ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 01/02/2013

A Long Term Safety Study of Degarelix in Patients With Prostate Cancer

This study has been completed.

Sponsor:	Ferring Pharmaceuticals
Collaborators:	
Information provided by (Responsible Party):	Ferring Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00967018

Purpose

Patients that completed any of the trials; CS27 (NCT00738673), CS28 (NCT00831233), CS30 (NCT00833248) or CS31 (NCT00884273) will be given the opportunity to receive monthly doses of degarelix until the drug is launched in their country. Safety parameters such as electrocardiogram (ECG), blood and urine samples and general health state will be studied. Note: patients completing the CS27 trial did not participate in the CS34 trial.

Condition	Intervention	Phase
Prostate Cancer	Drug: Degarelix	Phase 3

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety Study
Official Title: A Phase IIIb, Non-randomized, Open-label, Multi-Centre, Follow-on Safety Trial of Monthly Doses of Degarelix in Patients With Prostate Cancer

Further study details as provided by Ferring Pharmaceuticals:

Primary Outcome Measure:

- Number of Participants With Markedly Abnormal Values in Safety Laboratory Variables [Time Frame: Up to 22.5 months] [Designated as safety issue: Yes]
  The figures present the number of participants who had markedly abnormal levels of safety laboratory variables. Only the laboratory variables that had at least one percentage of participants in either group with abnormal value are presented, more variables were included in the study.
- Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [Time Frame: Up to 22.5 months] [Designated as safety issue: Yes]

This outcome measure included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight. The table presents the number of participants with normal baseline and at least one post-baseline markedly abnormal value.

Other Pre-specified Outcome Measures:

- Serum Levels of Prostate Specific Antigen (PSA)Over Time [Time Frame: from baseline to 72 weeks] [Designated as safety issue: No]
  PSA levels were measured over time. The table below shows median levels at baseline (n=77 participants), 24 weeks (n=56), 36 weeks (n=58), 48 weeks (n=48), 72 weeks (n=9)
- Serum Levels of Testosterone Over Time [Time Frame: from baseline to week 72] [Designated as safety issue: No]
  Testosterone levels were measured over time. The table below shows median levels at baseline (n=77 participants), 24 weeks (n=68), 36 weeks (n=59), 48 weeks (n=54), 72 weeks (n=9)

Enrollment: 77
Study Start Date: August 2009
Primary Completion Date: November 2011
Study Completion Date: December 2011

Arms	Assigned Interventions
Experimental: Degarelix The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.	Drug: Degarelix

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Completed any of the trials; FE 200486 CS27, CS28, CS30 or CS31

Exclusion Criteria:

- Discontinued any of the trials: FE 200486 CS27, CS28, CS30 or CS31

Contacts and Locations

Locations

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Investigators

Study Director:	Clinical Development Support	Ferring Pharmaceuticals

More Information

Responsible Party:	Ferring Pharmaceuticals
Study ID Numbers:	FE200486 CS34 EudraCT No: 2008-006827-29
Health Authority:	Sweden: Medical Products Agency Finland: Finnish Medicines Agency Norway: Norwegian Medicines Agency Portugal: National Pharmacy and Medicines Institute Italy: The Italian Medicines Agency Belgium: Federal Agency for Medicinal Products and Health Products Turkey: Ministry of Health Spain: Spanish Agency of Medicines France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Greece: National Organization of Medicines

Study Results

Participant Flow

Recruitment Details	The patients were recruited from 16 sites in Belgium, France, Italy, Spain, Sweden and Turkey. The study was conducted between 31 August 2009 (FPFV) and 29 November 2011 (LPLV).

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Overall Study

	Degarelix
Started	77
Completed	56
Not Completed	21
Adverse Event	2
Physician Decision	7
Lost to Follow-up	2
Withdrawal by Subject	1
Miscellaneous Reasons	9

Baseline Characteristics

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Baseline Measures

	Degarelix
Number of Participants	77

	Degarelix
Age, Continuous [units: years] Mean (Standard Deviation)	71.9 (7.59)
Gender, Male/Female [units: participants]	
Female	0
Male	77
Region of Enrollment [units: participants]	
France	2
Spain	11
Belgium	2
Turkey	14
Italy	35
Sweden	13
Body Mass Index (BMI) [units: kilogram per square meter] Mean (Standard Deviation)	27.2 (4.2)
Gleason Score [1] [units: Participants]	
Gleason Score 2-4	1
Gleason Score 5-6	18
Gleason Score 7-10	58
Stage of Prostate Cancer [2] [units: Participants]	
Localized	36
Locally Advanced	19
Metastatic	15
Not Classifiable	7

[1] The Gleason score is a system of grading the aggressiveness of the prostate cancer and how fast it is likely to grow and spread. Scale is 2-10, with low numbers being the least aggressive and 10 being the most aggressive.

[2] Prostate cancer stage was classified according to the Tumor, Nodes, and Metastatic (TNM) scale to describe the extent of cancer. Localized refers to tumors without involvement of lymph nodes or metastasis. Advanced localized can be larger tumors that may involve the lymph nodes but no metastasis. Metastatic are more advanced cancers that are spreading beyond the original tumor. Some participants did not have their prostate cancer classified for the complete TNM scale (7 participants).

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Markedly Abnormal Values in Safety Laboratory Variables
Measure Description	The figures present the number of participants who had markedly abnormal levels of safety laboratory variables. Only the laboratory variables that had at least one percentage of participants in either group with abnormal value are presented, more variables were included in the study.
Time Frame	Up to 22.5 months
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Measured Values

	Degarelix
Number of Participants Analyzed	77
Number of Participants With Markedly Abnormal Values in Safety Laboratory Variables [units: Participants]	
B-Haematocrit (Ratio) <=0.37	24

	Degarelix
B-Haemoglobin (g/L) <=115	6
B-White blood cell count (10^9/L) <=2.8	2
B-White blood cell count (10^9/L) >=16.0	1
B-Red blood cell count (10^12/L) <=3.5	3
B-Platelet count (10^9/L) <=75	1
S-Aspartate aminotransferase (IU/L) >3xULN	1
S-Potassium (mmol/L) >=5.8	1
S-Urea nitrogen (mmol/L) >=10.7	5

2. Primary Outcome Measure:

Measure Title	Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight
Measure Description	This outcome measure included incidence of markedly abnormal changes in blood pressure (systolic and diastolic), pulse, and body weight. The table presents the number of participants with normal baseline and at least one post-baseline markedly abnormal value.
Time Frame	Up to 22.5 months
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Measured Values

	Degarelix
Number of Participants Analyzed	77
Number of Participants With Markedly Abnormal Values in Vital Signs and Body Weight [units: Participants]	
Diastolic blood pressure <=50 and decrease >=15	1
Diastolic blood pressure >=105 and increase >=15	1
Systolic blood pressure <=90 and decrease >=20	1
Systolic blood pressure >=180 and increase >=20	0
Heart rate <=50 and decrease >=15	0
Heart rate >=120 and increase >=15	1
Body weight decrease of >=7 percent	0
Body weight increase of >=7 percent	2

3. Other Pre-specified Outcome Measure:

Measure Title	Serum Levels of Prostate Specific Antigen (PSA)Over Time
Measure Description	PSA levels were measured over time. The table below shows median levels at baseline (n=77 participants), 24 weeks (n=56), 36 weeks (n=58), 48 weeks (n=48), 72 weeks (n=9)
Time Frame	from baseline to 72 weeks
Safety Issue?	No

Analysis Population Description

The table below shows median levels at baseline (n=77 participants), 24 weeks (n=56), 36 weeks (n=58), 48 weeks (n=48), 72 weeks (n=9)

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Measured Values

	Degarelix
Number of Participants Analyzed	77
Serum Levels of Prostate Specific Antigen (PSA)Over Time [units: ng/mL] Median (Full Range)	
Baseline (0 weeks)	1.4 (0.05 to 431.3)
Week 24	0.75 (0.05 to 58.5)
Week 36	0.6 (0.05 to 508.8)
Week 48	0.55 (0.05 to 606.5)
Week 72	1.9 (0.05 to 168)

4. Other Pre-specified Outcome Measure:

Measure Title	Serum Levels of Testosterone Over Time
Measure Description	Testosterone levels were measured over time. The table below shows median levels at baseline (n=77 participants), 24 weeks (n=68), 36 weeks (n=59), 48 weeks (n=54), 72 weeks (n=9)
Time Frame	from baseline to week 72
Safety Issue?	No

Analysis Population Description

The table below shows median levels at baseline (n=77 participants), 24 weeks (n=68), 36 weeks (n=59), 48 weeks (n=54), 72 weeks (n=9)

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Measured Values

	Degarelix
Number of Participants Analyzed	77
Serum Levels of Testosterone Over Time [units: ng/mL] Median (Full Range)	
Baseline (Week 0)	0.05 (0.05 to 8.07)
Week 24	0.05 (0.05 to 0.54)
Week 36	0.05 (0.05 to 0.26)
Week 48	0.08 (0.05 to 0.62)
Week 72	0.12 (0.05 to 0.22)

Reported Adverse Events

Time Frame	Baseline to end of treatment (maximum exposure to degarelix is approximately 25 months)
Additional Description	Each participant's condition was monitored throughout the trial from the time of signing the informed consent until the end of the follow-up period. The investigator was to record all adverse events (AEs) in the AE log of the participant's Case Report Form.

Reporting Groups

	Description
Degarelix	The degarelix doses were administered into the abdominal wall every 28 days. For patients treated with goserelin in the previous trials (CS28, CS30 and CS31),a starting dose of 240 mg (40 mg/mL) degarelix was administered on Day 0 as two 3 mL subcutaneous (s.c.) injections. The subsequent maintenance of 80 mg (20 mg/mL) degarelix were administered as single 4 mL s.c. injections at 28 day intervals from day 28 to the end of the trial. For patients treated with degarelix in the previous trials, maintenance doses of 80 mg (20 mg/mL) degarelix were continued and were administered as single 4 mL s.c. injections at 28 day intervals to the end of the trial.

Serious Adverse Events

	Degarelix
	Affected/At Risk (%)
Total	5/77 (6.49%)
Blood and lymphatic system disorders	
Thrombocytopenia [A] †	1/77 (1.3%)
Eye disorders	
Vitreous haemorrhage [A] †	1/77 (1.3%)
General disorders	
Chest pain [A] †	1/77 (1.3%)
Infections and infestations	
Gastroenteritis [A] †	1/77 (1.3%)
Nervous system disorders	
Convulsion [A] †	1/77 (1.3%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Degarelix
	Affected/At Risk (%)
Total	30/77 (38.96%)

	Degarelix
	Affected/At Risk (%)
Gastrointestinal disorders	
Haematochezia [A] †	2/77 (2.6%)
Rectal tenesmus [A] †	2/77 (2.6%)
General disorders	
Chest pain [A] †	2/77 (2.6%)
Chills [A] †	4/77 (5.19%)
Injection site inflammation [A] †	7/77 (9.09%)
Injection site pain [A] †	4/77 (5.19%)
Infections and infestations	
Gastroenteritis [A] †	2/77 (2.6%)
Influenza [A] †	6/77 (7.79%)
Viral upper respiratory tract [A] †	2/77 (2.6%)
Musculoskeletal and connective tissue disorders	
Back pain [A] †	2/77 (2.6%)
Musculoskeletal pain [A] †	4/77 (5.19%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Prostate cancer [A] †	2/77 (2.6%)
Nervous system disorders	
Dizziness [A] †	2/77 (2.6%)
Syncope [A] †	2/77 (2.6%)
Vascular disorders	
Hot flush [A] †	2/77 (2.6%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

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 only disclosure restriction on the PI is that the sponsor can review the draft manuscript prior to publication and can request delay of publication where any contents are deemed patentable by the sponsor or confidential to the sponsor. Comments will be given within four weeks from receipt of the draft manuscript. Additional time may be required to allow Ferring to seek patent protection of the invention.

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