ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 02/13/2014

ClinicalTrials.gov ID: NCT00952588

Study Identification

Unique Protocol ID:	D1531C00009
Brief Title:	Study to Investigate the Efficacy, Safety and Tolerability of AZD1152 Alone and in Combination With Low Dose Cytosine Arabinoside (LDAC)in Acute Myeloid Leukaemia (AML) Patients (SPARK-AML1)
Official Title:	A Randomised, Open-label, Multi-centre, 2-stage, Parallel Group Study to Assess the Efficacy, Safety and Tolerability of AZD1152 Alone and in Combination With Low Dose Cytosine Arabinoside (LDAC) in Comparison With LDAC Alone in Patients Aged ≥ 60 With Newly Diagnosed Acute Myeloid Leukaemia (AML)
Secondary IDs:	

Study Status

Record Verification:	February 2014
Overall Status:	Completed
Study Start:	July 2009
Primary Completion:	June 2011 [Actual]
Study Completion:	June 2011 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 70,836 Serial Number: 097 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Italy: Ethics Committee Italy: The Italian Medicines Agency Spain: Comité Ético de Investigación Clínica Spain: Spanish Agency of Medicines Australia: Department of Health and Ageing Therapeutic Goods Administration Japan: Ministry of Health, Labor and Welfare Romania: National Medicines Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	The purpose of this study is to assess the efficacy, safety and tolerability of AZD1152 alone and in combination with low dose cytosine arabinoside (LDAC) in comparison with LDAC alone in AML patients.
Detailed Description:	

Conditions

Conditions:	Acute Myeloid Leukemia

Keywords: Acute Myeloid Leukaemia,
AML

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 2/Phase 3
Intervention Model: Parallel Assignment
Number of Arms: 2
Masking: Open Label
Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Enrollment: 74 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: AZD1152 1200 mg AZD1152 1200 mg, iv, 7 day infusion monotherapy	Drug: AZD1152 1200 mg, iv, 7 day infusion
Active Comparator: LDAC 20 mg LDAC 20 mg, sc, bd, 10 days (400mg per cycle)	Drug: LDAC 20 mg, sc, bd, 10 days

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 60 Years
Maximum Age:
Gender: Both
Accepts Healthy Volunteers?: No
Criteria: Inclusion Criteria:

- Provision of written informed consent

- Newly diagnosed male or female patients aged 60 and over
- De Novo or Secondary AML
- Not eligible for intensive induction with anthracycline-based combination chemotherapy as a result of at least one of the following:Age ≥75 years; Adverse cytogenetics, e.g., as defined by the MRC Prognostic Groupings; WHO performance status >2; Organ dysfunction arising from significant co-morbidities not directly linked to leukaemia

Exclusion Criteria:

- Participation in another clinical study in which an investigational product was received within 14 days before the first dose in this study, or at any time if the patient has not recovered from side-effects associated with that investigational product
- Administration of LDAC is clinically contraindicated
- Patients with AML of FAB M3 classification Acute Promyelocytic Leukaemia (APL)
- Patients with blast crisis of chronic myeloid leukaemia

Contacts/Locations

Study Officials: Paul Stockman
Study Director
AstraZeneca

Hagop Kantarjian
Study Principal Investigator
M.D. Anderson Cancer Center

Locations: Australia, Queensland
Research Site
Herston, Queensland, Australia

Australia, Victoria
Research Site
Melbourne, Victoria, Australia

Research Site
Parkville, Victoria, Australia

Australia, New South Wales
Research Site
Westmead, New South Wales, Australia

France
Research Site
Angers Cedex 01, France

Research Site
Clermont-ferrand, France

Research Site
Grenoble Cedex 09, France

Research Site
Lyon Cedex 03, France

Research Site
Marseille Cedex 09, France

Research Site
Nantes, France

Germany
Research Site
Duisburg, Germany

Research Site
Erlangen, Germany

Research Site
Frankfurt, Germany

Research Site
Munster, Germany

Research Site
Villingen-schwenningen, Germany

United Kingdom
Research Site
Brighton, United Kingdom

Research Site
London, United Kingdom

Italy
Research Site
Bologna, BO, Italy

Research Site
Genova, GE, Italy

Research Site
Orbassano, TO, Italy

Research Site

Roma, Roma, Italy

Research Site
Udine, UD, Italy

Japan
Research Site
Chuo, Tokyo, Japan

Research Site
Fukuoka, Fukuoka, Japan

Research Site
Isehara, Kanagawa, Japan

Research Site
Maebashi, Gunma, Japan

Research Site
Nagoya, Aichi, Japan

Research Site
Yokohama, Kanagawa, Japan

Research Site
Yoshida-gun, Fukui, Japan

Romania
Research Site
Brasov, Romania

Research Site
Tg Mures, Romania

Spain
Research Site
Badalona(barcelona), Cataluna, Spain

Research Site
Barcelona, Cataluna, Spain

Research Site
Madrid, Comunidad de Madrid, Spain

Research Site
Majadahonda, Madrid, Spain

Research Site
Oviedo, Asturias, Spain

Research Site
Valencia, Comunidad Valenciana, Spain

United States, Georgia
Research Site
Atlanta, Georgia, United States

United States, Illinois
Research Site
Chicago, Illinois, United States

United States, Ohio
Research Site
Cleveland, Ohio, United States

United States, South Carolina
Research Site
Greenville, South Carolina, United States

United States, Texas
Research Site
Houston, Texas, United States

United States, Tennessee
Research Site
Nashville, Tennessee, United States

United States, New York
Research Site
New York, New York, United States

United States, Oregon
Research Site
Portland, Oregon, United States

References

Citations:

Links: URL: http://www.astrazeneca-us.com/cancerstudylocator
Description Cancer Study Locator (US and CA only)

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	First patient was randomized on 22/07/2009 and last patient last visit has occurred on 27/06/2011.

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Overall Study

	AZD1152 1200mg	LDAC 20mg
Started	48	26
Completed	12	2
Not Completed	36	24
Death	28	13
Withdrawal by Subject	2	5
Adverse Event	2	3
Lost to Follow-up	2	0
Physician Decision	0	1
Lack of Efficacy	2	2

Baseline Characteristics

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Baseline Measures

	AZD1152 1200mg	LDAC 20mg	Total
Number of Participants	48	26	74
Age, Continuous [units: years] Mean (Standard Deviation)	75.3 (5.79)	71.5 (5.75)	74.0 (6.03)
Gender, Male/Female [units: Participants]			
Female	23	8	31
Male	25	18	43

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients With Overall Complete Response for Stage I
Measure Description	Percentage of patients achieving either a complete response (CR) or a confirmed complete remission with incomplete recovery of neutrophils or platelets (confirmed CRi). Per Cheson Criteria: Confirmed complete remission (CRi) is defined as a disappearance of blasts in the peripheral blood; a decrease in bone marrow blasts to <5% total bone marrow nucleated cells demonstrated in bone marrow aspirate; absence of Auer rods; no persistent extramedullary leukaemia. Complete response (CR) is defined as all requirements to meet CRi and in addition: recovery of neutrophils to ≥1.0 x 109/L and platelets to ≥100 x 109/L; transfusion-independence.
Time Frame	IWG Cheson criteria every 28 days from randomization for study duration (24 months, between 2009 - 2011)
Safety Issue?	No

Analysis Population Description
modified Intent to Treat (ITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	48	26

	AZD1152 1200mg	LDAC 20mg
Percentage of Patients With Overall Complete Response for Stage I [units: percentage of participants]	35.4	11.5

2. Secondary Outcome Measure:

Measure Title	Duration of Response (DoR): Stage I and Transition Phase
Measure Description	DoR was defined for the median of days which showed a confirmed CRi or CR, as the time from first documented evidence of CRi or CR until the first documented sign of disease progression or death. Duration of Response was measured from the Response Start date until evidence of patient relapse or death. Stage I : 45 patients randomized in a 2:1 ratio to AZD1152 or LDAC. Transition phase: enrollment of up to 30 additional patients randomized as per stage I.
Time Frame	DoR was measured every 28 days from randomization for study duration (24 months, between 2009 - 2011)
Safety Issue?	No

Analysis Population Description
modified Intent to Treat (mITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	17	3
Duration of Response (DoR): Stage I and Transition Phase [units: days] Median (Inter-Quartile Range)	82 (43 to 189)	NA (NA to NA) [1]

[1] This was not calculable because there were only 3 responses (events) in this group and the method of estimating the median was using Kaplan-Meier methods.

3. Secondary Outcome Measure:

Measure Title	Disease Free Survival (DFS)
Measure Description	Disease-free Survival is defined as the time from randomisation to relapse or death from any cause.
Time Frame	DFS was measured every 28 days from randomization for study duration (24 months, between 2009 - 2011)
Safety Issue?	No

Analysis Population Description
modified Intent to Treat (mITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	17	3
Disease Free Survival (DFS) [units: months] Median (Inter-Quartile Range)	5.6 (3.3 to 7.9)	NA (NA to NA) [1]

[1] This was not calculable because there were only 3 responses (events) in this group and the method of estimating the median was using Kaplan-Meier methods.

4. Secondary Outcome Measure:

Measure Title	Time To Complete Response (TTCR)
Measure Description	TTCR is measured as time from randomization to either a complete response (CR) or a confirmed complete remission with incomplete recovery of neutrophils or platelets (confirmed CRi)
Time Frame	Response was measured every 28 days from randomization for study duration (24 months, between 2009 - 2011)
Safety Issue?	No

Analysis Population Description
modified Intent to Treat (mITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	17	3
Time To Complete Response (TTCR) [units: days] Median (Inter-Quartile Range)	59 (27 to 180)	64 (63 to 96)

5. Secondary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	Overall Survival is defined as the median time from randomisation to death from any cause. Patients who were not known to have died at the time of the analysis were censored at the date they were last known to be alive.
Time Frame	Assessed from randomisation until the date of death from any cause, assessed up to 24 months
Safety Issue?	No

Analysis Population Description
modified Intent to Treat (mITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	48	26
Overall Survival (OS) [units: months] Median (Full Range)	8.2 (0.1 to 15.9)	4.5 (0.2 to 20.4)

6. Secondary Outcome Measure:

Measure Title	Percent of Patients With Worsened Trial Outcome Index (TOI)
Measure Description	TOI is derived from the sum of the Functional Well Being (FWB), Physical Well Being (PWB) and additional subscales of the FACT-Leu. The TOI subscale consists of 31 items with TOI scores ranging from 0 to 124. The TOI is described as a summary measure of HRQoL. Higher scores indicate better HRQoL. Negative changes from baseline indicate a worsening of HRQoL while positive changes indicate an improvement in HRQoL. A response of “Worsened” was a change from baseline in score of less than or equal to -9.
Time Frame	TOI was measured every 28 days from randomization for study duration (24 months, between 2009 - 2011)
Safety Issue?	Yes

Analysis Population Description
modified Intent to Treat (mITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	48	26
Percent of Patients With Worsened Trial Outcome Index (TOI) [units: percentage of participants]	31.3	11.5

7. Secondary Outcome Measure:

Measure Title	Percent of Patients With Worsened Functional Assessment of Cancer Therapy - Leukaemia (FACT-Leu) Score.
Measure Description	The total FACT-Leu score consists of 44 items with total scores ranging from 0 to 176. Higher scores indicate better HRQoL. Negative changes from baseline indicate a worsening of HRQoL while positive changes indicate an improvement in HRQoL. A response of “Worsened” was a change from baseline in score of less than or equal to -11.
Time Frame	FACT-Leu was measured every 28 days from randomization for study duration (24 months, between 2009 - 2011)
Safety Issue?	No

Analysis Population Description
modified Intent to Treat (mITT)

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Measured Values

	AZD1152 1200mg	LDAC 20mg
Number of Participants Analyzed	48	26
Percent of Patients With Worsened Functional Assessment of Cancer Therapy - Leukaemia (FACT-Leu) Score. [units: percentage of participants]	29.2	11.5

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
AZD1152 1200mg	AZD1152 1200 mg, iv, 7 day infusion monotherapy
LDAC 20mg	LDAC 20 mg, sc, bd, 10 days (400mg per cycle)

Serious Adverse Events

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	23/48 (47.92%)	10/26 (38.46%)
Blood and lymphatic system disorders		

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Anaemia [A] †	1/48 (2.08%)	1/26 (3.85%)
Febrile Bone Marrow Aplasia [A] †	0/48 (0%)	1/26 (3.85%)
Febrile Neutropenia [A] †	5/48 (10.42%)	0/26 (0%)
Neutropenia [A] †	2/48 (4.17%)	0/26 (0%)
Pancytopenia [A] †	1/48 (2.08%)	0/26 (0%)
Cardiac disorders		
Angina Pectoris [A] †	1/48 (2.08%)	0/26 (0%)
Atrial Fibrillation [A] †	1/48 (2.08%)	0/26 (0%)
Myocardial Ischaemia [A] †	1/48 (2.08%)	0/26 (0%)
Gastrointestinal disorders		
Stomatitis [A] †	3/48 (6.25%)	0/26 (0%)
General disorders		
Device Occlusion [A] †	1/48 (2.08%)	0/26 (0%)
Hyperthermia [A] †	1/48 (2.08%)	0/26 (0%)
Pyrexia [A] †	4/48 (8.33%)	1/26 (3.85%)
Infections and infestations		
Arthritis Infective [A] †	1/48 (2.08%)	0/26 (0%)
Cellulitis [A] †	1/48 (2.08%)	0/26 (0%)
Clostridium Difficile Sepsis [A] †	0/48 (0%)	1/26 (3.85%)
Enterococcal Bacteraemia [A] †	1/48 (2.08%)	0/26 (0%)
Escherichia Infection [A] †	1/48 (2.08%)	0/26 (0%)
Lobar Pneumonia [A] †	1/48 (2.08%)	0/26 (0%)
Lung Infection [A] †	0/48 (0%)	1/26 (3.85%)

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Neutropenic Sepsis [A] †	0/48 (0%)	1/26 (3.85%)
Oral Candidiasis [A] †	1/48 (2.08%)	0/26 (0%)
Pneumonia [A] †	6/48 (12.5%)	2/26 (7.69%)
Pulmonary Mycosis [A] †	1/48 (2.08%)	0/26 (0%)
Sepsis [A] †	1/48 (2.08%)	1/26 (3.85%)
Injury, poisoning and procedural complications		
Subdural Haematoma [A] †	1/48 (2.08%)	0/26 (0%)
Investigations		
White Blood Cell Count Increased [A] †	0/48 (0%)	1/26 (3.85%)
Musculoskeletal and connective tissue disorders		
Myopathy [A] †	1/48 (2.08%)	0/26 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Blast Cell Proliferation [A] †	1/48 (2.08%)	0/26 (0%)
Nervous system disorders		
Convulsion [A] †	1/48 (2.08%)	0/26 (0%)
Presyncope [A] †	1/48 (2.08%)	0/26 (0%)
Renal and urinary disorders		
Renal Failure [A] †	1/48 (2.08%)	0/26 (0%)
Renal Failure Acute [A] †	1/48 (2.08%)	0/26 (0%)
Respiratory, thoracic and mediastinal disorders		
Acute Respiratory Distress Syndrome [A] †	1/48 (2.08%)	0/26 (0%)
Hypoxia [A] †	0/48 (0%)	1/26 (3.85%)
Lung Infiltration [A] †	1/48 (2.08%)	0/26 (0%)

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Pleural Effusion [A] †	0/48 (0%)	1/26 (3.85%)
Vascular disorders		
Hypertension [A] †	1/48 (2.08%)	0/26 (0%)
Thrombophlebitis [A] †	1/48 (2.08%)	0/26 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	33/48 (68.75%)	10/26 (38.46%)
Blood and lymphatic system disorders		
Anaemia [A] †	12/48 (25%)	3/26 (11.54%)
Coagulopathy [A] †	3/48 (6.25%)	1/26 (3.85%)
Febrile Neutropenia [A] †	32/48 (66.67%)	5/26 (19.23%)
Leukopenia [A] †	6/48 (12.5%)	0/26 (0%)
Lymphopenia [A] †	4/48 (8.33%)	0/26 (0%)
Neutropenia [A] †	5/48 (10.42%)	2/26 (7.69%)
Thrombocytopenia [A] †	9/48 (18.75%)	6/26 (23.08%)
Cardiac disorders		
Tachycardia [A] †	3/48 (6.25%)	3/26 (11.54%)
Ear and labyrinth disorders		
Vertigo [A] †	3/48 (6.25%)	0/26 (0%)
Eye disorders		

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Conjunctival Haemorrhage [A] †	3/48 (6.25%)	0/26 (0%)
Gastrointestinal disorders		
Abdominal Pain [A] †	3/48 (6.25%)	4/26 (15.38%)
Abdominal Pain Upper [A] †	3/48 (6.25%)	0/26 (0%)
Constipation [A] †	23/48 (47.92%)	8/26 (30.77%)
Diarrhoea [A] †	24/48 (50%)	3/26 (11.54%)
Dry Mouth [A] †	4/48 (8.33%)	0/26 (0%)
Dyspepsia [A] †	4/48 (8.33%)	0/26 (0%)
Dysphagia [A] †	4/48 (8.33%)	1/26 (3.85%)
Gingival Bleeding [A] †	3/48 (6.25%)	3/26 (11.54%)
Haemorrhoids [A] †	7/48 (14.58%)	1/26 (3.85%)
Nausea [A] †	21/48 (43.75%)	10/26 (38.46%)
Oral Pain [A] †	5/48 (10.42%)	0/26 (0%)
Stomatitis [A] †	33/48 (68.75%)	4/26 (15.38%)
Tongue Ulceration [A] †	4/48 (8.33%)	1/26 (3.85%)
Toothache [A] †	3/48 (6.25%)	0/26 (0%)
Vomiting [A] †	17/48 (35.42%)	5/26 (19.23%)
General disorders		
Asthenia [A] †	7/48 (14.58%)	8/26 (30.77%)
Catheter Site Haematoma [A] †	0/48 (0%)	2/26 (7.69%)
Catheter Site Pain [A] †	3/48 (6.25%)	2/26 (7.69%)
Catheter Site Related Reaction [A] †	3/48 (6.25%)	0/26 (0%)

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Chills [A] †	3/48 (6.25%)	3/26 (11.54%)
Fatigue [A] †	9/48 (18.75%)	6/26 (23.08%)
Hyperthermia [A] †	5/48 (10.42%)	0/26 (0%)
Injection Site Haematoma [A] †	0/48 (0%)	2/26 (7.69%)
Oedema [A] †	4/48 (8.33%)	1/26 (3.85%)
Oedema Peripheral [A] †	8/48 (16.67%)	7/26 (26.92%)
Pain [A] †	4/48 (8.33%)	1/26 (3.85%)
Pyrexia [A] †	13/48 (27.08%)	8/26 (30.77%)
Infections and infestations		
Bacteraemia [A] †	3/48 (6.25%)	0/26 (0%)
Cellulitis [A] †	3/48 (6.25%)	0/26 (0%)
Oral Candidiasis [A] †	5/48 (10.42%)	0/26 (0%)
Pneumonia [A] †	6/48 (12.5%)	1/26 (3.85%)
Sepsis [A] †	6/48 (12.5%)	0/26 (0%)
Injury, poisoning and procedural complications		
Contusion [A] †	3/48 (6.25%)	1/26 (3.85%)
Investigations		
Alanine Aminotransferase Increased [A] †	4/48 (8.33%)	0/26 (0%)
Blood Creatinine Increased [A] †	3/48 (6.25%)	1/26 (3.85%)
Blood Pressure Decreased [A] †	0/48 (0%)	2/26 (7.69%)
Breath Sounds Abnormal [A] †	3/48 (6.25%)	0/26 (0%)
Weight Decreased [A] †	3/48 (6.25%)	4/26 (15.38%)

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Weight Increased [A] †	0/48 (0%)	2/26 (7.69%)
Metabolism and nutrition disorders		
Decreased Appetite [A] †	10/48 (20.83%)	5/26 (19.23%)
Hyperglycaemia [A] †	4/48 (8.33%)	1/26 (3.85%)
Hyperuricaemia [A] †	0/48 (0%)	2/26 (7.69%)
Hypoalbuminaemia [A] †	5/48 (10.42%)	0/26 (0%)
Hypokalaemia [A] †	10/48 (20.83%)	2/26 (7.69%)
Hyponatraemia [A] †	4/48 (8.33%)	1/26 (3.85%)
Musculoskeletal and connective tissue disorders		
Back Pain [A] †	8/48 (16.67%)	2/26 (7.69%)
Bone Pain [A] †	1/48 (2.08%)	3/26 (11.54%)
Joint Swelling [A] †	3/48 (6.25%)	1/26 (3.85%)
Muscle Spasms [A] †	1/48 (2.08%)	2/26 (7.69%)
Musculoskeletal Chest Pain [A] †	5/48 (10.42%)	0/26 (0%)
Musculoskeletal Pain [A] †	2/48 (4.17%)	2/26 (7.69%)
Myalgia [A] †	0/48 (0%)	2/26 (7.69%)
Pain In Extremity [A] †	2/48 (4.17%)	3/26 (11.54%)
Nervous system disorders		
Dizziness [A] †	4/48 (8.33%)	4/26 (15.38%)
Dysgeusia [A] †	5/48 (10.42%)	0/26 (0%)
Headache [A] †	8/48 (16.67%)	1/26 (3.85%)
Psychiatric disorders		
Anxiety [A] †	4/48 (8.33%)	1/26 (3.85%)

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Confusional State [A] †	4/48 (8.33%)	1/26 (3.85%)
Insomnia [A] †	11/48 (22.92%)	3/26 (11.54%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	7/48 (14.58%)	3/26 (11.54%)
Dyspnoea [A] †	8/48 (16.67%)	5/26 (19.23%)
Epistaxis [A] †	11/48 (22.92%)	6/26 (23.08%)
Hypoxia [A] †	3/48 (6.25%)	3/26 (11.54%)
Oropharyngeal Pain [A] †	7/48 (14.58%)	0/26 (0%)
Pleural Effusion [A] †	4/48 (8.33%)	0/26 (0%)
Rales [A] †	2/48 (4.17%)	2/26 (7.69%)
Skin and subcutaneous tissue disorders		
Alopecia [A] †	11/48 (22.92%)	0/26 (0%)
Dermatitis [A] †	1/48 (2.08%)	2/26 (7.69%)
Erythema [A] †	1/48 (2.08%)	3/26 (11.54%)
Hyperhidrosis [A] †	0/48 (0%)	4/26 (15.38%)
Petechiae [A] †	4/48 (8.33%)	4/26 (15.38%)
Pruritus [A] †	3/48 (6.25%)	1/26 (3.85%)
Rash [A] †	10/48 (20.83%)	2/26 (7.69%)
Vascular disorders		
Haematoma [A] †	2/48 (4.17%)	3/26 (11.54%)
Hypotension [A] †	5/48 (10.42%)	1/26 (3.85%)
Pallor [A] †	0/48 (0%)	2/26 (7.69%)

	AZD1152 1200mg	LDAC 20mg
	Affected/At Risk (%)	Affected/At Risk (%)
Phlebitis [A] †	1/48 (2.08%)	2/26 (7.69%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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