotherapy in Combination With Herceptin
Secondary IDs:	

Study Status

Record Verification:	October 2014
Overall Status:	Completed
Study Start:	April 2007
Primary Completion:	September 2010 [Actual]
Study Completion:	September 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 114/06 Board Name: Universtià degli studi di Napoli Federico II Comitato etico per le attività biomediche Board Affiliation: Unknown Phone: Email: comitato.etico@unina.it
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Italy: Ministry of Health

Study Description

Brief Summary:	This 2 arm study will compare the efficacy and safety of continuation or discontinuation of Herceptin treatment in combination with 2nd line chemotherapy, in patients with HER2 positive metastatic breast cancer whose condition has progressed on 1st line chemotherapy plus Herceptin. Patients will be randomized either to continue or discontinue Herceptin treatment (2mg/kg iv infusion weekly, or 6mg/kg iv infusion every 3 weeks) while receiving 2nd line chemotherapy of the investigator's choice. The anticipated time on study treatment is until disease progression, and the target sample size is 100-500 individuals.
Detailed Description:	

Conditions

Conditions:	Breast Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2

Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	58 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Chemotherapy Alone Chemotherapy, schedule and dose at the investigator’s discretion.	Drug: Chemotherapy Schedule and dose at the investigator's discretion
Experimental: Chemotherapy, Trastuzumab Trastuzumab, at the investigator’s discretion, either 2 milligrams per kilogram (mg/kg) intravenous (i.v.) every 7 days or 6 mg/kg i.v. every 3 weeks. Chemotherapy, schedule and dose at the investigator’s discretion.	Drug: trastuzumab 2mg/kg i.v. weekly, or 6mg/kg i.v. every 3 weeks Other Names: • Herceptin Drug: Chemotherapy Schedule and dose at the investigator's discretion

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Female
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- female patients, >=18 years of age;
- metastatic breast cancer;
- HER2 overexpression (IHC 3+ and/or FISH positive);
- disease progression during or after previous 1st line chemotherapy plus Herceptin;
- scheduled to receive 2nd line chemotherapy.

Exclusion Criteria:

- incompatibility with previous Herceptin therapy;
- pregnancy.

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: Italy
Perugia, Italy, 06122

Meldola, Italy, 47014

Pordenone, Italy, 33170

Rionero in Vulture, Italy, 85028

Torino, Italy, 10125

Candiolo, Italy, 10060

Avellino, Italy, 83100

Sora, Italy, 03039

Sassari, Italy, 07100

Lecce, Italy, 73100

Napoli, Italy, 80131

Mantova, Italy, 46100

Pavia, Italy, 27100

Roma, Italy, 00128

Crotone - Kr, Italy, 88900

Nocera Inferiore, Italy, 84014

Cona (Ferrara), Italy, 44124

Carrara, Italy, 54033

Taormina, Italy, 98030

Potenza, Italy, 85100

Frattaminore, Italy, 80026

Fano, Italy, 61032

Genova, Italy, 16132

Ragusa, Italy, 97100

Padova, Italy, 35128

Sassari, Italy, 07100

Firenze, Italy, 50139

Reggio Calabria, Italy, 89100

Pavia, Italy, 27100

Brescia, Italy, 25123

Cosenza, Italy, 87100

Salerno, Italy, 84131

Napoli, Italy, 80131

San Giovanni Rotondo, Italy, 71013

Palermo, Italy, 90127

Livorno, Italy, 57100

Roma, Italy, 00153

Napoli, Italy, 80131

Udine, Italy, 33100

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy Plus (+) Trastuzumab	Participants received trastuzumab at either 2 milligrams per kilogram (mg/kg), intravenously (IV), every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Overall Study

	Chemotherapy Alone	Chemotherapy Plus (+) Trastuzumab
Started	29	29
Completed	0	0
Not Completed	29	29
Lost to Follow-up	2	2
Adverse Event	1	1
Disease progression	16	18
Withdrawal by Subject	4	3
Not specified	6	4
Protocol Violation	0	1

Baseline Characteristics

Analysis Population Description

Intent-to-treat (ITT) population: all randomized participants.

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Baseline Measures

	Chemotherapy Alone	Chemotherapy + Trastuzumab	Total
Number of Participants	29	29	58
Age, Continuous [units: years] Median (Full Range)	59 (38 to 81)	57 (39 to 82)	58 (38 to 82)
Gender, Male/Female [units: participants]			
Female	29	29	58
Male	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression-Free Survival (PFS) - Percentage of Participants With an Event
Measure Description	PFS was defined as the time from randomization to the date of documented disease progression according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, or the date of occurrence of a second primary cancer, or date of death from any cause, whichever comes first. Participants were censored at the last tumour evaluation.
Time Frame	Baseline (BL) and every 8 weeks thereafter
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Measured Values

	Chemotherapy Alone	Chemotherapy + Trastuzumab
Number of Participants Analyzed	29	29
Progression-Free Survival (PFS) - Percentage of Participants With an Event [units: percentage of participants]	58.6	58.6

2. Primary Outcome Measure:

Measure Title	Progression-Free Survival - Time to Event
Measure Description	The median time from randomization to PFS event. Participants were censored at the last tumour evaluation.
Time Frame	BL and every 8 weeks thereafter
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.

	Description
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Measured Values

	Chemotherapy Alone	Chemotherapy + Trastuzumab
Number of Participants Analyzed	29	29
Progression-Free Survival - Time to Event [units: months] Median (95% Confidence Interval)	9.7 (5.5 to 18.9)	9.4 (6.7 to 12.0)

3. Secondary Outcome Measure:

Measure Title	Overall Survival (OS) - Percentage of Participants With an Event
Measure Description	OS was defined as the time from randomization to the date of death from any cause. Participants were censored at the last contact date at which the participant was known to be alive.
Time Frame	BL and every 8 weeks thereafter
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Measured Values

	Chemotherapy Alone	Chemotherapy + Trastuzumab
Number of Participants Analyzed	29	29
Overall Survival (OS) - Percentage of Participants With an Event [units: percentage of participants]	55.2	34.5

4. Secondary Outcome Measure:

Measure Title	Overall Survival - Time to Event
Measure Description	The median time from randomization to OS event. Participants were censored at the last contact date at which the participant was known to be alive.
Time Frame	BL and every 8 weeks thereafter
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Measured Values

	Chemotherapy Alone	Chemotherapy + Trastuzumab
Number of Participants Analyzed	29	29
Overall Survival - Time to Event [units: months] Median (95% Confidence Interval)	19.1 (17.0 to 32.7)	26.7 (14.0 to NA) [1]

[1] Upper limit of the 95 percent (%) confidence interval (CI) could not be determined as follow-up was too short to observe enough survival events for complete data estimation.

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants by Best Overall Response (BOR)
Measure Description	BOR was defined as the best objective response observed during the treatment period according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Complete response (CR): disappearance of all target lesions (TLs), with any pathological lymph nodes (whether target or non-target) having a reduction in short axis to less than 10 millimeters (mm). Partial response (PR): at least a 30 percent (%) decrease in the sum of diameters of TLs, taking as reference the BL sum diameters. Progressive disease (PD): at least a 20% increase in the sum of diameters of TLs, taking as a reference the smallest sum on study (this included the BL sum if that is the smallest on study). In addition to the relative increase in 20%, the sum must also have demonstrated an absolute increase of at least 5 mm. Stable disease (SD) was defined as neither sufficient shrinkages to qualify for PR, nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study.
Time Frame	BL and every 8 weeks thereafter
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Measured Values

	Chemotherapy Alone	Chemotherapy + Trastuzumab
Number of Participants Analyzed	29	29
Percentage of Participants by Best Overall Response (BOR) [units: percentage of participants]		

	Chemotherapy Alone	Chemotherapy + Trastuzumab
CR	0	10.3
PR	27.6	20.7
SD	24.1	24.1
PD	17.2	13.8
Not Evaluated	31.0	31.0

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Best Overall Response of CR or PR
Measure Description	BOR was defined as the best objective response observed during the treatment period according to RECIST version 1.1. CR: disappearance of all TLs, with any pathological lymph nodes (whether target or non-target) having a reduction in short axis to less than 10 mm. PR: at least a 30% decrease in the sum of diameters of TLs, taking as reference the BL sum diameters. PD: at least a 20% increase in the sum of diameters of TLs, taking as a reference the smallest sum on study (this included the BL sum if that is the smallest on study). In addition to the relative increase in 20%, the sum must also have demonstrated an absolute increase of at least 5 mm. SD: neither sufficient shrinkages to qualify for PR, nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study.
Time Frame	BL and every 8 weeks thereafter
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator’s discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator’s discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Measured Values

	Chemotherapy Alone	Chemotherapy + Trastuzumab
Number of Participants Analyzed	29	29
Percentage of Participants With a Best Overall Response of CR or PR [units: percentage of participants] Number (95% Confidence Interval)	27.6 (12.7 to 47.2)	31.0 (15.3 to 50.8)

Reported Adverse Events

Time Frame	Adverse events (AEs) were recorded throughout the study. Drug-related serious AEs (SAEs) were collected, regardless of the time elapsed from last study treatment administration, even if the study had been closed.
Additional Description	All randomized participants who received at least 1 dose of study treatment were included in the safety evaluation.

Reporting Groups

	Description
Chemotherapy Alone	Participants received chemotherapy until disease progression, unacceptable toxicity, or death; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine.
Chemotherapy + Trastuzumab	Participants received trastuzumab at either 2 mg/kg, IV, every 7 days, or 6 mg/kg, IV, every 3 weeks, per the investigator's discretion. Participants also received chemotherapy; the schedule and dose at the investigator's discretion and per local prescribing guidelines and standard center practice. Allowed chemotherapy regimens included paclitaxel, gemcitabine, platinum compounds, docetaxel, capecitabine, or vinorelbine. Study treatment was administered until disease progression, unacceptable toxicity, or death.

Serious Adverse Events

	Chemotherapy Alone	Chemotherapy + Trastuzumab
	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/26 (15.38%)	1/28 (3.57%)
Blood and lymphatic system disorders		
Febrile neutropenia [A] *	1/26 (3.85%)	0/28 (0%)

	Chemotherapy Alone	Chemotherapy + Trastuzumab
	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal disorders		
Gastric volvulus [B] *	0/26 (0%)	1/28 (3.57%)
General disorders		
General Malaise [B] *	1/26 (3.85%)	0/28 (0%)
Hospitalisation for intrapleuric chemotherapy and thoracentesis [B] *	1/26 (3.85%)	0/28 (0%)
Renal and urinary disorders		
Acute renal failure [B] *	1/26 (3.85%)	0/28 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, SOURCE VOCAB NEEDED
B Term from vocabulary, NCI CTC 3.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Chemotherapy Alone	Chemotherapy + Trastuzumab
	Affected/At Risk (%)	Affected/At Risk (%)
Total	26/26 (100%)	26/28 (92.86%)
Blood and lymphatic system disorders		
Anemia [A] *	5/26 (19.23%)	1/28 (3.57%)
Febrile Neutropenia [A] *	1/26 (3.85%)	0/28 (0%)
Leukopenia [A] *	13/26 (50%)	7/28 (25%)
Neutropenia [A] *	16/26 (61.54%)	9/28 (32.14%)
Cardiac disorders		
Pericardial effusion [A] *	1/26 (3.85%)	0/28 (0%)
Gastrointestinal disorders		
Abdominal cramps [A] *	1/26 (3.85%)	0/28 (0%)

	Chemotherapy Alone	Chemotherapy + Trastuzumab
	Affected/At Risk (%)	Affected/At Risk (%)
Bilateral mandibular pain [A] *	1/26 (3.85%)	0/28 (0%)
Constipation [A] *	1/26 (3.85%)	1/28 (3.57%)
Diarrhea [A] *	2/26 (7.69%)	5/28 (17.86%)
Epigastric pain [A] *	1/26 (3.85%)	1/28 (3.57%)
Gingival [A] *	1/26 (3.85%)	0/28 (0%)
Heartburn [A] *	1/26 (3.85%)	0/28 (0%)
Mucositis [A] *	1/26 (3.85%)	0/28 (0%)
Nausea [A] *	8/26 (30.77%)	1/28 (3.57%)
Sore throat [A] *	1/26 (3.85%)	0/28 (0%)
Vomiting [A] *	5/26 (19.23%)	1/28 (3.57%)
General disorders		
Achy hands and feet [A] *	0/26 (0%)	1/28 (3.57%)
Asthenia [A] *	7/26 (26.92%)	1/28 (3.57%)
Edema [A] *	0/26 (0%)	1/28 (3.57%)
Fatigue [A] *	0/26 (0%)	1/28 (3.57%)
Fever [A] *	5/26 (19.23%)	3/28 (10.71%)
Hand fissures [A] *	1/26 (3.85%)	0/28 (0%)
Other - unspecified [A] *	8/26 (30.77%)	9/28 (32.14%)
Pain [A] *	1/26 (3.85%)	1/28 (3.57%)
Scapular pain [A] *	1/26 (3.85%)	1/28 (3.57%)
Hepatobiliary disorders		
Liver-ALP [A] *	1/26 (3.85%)	1/28 (3.57%)

	Chemotherapy Alone	Chemotherapy + Trastuzumab
	Affected/At Risk (%)	Affected/At Risk (%)
Liver-GOT,GPT [A] *	1/26 (3.85%)	1/28 (3.57%)
Liver-bilirubin [A] *	0/26 (0%)	1/28 (3.57%)
Immune system disorders		
Allergy [A] *	0/26 (0%)	1/28 (3.57%)
Infections and infestations		
Urinary infection [A] *	0/26 (0%)	1/28 (3.57%)
Investigations		
Hypercholesterolemia [A] *	0/26 (0%)	1/28 (3.57%)
Metabolism and nutrition disorders		
Anorexia [A] *	2/26 (7.69%)	0/28 (0%)
Diabetes [A] *	1/26 (3.85%)	0/28 (0%)
Hypocalcemia [A] *	1/26 (3.85%)	0/28 (0%)
Musculoskeletal and connective tissue disorders		
Bone pain [A] *	2/26 (7.69%)	3/28 (10.71%)
Cranial pain [A] *	0/26 (0%)	1/28 (3.57%)
Dorsal spine pain [A] *	1/26 (3.85%)	0/28 (0%)
Pain - Spine [A] *	1/26 (3.85%)	1/28 (3.57%)
Pelvic pain [A] *	1/26 (3.85%)	0/28 (0%)
Plantar foot pain [A] *	1/26 (3.85%)	0/28 (0%)
Right upper limb pain [A] *	0/26 (0%)	1/28 (3.57%)
Nervous system disorders		
Dysgeusia [A] *	2/26 (7.69%)	0/28 (0%)
Headache [A] *	2/26 (7.69%)	0/28 (0%)

	Chemotherapy Alone	Chemotherapy + Trastuzumab
	Affected/At Risk (%)	Affected/At Risk (%)
Memory deficit [A] *	1/26 (3.85%)	0/28 (0%)
Neuro device [A] *	0/26 (0%)	3/28 (10.71%)
Paraesthesia hand and feet [A] *	0/26 (0%)	1/28 (3.57%)
Paresthesia - hand [A] *	1/26 (3.85%)	0/28 (0%)
Vertigo syndrome [A] *	1/26 (3.85%)	0/28 (0%)
Psychiatric disorders		
Anxiety [A] *	0/26 (0%)	2/28 (7.14%)
Decline in mood [A] *	1/26 (3.85%)	0/28 (0%)
Depression [A] *	0/26 (0%)	1/28 (3.57%)
Insomnia [A] *	1/26 (3.85%)	0/28 (0%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] *	1/26 (3.85%)	0/28 (0%)
Dyspnea [A] *	3/26 (11.54%)	0/28 (0%)
Epistaxis [A] *	1/26 (3.85%)	1/28 (3.57%)
Exertional dyspnea [A] *	1/26 (3.85%)	0/28 (0%)
Pleural effusion [A] *	1/26 (3.85%)	0/28 (0%)
Skin and subcutaneous tissue disorders		
Alopecia [A] *	3/26 (11.54%)	3/28 (10.71%)
Cutanea SMP [A] *	1/26 (3.85%)	3/28 (10.71%)
Erythema hand and foot [A] *	1/26 (3.85%)	0/28 (0%)
Vascular disorders		
Hypertension [A] *	0/26 (0%)	2/28 (7.14%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, NCI CTC 3.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

Name/Official Title: Medical Communications
Organization: Hoffman-LaRoche
Phone: 800-821-8590
Email: genentech@druginfo.com