TITLE PAGE

RESEARCH REPORT NO. 1054959

Clinical Study Report - NC25608 - A phase 3b, multi-center, double-blind, placebo-controlled, parallel group, study to evaluate the effect of dalcetrapib 600 mg on cardiovascular (CV) events in adult patients with stable coronary heart disease (CHD), CHD risk equivalents or at elevated risk for cardiovascular disease (CVD).
Report 1054959, January 2013.

This report is presented in a synopsis format due to termination of the study following the Sponsor's decision to discontinue the clinical development program.

Date of Report:	January 2013
Study Sponsor(s)	F. Hoffmann-La Roche Ltd.
Study Dates:	January 19, 2012 (first informed consent) to July 18, 2012 (last patient contact).
Trial Phase:	IIIb
Indication:	
Name of Principal Investigator:	**Affiliation:**
Dr. [redacted]	[redacted] USA
Sponsor's Signatory:	[redacted]

Personnel Responsible for Clinical and Statistical Analyses:

[redacted]	Clinical Science
[redacted]	Statistics

GCP Compliance: This study was conducted in accordance with the principles of GCP

Overall Table of Contents

Table of Contents - Core Report

List of Supporting Data Presentations

SYNOPSIS OF RESEARCH REPORT 1054959 (PROTOCOL NC25608)

COMPANY: NAME OF FINISHED PRODUCT: NAME OF ACTIVE SUBSTANCE(S):	(FOR NATIONAL AUTHORITY USE ONLY)

TITLE OF THE STUDY / REPORT No. / DATE OF REPORT	A phase 3b, multi-center, double-blind, placebo-controlled, parallel group, study to evaluate the effect of dalcetrapib 600 mg on cardiovascular (CV) events in adult patients with stable coronary heart disease (CHD), CHD risk equivalents or at elevated risk for cardiovascular disease (CVD). Report 1054959, January 2013. Synopsis format report due to no further clinical development of dalcetrapib.		
INVESTIGATORS / CENTERS AND COUNTRIES	United States (111 centers), Canada (22), Mexico (17), Netherlands (12), Denmark (4), Hungary (4), Poland (2), Spain (2),		
PUBLICATION (REFERENCE)	NA		
PERIOD OF TRIAL	January 19, 2012 (first informed consent) to July 18, 2012 (last patient contact).	CLINICAL PHASE	IIIb
OBJECTIVES	The primary objective was to evaluate the potential of dalcetrapib to reduce CV morbidity and mortality in adult patients with stable CHD, CHD risk equivalents or at elevated risk for CVD. Secondary objectives of this study were: • Assessment of long term safety and tolerability of dalcetrapib. • Evaluation of the effect of dalcetrapib on lipid markers and biomarkers of CV risk.		
STUDY DESIGN	This was a randomized, double-blind, placebo-controlled, parallel group, multicenter study in adult patients with stable CHD, CHD risk equivalents or at elevated risk for CVD. Eligible patients were randomized in a 1:1 ratio to 600 mg dalcetrapib or matching placebo. Patients received dalcetrapib on a background of contemporary, guidelines-based medical care for patients with stable CHD, CHD risk equivalents or at elevated risk for CVD. It was intended that patients would visit the clinic one and 6 months after randomization and every 6 months thereafter until completion of the trial. Patients were to be contacted by phone 3 months after randomization. Patients prematurely discontinuing study treatment were to be followed up by adhering to the visit schedule or were contacted by phone every 6 months until the end of the		

	study to assess occurrence of CV events/vital status. In case of premature discontinuation of study treatment patients were allowed and encouraged to restart study treatment if appropriate. The trial was scheduled to last until approximately 1,250 patients had experienced a primary endpoint event, which was anticipated to occur approximately 4 to 5 years after the first patient had been randomized. A phone safety follow-up visit was planned 4 weeks after the end of study treatment. Three interim analyses of efficacy were planned when approximately 600, 850 and 1050 patients were anticipated to have experienced a primary endpoint event that had been positively adjudicated. The end of the study was defined as the date of the last patient visit of the last patient to complete the study, or the date at which the last data point, which was required for statistical analysis, was received, whichever was the later date.
NUMBER OF SUBJECTS	Approximately 20,000 patients (about 10,000 per treatment arm) were planned to be enrolled over an anticipated recruitment period of approximately 1½ years. Enrollment of patients qualifying on the sole basis of "3 or more risk factors for CVD" was to be limited to a maximum of 4,000 patients.
DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION	The target patient population comprised male and female patients ≥45 years of age with stable CHD, CHD risk equivalents or at elevated risk for CVD. Patients were categorized according to type of CV risk factors as follows: **Patients with established CVD** A. Stable coronary heart disease (CHD) B. Cerebrovascular disease C. Peripheral arterial disease (PAD) **Patients without established CVD** D. Patients with pharmacologically treated type 2 diabetes (T2D) and one or more additional risk factor for CVD: • Age ≥70 years. • History of type 2 diabetes ≥15 years. • Estimated glomerular filtration rate (eGFR ≥ 30 and ≤ 60 mL/min/1.73m^2 using the Modification of Diet in Renal Disease (MDRD) formula within 1 year prior to randomization. • Albuminuria defined as spot urine albumin to creatinine ratio (ACR) ≥30 µg albumin/mg creatinine within 1 year prior to randomization. E. Patients with 3 or more of the following risk factors for CVD but without T2D: • HDL-C < 40 mg/dL (1.03 mmol/L) for men; < 50 mg/dL (1.29 mmol/L) for women within 1 year prior to randomization. • Waist circumference ≥ 94 cm (men) ≥ 80 cm (women); ≥ 90 cm (men) ≥ 80 cm (women) for Asians and

	patients of Asian descent within 1 year prior to randomization. • Hypertension: persistent elevated systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg despite treatment for hypertension. • Family history of premature CHD (symptomatic CHD in male first degree relative < 55 years or in female first degree relative < 65 years. Symptomatic CHD defined as myocardial infarction or coronary revascularization). • Albuminuria defined as spot urine ACR ≥ 30 μg albumin /mg creatinine within 1 year prior to randomization. • eGFR ≥ 30 and ≤ 60 mL/min/1.73m^2 using the MDRD formula within 1 year prior to randomization. • Current cigarette smoking. Definitions of the risk categories and full details of inclusion and exclusion criteria are provided in the protocol (page 178).
TRIAL DRUG / STROKE (BATCH) No.	Dalcetrapib was provided as 300 mg film-coated tablets.
DOSE / ROUTE / REGIMEN / DURATION	600 mg (2 x 300 mg tablets) of dalcetrapib once daily, with food.
REFERENCE DRUG / STROKE (BATCH) No.	The placebo was identical in appearance to the active drug.
DOSE / ROUTE / REGIMEN / DURATION	Two matching placebo tablets once daily, with food. Dosing was scheduled as for active medication.
CRITERIA FOR EVALUATION	
EFFICACY:	The primary efficacy endpoint was the time to first occurrence of any component of the composite endpoint; including: • Coronary heart disease death. • Non-fatal myocardial infarction (MI). • Fatal and non-fatal stroke of ischemic origin. Secondary efficacy assessments, secondary laboratory efficacy assessments and tertiary efficacy assessments are described in the protocol (page 190). Due to premature termination of the study no statistical evaluation of efficacy parameters has been carried out.
PHARMACODYNAMICS:	Blood samples were to be collected according to the schedule of assessments for biomarker research purposes. No bioanalysis of these samples has been done.

SAFETY:	Adverse events (AEs) (serious and non-serious) reported by the patient or observed by the investigator or designated medically qualified study site personnel were collected after the first dose of study medication and up to 4 weeks after last dose. CV events described in Section 5.6 of the protocol (page 189) and deaths were not reported as serious adverse events (SAEs) but were reported on dedicated CV event/death endpoint form and made available for adjudication and review. Vital signs (blood pressure and heart rate) were measured at all clinic visits. Data are not reported in this CSR. Physical examination was conducted at baseline and end of trial (EOT) visits. Data are not reported in this CSR. Waist circumference was measured at baseline and EOT visits. Data are not reported in this CSR. Safety laboratory assessments (serum chemistry and hematology) were conducted according to the schedule of assessments. Details of the laboratory parameters assessed are provided in the protocol on page 192.
STATISTICAL METHODS	A non-stratified Cox proportional hazards regression analysis was planned for the primary analysis. However, due to termination of the study by the Sponsor no statistical evaluations were performed. All patients randomized to either of the 2 treatment arms and receiving at least one dose of study medication (dalcetrapib or placebo) were included in the safety analysis population (SAP). Adverse events were grouped by system organ class (SOC) as defined by the Medical Dictionary for Regulatory Activities (MedDRA) (version 15), following classification of investigator assessments into MedDRA preferred terms. A glossary of preferred terms is provided on page 248.

METHODOLOGY

The investigator ensured that the study was conducted in accordance with the principles of the Declaration of Helsinki or with the laws and regulations of the country in which the research was conducted, whichever afforded the greater protection to the individual. Written informed consent was obtained from each patient before they participated in the study. Documented approval of the protocol was obtained from an independent ethics committee (IEC)/independent review board (IRB) before starting the study.

Full details of the study assessments and procedures are provided in the study protocol (page 184).

Patients who had provided written informed consent were assessed for eligibility to enter the study. Patients fulfilling all inclusion and none of the exclusion criteria were randomized to dalcetrapib or placebo using an Interactive Voice Response System (IVRS)/ Interactive Web Response System (IWRS). Baseline assessments included physical examination, vital signs, blood samples for fasting lipid profile, serum chemistry, hematology and biomarkers. A beta human chorionic gonadotropin (β-hCG) pregnancy test was done for women of childbearing potential. Information on medical history, demographics and concomitant medication was collected.

Patients were given a supply of study drug (double-blinded placebo or dalcetrapib) and received instructions on how to take the study drug (see protocol page 193).

Patients were to visit the clinic 1 and 6 months after randomization and every 6 months thereafter until completion of the trial. At each visit, information on concomitant medications, vital signs and AEs/CV events/vital status were to be collected. Blood samples were to be taken for serum chemistry at Visit 2 (1 month), Visit 4 (6 months), Visit 5 (12 months), Visit 7 (24 months) and Visit 9 (36 months) and for lipid profile and biomarkers at Visit 5. Visit 3 (3 months) was to be a telephone contact to obtain information on AEs/CV events/vital status.

Patients were to be given new supply of study drug (double-blinded placebo or dalcetrapib) at each clinic visit (except V2 – 1 month).

Patients were scheduled to be followed until approximately 1250 patients were anticipated to have experienced a primary endpoint event. An EOT visit was to be carried out no later than 4 weeks after notification by the Sponsor.

A safety follow-up visit was to be conducted by telephone for all patients 4 weeks after the EOT visit.

STUDY POPULATION

Disposition of Patients

A total of 2208 patients were randomized in to the study; 1103 patients were randomized to dalcetrapib 600 mg and 1105 patients were randomized to matching placebo. The study was terminated before any patient reached Visit 4 (6 months).

Premature Withdrawals

Withdrawals from study treatment are listed on page 67 . AEs leading to withdrawal from study treatment occurred in 26 dalcetrapib patients (2.4%) and 23 placebo patients (2.1%) (Table 1).

Analysis Populations

The safety analysis population (SAP) comprised 2196 patients. Five patients randomized to dalcetrapib and 7 patients randomized to placebo were excluded from the safety population as they received no study medication (page 11). For the safety evaluation, patients were analyzed according to the treatment received and not according to randomization. Hence, the SAP includes 1106 patients in the dalcetrapib group and 1090 patients in the placebo group due to 8 patients randomized to placebo being dispensed with dalcetrapib at one or more of their study visits.

Demographic Data and Baseline Characteristics

The 2 groups were similar with respect to age, gender, ethnicity, race and weight (page 12).

The profile of risk factors was similar in the 2 treatment groups and most patients were in CHD category A (67% in both treatment groups) Sixteen percent of patients in each treatment group were in CHD category D and 11% of dalcetrapib patients and 10% of placebo patients were in CHD category B (page 13).

The profile of baseline concomitant medication use was similar in the 2 groups. The majority of patients were on statin therapy. ACE inhibitors were being taken by 44.7% of dalcetrapib patients and 48.3% of placebo patients, beta blockers by 64.4% and 62.3%, aspirin by 78.8% and 78.1%, anti-platelet P2Y12 inhibitors by 29.1% and 32.8%, oral diabetic medication by 39.5% and 37.4%, and ezetimibe by 10.6% and 10.4% of dalcetrapib and placebo patients, respectively (page 14).

RESULTS

Efficacy

No statistical analysis of efficacy has been carried out. Overall, the incidence of investigator-reported CV events was similar in the 2 treatment groups. Note that the data presented in these listings have not been adjudicated. Data are listed from page 133 to page 145. These events were not reported as SAEs.

In the dalcetrapib group, median value of HDL-C showed an increase from baseline (1.09 mmol/L) to EOT (1.22 mmol/L) and TC increased from 3.80 mmol/L to 4.01 mmol/L. There was no change in the placebo group between baseline and EOT (1.11 and 1.09 for HDL-C, 3.90 and 3.86 for TC). Little change was observed in other lipid parameters from baseline to end of treatment (page 15). Due to the early study termination and consequently the discontinuation

of many patients from treatment, the increase in median HDL-C of 12% for patients assigned to dalcetrapib therapy was modest compared to the rest of the program.

Safety

The AE profile is summarized in Table 1.

Table 1 Adverse Events Profile

Adverse events profile table
Population: Safety Analysis Population

	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Total number of patients with at least one adverse event	230 (20.8%)	212 (19.4%)
Total number of events	331	321
Total number of patients with at least one		
Serious AE	16 (1.4%)	25 (2.3%)
Serious AE leading to withdrawal from treatment	2 (0.2%)	3 (0.3%)
Serious AE leading to dose modification/interruption	5 (0.5%)	9 (0.8%)
AE leading to withdrawal from treatment	26 (2.4%)	23 (2.1%)
AE leading to dose modification/interruption	25 (2.3%)	18 (1.7%)

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae01_SE.out
02OCT2012 15:32 Page 1 of 1

In the dalcetrapib 600 mg group, 331 AEs were reported in 230 patients and in the placebo group 321 events were reported in 212 patients. The most frequently reported events were in the Gastrointestinal Disorders system order class (SOC) and more patients in the dalcetrapib 600 mg group than in the placebo group reported AEs in this class (7.0% versus 4.3%) (page 22 , page 34). This difference was apparently due to the incidence of diarrhea (49 patients [4.4%] and 22 patients [2.0%] in the 2 treatment groups, respectively). In the Infections and Infestations SOC, 42 patients (3.8%) in the dalcetrapib group and 49 patients (4.5%) in the placebo group reported AEs including bronchitis (8 and 4 patients, respectively), upper respiratory tract infection (3 and 7 patients), nasopharyngitis (4 and 4 patients), urinary tract infection (4 and 3 patients) and pneumonia (1 and 5 patients).

No deaths were reported during the study.

SAEs were reported for 16 patients (1.4%) in the dalcetrapib 600 mg group and 25 patients (2.3%) in the placebo group (page 30). None of these were considered by the investigator to have been caused by study drug. SAEs were most frequently reported in the Infections and Infestations SOC but these involved less than 1% of patients in each treatment group. In the dalcetrapib group SAEs in this SOC were pneumonia (1 patient), appendicitis (1), gastroenteritis viral (1), localized infection (2), bronchitis (1), labyrinthitis (1), lower respiratory tract infection (1), sialoadenitis (1). In the placebo group SAEs in this SOC were pneumonia (4 patients), appendicitis (1), gastroenteritis viral (1), candidiasis (1), gastroenteritis (1), influenza (1), Ludwig angina (1). Three malignancies were reported, all of which occurred in the placebo group (colon cancer, malignant melanoma, rectal cancer).

In the dalcetrapib 600 mg group, 26 patients (2.4%) withdrew from study treatment due to AEs and 25 patients (2.3%) experienced AEs leading to dose modification or interruption. Corresponding figures for the placebo group were 23 patients (2.1%) and 18 patients (1.7%) (Table 1).

No clinically significant laboratory abnormalities were reported. One patient in the dalcetrapib group had alkaline phosphatase > x3 upper limit of normal (ULN), and one patient in each group had creatine kinase > x5 ULN; both were asymptomatic.

CONCLUSIONS

- Incidence and nature of AEs and SAEs were similar in the dalcetrapib and placebo groups.
- Incidence of AEs leading to discontinuation was similar in the 2 treatment groups.
- Incidence of CV events identified as study endpoints were comparable in the dalcetrapib and placebo groups.
- There were no clinically relevant laboratory abnormalities.

Summary of Analysis Populations by Trial Treatment

Analysis Population Reasons for Exclusion	DALCETRAPIB 600MG (N=1103)	PLACEBO (N=1105)
Randomized Patients		
n	1103 (100.0%)	1105 (100.0%)
Safety-Evaluable Patients (SE)		
n	1098 (99.5%)	1098 (99.4%)
Exclusions	5 (0.5%)	7 (0.6%)
No Study medication intake	5 (0.5%)	7 (0.6%)

Percentages are based on N

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stapt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stapt01.out
17SEP2012 16:34

Demography
Population: Safety Analysis Population

	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Age (yr)		
n	1106	1090
Mean (SD)	66.6 (8.9)	66.3 (9.1)
Median	67.0	67.0
Min - Max	45 - 91	45 - 90
Age group (yr)		
n	1106	1090
< 65	430 (38.9%)	428 (39.3%)
>= 65	676 (61.1%)	662 (60.7%)
Sex		
n	1106	1090
Male	801 (72.4%)	790 (72.5%)
Female	305 (27.6%)	300 (27.5%)
Ethnicity		
n	1106	1090
Hispanic or Latino	210 (19.0%)	190 (17.4%)
Not Hispanic or Latino	896 (81.0%)	900 (82.6%)
Race		
n	1106	1090
American Indian or Alaska Native	34 (3.1%)	31 (2.8%)
Asian	9 (0.8%)	12 (1.1%)
Black or African American	56 (5.1%)	74 (6.8%)
White	1000 (90.4%)	963 (88.3%)
Other	3 (0.3%)	5 (0.5%)
Unknown	4 (0.4%)	5 (0.5%)
Weight (kg) at baseline		
n	1105	1089
Mean (SD)	97.67 (277.84)	88.71 (19.23)
Median	88.00	87.73
Min - Max	45.3 - 9303.0	38.6 - 187.3

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stdm01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stdm01_SE.out
17SEP2012 16:03

Summary of CHD Categories by trial treatment
Population: Safety Analysis Population

	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
CHD Category		
A	745 (67.4%)	734 (67.3%)
B	120 (10.8%)	110 (10.1%)
C	24 (2.2%)	27 (2.5%)
D	175 (15.8%)	172 (15.8%)
E	42 (3.8%)	47 (4.3%)
Missing	0	0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stchd.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stchd_SE.out
16JAN2013 12:22 Page 1 of 1

Summary of baseline concomitant medication use
Population: Safety Analysis Population

	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Number of patients		
STATIN THERAPY, ATORVASTATIN	320 (28.9%)	343 (31.5%)
STATIN THERAPY, FLUVASTATIN	2 (0.2%)	3 (0.3%)
STATIN THERAPY, LOVASTATIN	25 (2.3%)	27 (2.5%)
STATIN THERAPY, PITAVASTATIN	7 (0.6%)	5 (0.5%)
STATIN THERAPY, PRAVASTATIN	114 (10.3%)	131 (12.0%)
STATIN THERAPY, ROSUVASTATIN	249 (22.5%)	213 (19.5%)
STATIN THERAPY, SIMVASTATIN	304 (27.5%)	293 (26.9%)
EZETIMIBE	117 (10.6%)	113 (10.4%)
FISH OIL	220 (19.9%)	230 (21.1%)
ACE INHIBITOR	494 (44.7%)	526 (48.3%)
ANGIOTENSIN RECEPTOR BLOCKERS	313 (28.3%)	280 (25.7%)
BETA BLOCKERS	712 (64.4%)	679 (62.3%)
ALDOSTERONE RECEPTOR BLOCKERS	50 (4.5%)	35 (3.2%)
CALCIUM CHANNEL BLOCKERS	263 (23.8%)	277 (25.4%)
ORAL DIURETIC	374 (33.8%)	342 (31.4%)
NITRATES, ORAL OR TOPICAL (DAILY USE)	159 (14.4%)	132 (12.1%)
ASPIRIN	872 (78.8%)	851 (78.1%)
ANTI-PLATELET P2Y12 INHIBITORS	322 (29.1%)	358 (32.8%)
LOW MOLECULAR WEIGHT HEPARIN	1 (<0.1%)	0
VITAMIN K ANTAGONISTS (VKA)	76 (6.9%)	56 (5.1%)
FACTOR XA INHIBITORS	17 (1.5%)	14 (1.3%)
INSULIN	172 (15.6%)	146 (13.4%)
ORAL DIABETES MEDICATION	437 (39.5%)	408 (37.4%)
NON-ORAL DIABETES MEDICATION, OTHER THAN INSULIN	22 (2.0%)	28 (2.6%)
ANTI-DEPRESSANTS	132 (11.9%)	133 (12.2%)

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stcm01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stcm01_SE.out
17SEP2012 16:04 Page 1 of 1

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:Apolipoprotein AI(g/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Day 1		
n	1104	1088
Mean (SD)	1.40 (0.25)	1.40 (0.24)
Median	1.37	1.38
Min - Max	0.8 - 2.8	0.4 - 2.4
Unscheduled		
n	2	2
Mean (SD)	1.53 (0.07)	1.05 (0.05)
Median	1.53	1.05
Min - Max	1.5 - 1.6	1.0 - 1.1
End Of Treatment		
n	741	711
Mean (SD)	1.46 (0.27)	1.38 (0.24)
Median	1.42	1.36
Min - Max	0.7 - 2.7	0.7 - 2.4

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:Apolipoprotein B(g/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Day 1		
n	1104	1088
Mean (SD)	0.80 (0.22)	0.79 (0.21)
Median	0.77	0.77
Min - Max	0.3 - 2.3	0.3 - 2.1
Unscheduled		
n	2	2
Mean (SD)	0.69 (0.01)	0.71 (0.05)
Median	0.69	0.71
Min - Max	0.7 - 0.7	0.7 - 0.7
End Of Treatment		
n	741	711
Mean (SD)	0.80 (0.23)	0.79 (0.21)
Median	0.78	0.76
Min - Max	0.3 - 2.7	0.3 - 1.8

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:Cholesterol(mmol/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Baseline		
n	705	671
Mean (SD)	3.93 (0.92)	3.98 (0.89)
Median	3.80	3.90
Min - Max	2.1 - 11.5	1.8 - 7.9
Day 1		
n	1087	1071
Mean (SD)	3.99 (0.91)	3.98 (0.91)
Median	3.89	3.86
Min - Max	2.0 - 12.7	2.0 - 10.1
Unscheduled		
n	2	2
Mean (SD)	3.79 (0.22)	3.10 (0.05)
Median	3.79	3.10
Min - Max	3.6 - 3.9	3.1 - 3.1
End Of Treatment		
n	742	712
Mean (SD)	4.15 (0.97)	3.97 (0.89)
Median	4.01	3.86
Min - Max	1.8 - 11.1	2.2 - 9.5

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:C Reactive Protein(mg/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Baseline		
n	78	88
Mean (SD)	4.03 (7.17)	5.84 (15.56)
Median	1.36	1.75
Min - Max	0.0 - 49.2	0.1 - 134.0
Month 1		
n	21	37
Mean (SD)	3.41 (3.76)	8.74 (30.23)
Median	2.70	1.50
Min - Max	0.0 - 13.4	0.0 - 179.7
Month 6		
n	0	1
Mean (SD)	NE (NE)	16.00 (NE)
Median	NE	16.00
Min - Max	NE - NE	16.0 - 16.0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:HDL Cholesterol(mmol/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Baseline		
n	722	686
Mean (SD)	1.18 (1.42)	1.15 (0.34)
Median	1.09	1.11
Min - Max	0.1 - 38.0	0.1 - 2.9
Day 1		
n	1089	1073
Mean (SD)	1.16 (0.34)	1.17 (0.34)
Median	1.09	1.11
Min - Max	0.5 - 3.1	0.2 - 3.0
Unscheduled		
n	2	2
Mean (SD)	1.44 (0.28)	0.73 (0.00)
Median	1.44	0.73
Min - Max	1.2 - 1.6	0.7 - 0.7
End Of Treatment		
n	742	711
Mean (SD)	1.29 (0.43)	1.14 (0.32)
Median	1.22	1.09
Min - Max	0.4 - 4.1	0.4 - 3.0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:LDL Cholesterol(mmol/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Baseline		
n	888	860
Mean (SD)	2.04 (0.70)	2.07 (0.69)
Median	1.97	2.00
Min - Max	0.1 - 8.5	0.3 - 5.8
Day 1		
n	935	912
Mean (SD)	2.13 (0.77)	2.12 (0.77)
Median	2.02	2.02
Min - Max	0.4 - 10.3	0.1 - 8.3
Unscheduled		
n	2	2
Mean (SD)	1.65 (0.23)	1.40 (0.22)
Median	1.65	1.40
Min - Max	1.5 - 1.8	1.2 - 1.6
End Of Treatment		
n	741	711
Mean (SD)	2.07 (0.78)	2.08 (0.75)
Median	1.97	1.94
Min - Max	0.3 - 9.0	0.3 - 7.2

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

Summary of lipids data by trial treatment
Population: Safety Analysis Population

Parameter:Triglycerides(mmol/L)

Visit	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Baseline		
n	942	913
Mean (SD)	1.60 (0.80)	1.77 (5.10)
Median	1.46	1.46
Min - Max	0.0 - 8.4	0.3 - 154.0
Day 1		
n	881	857
Mean (SD)	1.58 (0.79)	1.55 (0.84)
Median	1.41	1.38
Min - Max	0.4 - 6.3	0.4 - 8.4
Unscheduled		
n	2	2
Mean (SD)	1.54 (0.62)	2.12 (0.62)
Median	1.54	2.12
Min - Max	1.1 - 2.0	1.7 - 2.6
End Of Treatment		
n	742	712
Mean (SD)	1.76 (1.09)	1.64 (0.83)
Median	1.48	1.47
Min - Max	0.4 - 12.8	0.5 - 9.1

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/lbt01.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/lbt01_SE.out
25OCT2012 14:47

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Total number of patients with at least one adverse event	230 (20.8%)	212 (19.4%)
Overall total number of events	331	321
Gastrointestinal disorders		
Total number of patients with at least one adverse event	77 (7.0%)	47 (4.3%)
Total number of events	94	56
Diarrhoea	49 (4.4%)	22 (2.0%)
Nausea	4 (0.4%)	6 (0.6%)
Dyspepsia	4 (0.4%)	4 (0.4%)
Abdominal pain	5 (0.5%)	1 (<0.1%)
Abdominal distension	4 (0.4%)	1 (<0.1%)
Constipation	1 (<0.1%)	4 (0.4%)
Gastritis	3 (0.3%)	2 (0.2%)
Gastrooesophageal reflux disease	2 (0.2%)	3 (0.3%)
Flatulence	3 (0.3%)	1 (<0.1%)
Vomiting	3 (0.3%)	0
Abdominal pain upper	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorder	1 (<0.1%)	1 (<0.1%)
Abdominal discomfort	1 (<0.1%)	0
Abnormal faeces	1 (<0.1%)	0
Breath odour	1 (<0.1%)	0
Defaecation urgency	0	1 (<0.1%)
Diverticulum	1 (<0.1%)	0
Dry mouth	0	1 (<0.1%)
Duodenal ulcer haemorrhage	0	1 (<0.1%)
Epigastric discomfort	1 (<0.1%)	0
Faecal incontinence	0	1 (<0.1%)
Faeces hard	1 (<0.1%)	0
Frequent bowel movements	0	1 (<0.1%)
Functional gastrointestinal disorder	1 (<0.1%)	0
Haemorrhoidal haemorrhage	0	1 (<0.1%)
Hiatus hernia	0	1 (<0.1%)
Irritable bowel syndrome	0	1 (<0.1%)
Lip dry	1 (<0.1%)	0
Oesophagitis	0	1 (<0.1%)
Pancreatitis acute	1 (<0.1%)	0
Rectal haemorrhage	1 (<0.1%)	0
Small intestinal obstruction	0	1 (<0.1%)
Swollen tongue	1 (<0.1%)	0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28 Page 1 of 8

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Infections and infestations		
Total number of patients with at least one adverse event	42 (3.8%)	49 (4.5%)
Total number of events	46	52
Bronchitis	8 (0.7%)	4 (0.4%)
Upper respiratory tract infection	3 (0.3%)	7 (0.6%)
Nasopharyngitis	4 (0.4%)	4 (0.4%)
Urinary tract infection	4 (0.4%)	3 (0.3%)
Pneumonia	1 (<0.1%)	5 (0.5%)
Sinusitis	3 (0.3%)	2 (0.2%)
Gastroenteritis	2 (0.2%)	2 (0.2%)
Gastroenteritis viral	1 (<0.1%)	3 (0.3%)
Candidiasis	1 (<0.1%)	2 (0.2%)
Influenza	1 (<0.1%)	2 (0.2%)
Localised infection	3 (0.3%)	0
Pharyngitis	1 (<0.1%)	2 (0.2%)
Appendicitis	1 (<0.1%)	1 (<0.1%)
Cellulitis	0	2 (0.2%)
Herpes zoster	1 (<0.1%)	1 (<0.1%)
Diverticulitis	1 (<0.1%)	0
Ear infection	0	1 (<0.1%)
Eye infection	1 (<0.1%)	0
Gastroenteritis bacterial	0	1 (<0.1%)
Gingival infection	0	1 (<0.1%)
Herpes simplex	1 (<0.1%)	0
Infected dermal cyst	1 (<0.1%)	0
Infected skin ulcer	0	1 (<0.1%)
Infective exacerbation of chronic obstructive airways disease	0	1 (<0.1%)
Labyrinthitis	1 (<0.1%)	0
Lower respiratory tract infection	1 (<0.1%)	0
Ludwig angina	0	1 (<0.1%)
Onychomycosis	1 (<0.1%)	0
Orchitis	1 (<0.1%)	0
Otitis media	0	1 (<0.1%)
Otitis media acute	1 (<0.1%)	0
Pneumonia primary atypical	0	1 (<0.1%)
Rhinitis	0	1 (<0.1%)
Sialoadenitis	1 (<0.1%)	0
Subcutaneous abscess	0	1 (<0.1%)
Tinea infection	0	1 (<0.1%)
Tooth abscess	1 (<0.1%)	0
Tooth infection	1 (<0.1%)	0

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Musculoskeletal and connective tissue disorders		
Total number of patients with at least one adverse event	31 (2.8%)	31 (2.8%)
Total number of events	34	35
Myalgia	6 (0.5%)	6 (0.6%)
Back pain	6 (0.5%)	4 (0.4%)
Muscle spasms	5 (0.5%)	5 (0.5%)
Arthralgia	4 (0.4%)	3 (0.3%)
Pain in extremity	2 (0.2%)	4 (0.4%)
Musculoskeletal chest pain	2 (0.2%)	3 (0.3%)
Musculoskeletal pain	4 (0.4%)	1 (<0.1%)
Neck pain	2 (0.2%)	1 (<0.1%)
Groin pain	1 (<0.1%)	1 (<0.1%)
Musculoskeletal discomfort	0	2 (0.2%)
Tendonitis	2 (0.2%)	0
Arthropathy	0	1 (<0.1%)
Flank pain	0	1 (<0.1%)
Muscular weakness	0	1 (<0.1%)
Synovial cyst	0	1 (<0.1%)
Trismus	0	1 (<0.1%)
Nervous system disorders		
Total number of patients with at least one adverse event	28 (2.5%)	28 (2.6%)
Total number of events	33	29
Headache	14 (1.3%)	8 (0.7%)
Dizziness	7 (0.6%)	10 (0.9%)
Hypoaesthesia	2 (0.2%)	1 (<0.1%)
Sciatica	1 (<0.1%)	2 (0.2%)
Dysgeusia	1 (<0.1%)	1 (<0.1%)
Somnolence	1 (<0.1%)	1 (<0.1%)
Syncope	1 (<0.1%)	1 (<0.1%)
Ageusia	0	1 (<0.1%)
Burning sensation	1 (<0.1%)	0
Carpal tunnel syndrome	1 (<0.1%)	0
Dizziness postural	0	1 (<0.1%)
Narcolepsy	0	1 (<0.1%)
Neuralgia	1 (<0.1%)	0
Paraesthesia	0	1 (<0.1%)
Transient ischaemic attack	1 (<0.1%)	0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
General disorders and administration site conditions		
Total number of patients with at least one adverse event	19 (1.7%)	30 (2.8%)
Total number of events	22	32
Non-cardiac chest pain	5 (0.5%)	7 (0.6%)
Fatigue	0	8 (0.7%)
Oedema peripheral	4 (0.4%)	4 (0.4%)
Chest pain	4 (0.4%)	2 (0.2%)
Chest discomfort	1 (<0.1%)	4 (0.4%)
Oedema	1 (<0.1%)	2 (0.2%)
Device breakage	2 (0.2%)	0
Pain	1 (<0.1%)	1 (<0.1%)
Adverse drug reaction	1 (<0.1%)	0
Asthenia	0	1 (<0.1%)
Inflammation	0	1 (<0.1%)
Injection site inflammation	0	1 (<0.1%)
Injection site pain	1 (<0.1%)	0
Injection site swelling	1 (<0.1%)	0
No adverse event	0	1 (<0.1%)
Nodule	1 (<0.1%)	0
Skin and subcutaneous tissue disorders		
Total number of patients with at least one adverse event	20 (1.8%)	11 (1.0%)
Total number of events	24	11
Rash	4 (0.4%)	2 (0.2%)
Pruritus generalised	2 (0.2%)	2 (0.2%)
Skin lesion	2 (0.2%)	1 (<0.1%)
Dermatitis	1 (<0.1%)	1 (<0.1%)
Rash macular	1 (<0.1%)	1 (<0.1%)
Rash pruritic	2 (0.2%)	0
Skin ulcer	1 (<0.1%)	1 (<0.1%)
Alopecia	1 (<0.1%)	0
Dermatitis contact	1 (<0.1%)	0
Digital ulcer	0	1 (<0.1%)
Dry skin	1 (<0.1%)	0
Ecchymosis	1 (<0.1%)	0
Hyperhidrosis	0	1 (<0.1%)
Onychoclasis	1 (<0.1%)	0
Pemphigus	1 (<0.1%)	0
Skin burning sensation	1 (<0.1%)	0
Skin hyperpigmentation	0	1 (<0.1%)

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28 Page 4 of 8

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Injury, poisoning and procedural complications		
Total number of patients with at least one adverse event	13 (1.2%)	15 (1.4%)
Total number of events	13	22
Fall	0	5 (0.5%)
Contusion	2 (0.2%)	1 (<0.1%)
Joint injury	1 (<0.1%)	2 (0.2%)
Ligament sprain	2 (0.2%)	1 (<0.1%)
Excoriation	0	2 (0.2%)
Laceration	0	2 (0.2%)
Limb injury	1 (<0.1%)	1 (<0.1%)
Muscle strain	1 (<0.1%)	1 (<0.1%)
Burns second degree	1 (<0.1%)	0
Foreign body in eye	1 (<0.1%)	0
Gun shot wound	1 (<0.1%)	0
Head injury	0	1 (<0.1%)
Lower limb fracture	0	1 (<0.1%)
Muscle rupture	0	1 (<0.1%)
Post procedural haemorrhage	0	1 (<0.1%)
Rib fracture	0	1 (<0.1%)
Sunburn	1 (<0.1%)	0
Tendon rupture	1 (<0.1%)	0
Tooth injury	1 (<0.1%)	0
Respiratory, thoracic and mediastinal disorders		
Total number of patients with at least one adverse event	12 (1.1%)	14 (1.3%)
Total number of events	12	14
Dyspnoea	3 (0.3%)	5 (0.5%)
Chronic obstructive pulmonary disease	1 (<0.1%)	4 (0.4%)
Cough	2 (0.2%)	1 (<0.1%)
Epistaxis	2 (0.2%)	0
Wheezing	0	2 (0.2%)
Asthma	0	1 (<0.1%)
Nasal congestion	1 (<0.1%)	0
Oropharyngeal pain	1 (<0.1%)	0
Pneumothorax	0	1 (<0.1%)
Rhinitis allergic	1 (<0.1%)	0
Rhinorrhoea	1 (<0.1%)	0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28 Page 5 of 8

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Metabolism and nutrition disorders		
Total number of patients with at least one adverse event	4 (0.4%)	15 (1.4%)
Total number of events	4	17
Gout	1 (<0.1%)	2 (0.2%)
Hypoglycaemia	2 (0.2%)	1 (<0.1%)
Increased appetite	0	3 (0.3%)
Diabetes mellitus	0	2 (0.2%)
Hypertriglyceridaemia	1 (<0.1%)	1 (<0.1%)
Decreased appetite	0	1 (<0.1%)
Dehydration	0	1 (<0.1%)
Diabetes mellitus inadequate control	0	1 (<0.1%)
Fluid retention	0	1 (<0.1%)
Hyperglycaemia	0	1 (<0.1%)
Hyponatraemia	0	1 (<0.1%)
Lactose intolerance	0	1 (<0.1%)
Polydipsia	0	1 (<0.1%)
Cardiac disorders		
Total number of patients with at least one adverse event	9 (0.8%)	9 (0.8%)
Total number of events	9	9
Atrial fibrillation	4 (0.4%)	4 (0.4%)
Angina pectoris	2 (0.2%)	0
Bradycardia	1 (<0.1%)	1 (<0.1%)
Palpitations	0	2 (0.2%)
Angina unstable	1 (<0.1%)	0
Arrhythmia	1 (<0.1%)	0
Atrial tachycardia	0	1 (<0.1%)
Tachycardia	0	1 (<0.1%)
Vascular disorders		
Total number of patients with at least one adverse event	10 (0.9%)	6 (0.6%)
Total number of events	10	6
Hypertension	5 (0.5%)	2 (0.2%)
Hypotension	2 (0.2%)	2 (0.2%)
Venous insufficiency	2 (0.2%)	0
Flushing	1 (<0.1%)	0
Hot flush	0	1 (<0.1%)
Orthostatic hypotension	0	1 (<0.1%)
Renal and urinary disorders		
Total number of patients with at least one adverse event	9 (0.8%)	5 (0.5%)
Total number of events	9	5
Renal failure	2 (0.2%)	2 (0.2%)
Chromaturia	1 (<0.1%)	1 (<0.1%)
Calculus ureteric	1 (<0.1%)	0
Haematuria	1 (<0.1%)	0
Nephrolithiasis	0	1 (<0.1%)
Pollakiuria	1 (<0.1%)	0
Polyuria	0	1 (<0.1%)
Renal artery stenosis	1 (<0.1%)	0
Renal failure acute	1 (<0.1%)	0
Renal mass	1 (<0.1%)	0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28 Page 6 of 8

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Psychiatric disorders		
Total number of patients with at least one adverse event	3 (0.3%)	10 (0.9%)
Total number of events	3	10
Insomnia	1 (<0.1%)	5 (0.5%)
Depression	1 (<0.1%)	2 (0.2%)
Anxiety	0	1 (<0.1%)
Disorientation	0	1 (<0.1%)
Disturbance in sexual arousal	0	1 (<0.1%)
Mood altered	1 (<0.1%)	0
Investigations		
Total number of patients with at least one adverse event	2 (0.2%)	7 (0.6%)
Total number of events	3	7
Gamma-glutamyltransferase increased	1 (<0.1%)	2 (0.2%)
Weight increased	0	3 (0.3%)
Blood lactate dehydrogenase increased	1 (<0.1%)	0
Blood potassium increased	0	1 (<0.1%)
Liver function test abnormal	1 (<0.1%)	0
Peripheral pulse decreased	0	1 (<0.1%)
Eye disorders		
Total number of patients with at least one adverse event	2 (0.2%)	5 (0.5%)
Total number of events	2	5
Asthenopia	0	1 (<0.1%)
Blepharospasm	0	1 (<0.1%)
Cataract	1 (<0.1%)	0
Diplopia	1 (<0.1%)	0
Eye haemorrhage	0	1 (<0.1%)
Vision blurred	0	1 (<0.1%)
Vitreous detachment	0	1 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Total number of patients with at least one adverse event	3 (0.3%)	3 (0.3%)
Total number of events	3	3
Benign neoplasm of skin	1 (<0.1%)	0
Colon cancer	0	1 (<0.1%)
Lung adenocarcinoma	1 (<0.1%)	0
Malignant melanoma	0	1 (<0.1%)
Prostate cancer	1 (<0.1%)	0
Rectal adenoma	0	1 (<0.1%)
Blood and lymphatic system disorders		
Total number of patients with at least one adverse event	1 (<0.1%)	3 (0.3%)
Total number of events	1	3
Anaemia	1 (<0.1%)	1 (<0.1%)
Iron deficiency anaemia	0	2 (0.2%)

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28 Page 7 of 8

AE summary
Population: Safety Analysis Population

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Ear and labyrinth disorders		
Total number of patients with at least one adverse event	1 (<0.1%)	2 (0.2%)
Total number of events	1	2
Vertigo	1 (<0.1%)	1 (<0.1%)
Motion sickness	0	1 (<0.1%)
Immune system disorders		
Total number of patients with at least one adverse event	2 (0.2%)	1 (<0.1%)
Total number of events	2	1
Seasonal allergy	2 (0.2%)	1 (<0.1%)
Hepatobiliary disorders		
Total number of patients with at least one adverse event	1 (<0.1%)	1 (<0.1%)
Total number of events	2	1
Cholangitis	0	1 (<0.1%)
Cholecystitis acute	1 (<0.1%)	0
Gallbladder disorder	1 (<0.1%)	0
No Coding available		
Total number of patients with at least one adverse event	2 (0.2%)	0
Total number of events	3	0
No Coding available	2 (0.2%)	0
Reproductive system and breast disorders		
Total number of patients with at least one adverse event	1 (<0.1%)	1 (<0.1%)
Total number of events	1	1
Benign prostatic hyperplasia	0	1 (<0.1%)
Erectile dysfunction	1 (<0.1%)	0

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_SE.out
16OCT2012 15:28 Page 8 of 8

SAE summary by treatment and body system

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Total number of patients with at least one adverse event	16 (1.4%)	25 (2.3%)
Overall total number of events	16	30
Infections and infestations		
Total number of patients with at least one adverse event	9 (0.8%)	8 (0.7%)
Total number of events	9	10
Pneumonia	1 (<0.1%)	4 (0.4%)
Appendicitis	1 (<0.1%)	1 (<0.1%)
Gastroenteritis viral	1 (<0.1%)	1 (<0.1%)
Localised infection	2 (0.2%)	0
Bronchitis	1 (<0.1%)	0
Candidiasis	0	1 (<0.1%)
Gastroenteritis	0	1 (<0.1%)
Influenza	0	1 (<0.1%)
Labyrinthitis	1 (<0.1%)	0
Lower respiratory tract infection	1 (<0.1%)	0
Ludwig angina	0	1 (<0.1%)
Sialoadenitis	1 (<0.1%)	0
Gastrointestinal disorders		
Total number of patients with at least one adverse event	2 (0.2%)	4 (0.4%)
Total number of events	2	5
Diverticulum	1 (<0.1%)	0
Duodenal ulcer haemorrhage	0	1 (<0.1%)
Gastrooesophageal reflux disease	0	1 (<0.1%)
Hiatus hernia	0	1 (<0.1%)
Oesophagitis	0	1 (<0.1%)
Pancreatitis acute	1 (<0.1%)	0
Small intestinal obstruction	0	1 (<0.1%)
General disorders and administration site conditions		
Total number of patients with at least one adverse event	2 (0.2%)	3 (0.3%)
Total number of events	2	3
Non-cardiac chest pain	1 (<0.1%)	2 (0.2%)
Chest pain	1 (<0.1%)	1 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Total number of patients with at least one adverse event	0	3 (0.3%)
Total number of events	0	3
Colon cancer	0	1 (<0.1%)
Malignant melanoma	0	1 (<0.1%)
Rectal adenoma	0	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders		
Total number of patients with at least one adverse event	0	3 (0.3%)
Total number of events	0	3
Chronic obstructive pulmonary disease	0	2 (0.2%)
Pneumothorax	0	1 (<0.1%)

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_ser_SE.out
17SEP2012 16:06 Page 1 of 2

SAE summary by treatment and body system

MedDRA System Organ Class MedDRA Preferred Term	DALCETRAPIB 600 MG (N=1106)	PLACEBO (N=1090)
Cardiac disorders		
Total number of patients with at least one adverse event	0	2 (0.2%)
Total number of events	0	2
Atrial fibrillation	0	1 (<0.1%)
Bradycardia	0	1 (<0.1%)
Renal and urinary disorders		
Total number of patients with at least one adverse event	2 (0.2%)	0
Total number of events	2	0
Renal failure acute	1 (<0.1%)	0
Renal mass	1 (<0.1%)	0
Hepatobiliary disorders		
Total number of patients with at least one adverse event	1 (<0.1%)	0
Total number of events	1	0
Cholecystitis acute	1 (<0.1%)	0
Metabolism and nutrition disorders		
Total number of patients with at least one adverse event	0	1 (<0.1%)
Total number of events	0	1
Dehydration	0	1 (<0.1%)
Musculoskeletal and connective tissue disorders		
Total number of patients with at least one adverse event	0	1 (<0.1%)
Total number of events	0	1
Musculoskeletal chest pain	0	1 (<0.1%)
Nervous system disorders		
Total number of patients with at least one adverse event	0	1 (<0.1%)
Total number of events	0	1
Syncope	0	1 (<0.1%)
Skin and subcutaneous tissue disorders		
Total number of patients with at least one adverse event	0	1 (<0.1%)
Total number of events	0	1
Digital ulcer	0	1 (<0.1%)

Program: /opt/BIOSTAT/prod/cdp12036/nc25608/stae02.sas
Output: /opt/BIOSTAT/prod/cdp12036/nc25608/reports/stae02_ser_SE.out
17SEP2012 16:06 Page 2 of 2