ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 07/30/2010

Grantor: CDER IND/IDE Number: 48.106 Serial Number: S-274

IMPACT Study: A Study of Valcyte (Valganciclovir) for Prevention of Cytomegalovirus Disease (CMV) in Kidney Allograft Recipients

This study has been completed.

Sponsor:	Hoffmann-La Roche
Collaborators:	
Information provided by:	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT00294515

Purpose

This study will determine the relative efficacy and safety of up to 100 days Valcyte prophylaxis relative to up to 200 days Valcyte prophylaxis when given for the prevention of CMV disease in high-risk (D+/R-) kidney allograft recipients. The anticipated time on study treatment is 3-12 months and the target sample size is 100-500 individuals.

Condition	Intervention	Phase
Cytomegalovirus Infections	Drug: Valganciclovir	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Efficacy and Safety of up to 100 Days of Valganciclovir Versus up to 200 Days of Valganciclovir for Prevention of Cytomegalovirus (CMV) Disease in High-Risk Kidney Allograft Recipients

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measure:

- Percentage of Patients Who Developed Cytomegalovirus (CMV) Disease up to Month 12 Post-transplant [Time Frame: 12 months post-transplant] [Designated as safety issue: No]
  Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 12 months post-transplant.

Secondary Outcome Measures:

- Percentage of Patients Who Developed CMV Disease up to Month 6 Post-transplant [Time Frame: 6 months post-transplant] [Designated as safety issue: No]
  Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 6 months post-transplant.
- Percentage of Patients Who Developed CMV Disease up to Month 9 Post-transplant [Time Frame: 9 months post-transplant] [Designated as safety issue: No]
  Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 9 months post-transplant.
- Percentage of Patients Who Developed CMV Disease up to Month 18 Post-transplant [Time Frame: 18 months post-transplant] [Designated as safety issue: No]
  Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 18 months post-transplant.
- Percentage of Patients Who Developed CMV Disease up to Month 24 Post-transplant [Time Frame: 24 months post-transplant] [Designated as safety issue: No]
  Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 24 months post-transplant.

Enrollment: 326
Study Start Date: March 2006
Primary Completion Date: August 2008
Study Completion Date: August 2009

Arms	Assigned Interventions
Experimental: Valganciclovir up to 100 days Valganciclovir for up to 100 days post kidney transplant	Drug: Valganciclovir 900 mg orally daily for up to 100 days Other Names: Valcyte
Active Comparator: Valganciclovir up to 200 days Valganciclovir for up to 200 days post kidney transplant	Drug: Valganciclovir 900 mg orally daily for up to 200 days Other Names: Valcyte

Eligibility

Ages Eligible for Study: 16 Years and older

Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- ≥ 16 years of age
- CMV seronegative recipient of primary or secondary renal allograft from a living or cadaveric seropositive donor
- Adequate hematological and renal function
- Patients and partners must agree to maintain effective birth control for 90 days following cessation of study medication

Exclusion Criteria:

- CMV disease, or receipt of anti-CMV therapy within 30 days prior to screening
- Multi-organ transplant recipient
- Hepatitis B, hepatitis C or HIV positive
- Women who are pregnant or lactating

Contacts and Locations

Locations

United States, Alabama
Birmingham, Alabama, United States, 35294
United States, California
Los Angeles, California, United States, 90057
Los Angeles, California, United States, 90095
San Diego, California, United States, 92103-8401
San Francisco, California, United States, 94143-0116
San Francisco, California, United States, 94115
United States, Florida
Tampa, Florida, United States, 33606
United States, Illinois
Chicago, Illinois, United States, 60612-3824
United States, Indiana
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United States, Massachusetts
Boston, Massachusetts, United States, 02111
United States, Michigan
Ann Arbor, Michigan, United States, 48109-0331
United States, Minnesota
Minneapolis, Minnesota, United States, 55455
United States, New Jersey
Hackensack, New Jersey, United States, 07601
Livingston, New Jersey, United States, 07039
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United States, North Carolina
Winston-salem, North Carolina, United States, 27157-1082
United States, Oregon
Portland, Oregon, United States, 97201
United States, Pennsylvania
Philadelphia, Pennsylvania, United States, 19102-1192
Philadelphia, Pennsylvania, United States, 19104
United States, Tennessee
Nashville, Tennessee, United States, 37232
United States, Texas
San Antonio, Texas, United States, 78284
San Antonio, Texas, United States, 78229
United States, Washington
Seattle, Washington, United States, 98195
Australia
Camperdown, Australia, 2050
Clayton, Australia, 3186
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Bruxelles, Belgium, 1070
Gent, Belgium, 9000
Leuven, Belgium, 3000
Brazil
Campinas, Brazil, 13083-970
Porto Alegre, Brazil, 90035-003
Porto Alegre, Brazil, 90240-520
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Sao Paulo, Brazil, 18048-900
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Montpellier, France, 34090
Paris, France, 75651
Strasbourg, France, 67091
Toulouse, France, 31054
Tours, France, 37044
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Germany

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Düsseldorf, Germany, 40225
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Hannover, Germany, 30625
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Liverpool, United Kingdom, L7 8XP
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Newcastle Upon Tyne, United Kingdom, NE7 7DN
Nottingham, United Kingdom, NG5 1PB
Oxford, United Kingdom, OX3 7LJ

Investigators

Study Chair:	Clinical Trials	Hoffmann-La Roche

More Information

Clinical Study Report Synopsis
http://www.roche-trials.com/studyResultGet.action?studyResultNumber=NT18435

Responsible Party: Hoffmann-La Roche (Disclosures Group)
Study ID Numbers: NT18435
Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Overall Study

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Started	166 [1]	160 [1]
Completed	132	132
Not Completed	34	28

[1] Randomized

Baseline Characteristics

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Baseline Measures

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days	Total
Number of Participants	164	156	320
Age, Continuous [1] [units: years] Mean (Standard Deviation)	48.5 (13.76)	47.0 (13.51)	47.8 (13.64)
Gender, Male/Female [1] [units: participants]			
Female	45	40	85
Male	119	116	235

[1] Safety population

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients Who Developed Cytomegalovirus (CMV) Disease up to Month 12 Post-transplant
Measure Description	Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 12 months post-transplant.
Time Frame	12 months post-transplant
Safety Issue?	No

Analysis Population Description
Intent-to-treat population

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Measured Values

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Number of Participants Analyzed	163	155

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Percentage of Patients Who Developed Cytomegalovirus (CMV) Disease up to Month 12 Post-transplant [units: Percentage of patients] Mean (95% Confidence Interval)	43.6 (35.8 to 51.5)	23.9 (17.4 to 31.4)

Statistical Analysis 1 for Percentage of Patients Who Developed Cytomegalovirus (CMV) Disease up to Month 12 Post-transplant

Statistical Analysis Overview	Comparison Groups	Valganciclovir up to 100 Days, Valganciclovir up to 200 Days
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	≤ 0.0002
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Stratified by Center Pools

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	0.40
	Confidence Interval	(2-Sided) 95% 0.25 to 0.66
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Developed CMV Disease up to Month 6 Post-transplant
Measure Description	Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 6 months post-transplant.
Time Frame	6 months post-transplant
Safety Issue?	No

Analysis Population Description
Intent-to-treat population

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Measured Values

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Number of Participants Analyzed	163	155
Percentage of Patients Who Developed CMV Disease up to Month 6 Post-transplant [units: Percentage of patients] Mean (95% Confidence Interval)	36.2 (28.8 to 44.1)	10.3 (6.0 to 16.2)

Statistical Analysis 1 for Percentage of Patients Who Developed CMV Disease up to Month 6 Post-transplant

Statistical Analysis Overview	Comparison Groups	Valganciclovir up to 100 Days, Valganciclovir up to 200 Days
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Stratified by Center Pools

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	0.20
	Confidence Interval	(2-Sided) 95% 0.11 to 0.37
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Developed CMV Disease up to Month 9 Post-transplant
Measure Description	Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 9 months post-transplant.
Time Frame	9 months post-transplant
Safety Issue?	No

Analysis Population Description
Intent-to-treat population

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Measured Values

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Number of Participants Analyzed	163	155
Percentage of Patients Who Developed CMV Disease up to Month 9 Post-transplant [units: Percentage of patients] Mean (95% Confidence Interval)	43.6 (35.8 to 51.5)	22.6 (16.3 to 30.0)

Statistical Analysis 1 for Percentage of Patients Who Developed CMV Disease up to Month 9 Post-transplant

Statistical Analysis Overview	Comparison Groups	Valganciclovir up to 100 Days, Valganciclovir up to 200 Days
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0001
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel

	Comments	Stratified by Center Pools

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	0.37
	Confidence Interval	(2-Sided) 95% 0.22 to 0.60
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Developed CMV Disease up to Month 18 Post-transplant
Measure Description	Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 18 months post-transplant.
Time Frame	18 months post-transplant
Safety Issue?	No

Analysis Population Description

Intent-to-treat population

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Measured Values

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Number of Participants Analyzed	163	155
Percentage of Patients Who Developed CMV Disease up to Month 18 Post-transplant [units: Percentage of patients] Mean (95% Confidence Interval)	47.9 (40.0 to 55.8)	34.2 (26.8 to 42.2)

Statistical Analysis 1 for Percentage of Patients Who Developed CMV Disease up to Month 18 Post-transplant

Statistical Analysis Overview	Comparison Groups	Valganciclovir up to 100 Days, Valganciclovir up to 200 Days
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0126
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Stratified by Center Pools

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	0.56
	Confidence Interval	(2-Sided) 95% 0.35 to 0.88
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Developed CMV Disease up to Month 24 Post-transplant
Measure Description	Percentage of CMV-seronegative renal transplant recipients (R-) receiving a CMV-seropositive graft (D+) who developed CMV disease (confirmed and assumed) within 24 months post-transplant.
Time Frame	24 months post-transplant
Safety Issue?	No

Analysis Population Description
Intent-to-treat population

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Measured Values

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
Number of Participants Analyzed	163	155
Percentage of Patients Who Developed CMV Disease up to Month 24 Post-transplant [units: Percentage of patients] Mean (95% Confidence Interval)	48.5 (40.6 to 56.4)	34.2 (26.8 to 42.2)

Statistical Analysis 1 for Percentage of Patients Who Developed CMV Disease up to Month 24 Post-transplant

Statistical Analysis Overview	Comparison Groups	Valganciclovir up to 100 Days, Valganciclovir up to 200 Days
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0100
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Stratified by Center Pools
Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	0.55
	Confidence Interval	(2-Sided) 95% 0.34 to 0.86
	Estimation Comments	[Not specified]

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Safety Population

Reporting Groups

	Description
Valganciclovir up to 100 Days	900 mg valganciclovir orally daily for up to 100 days
Valganciclovir up to 200 Days	900 mg valganciclovir orally daily for up to 200 days

Serious Adverse Events

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Total	94/164 (57.32%)	78/156 (50%)
Blood and lymphatic system disorders		
Agranulocytosis	1/164 (0.61%)	0/156 (0%)
Anaemia	1/164 (0.61%)	0/156 (0%)
Bicytopenia	0/164 (0%)	1/156 (0.64%)
Febrile Neutropenia	1/164 (0.61%)	2/156 (1.28%)
Haemolytic Anaemia	1/164 (0.61%)	0/156 (0%)
Leukopenia	2/164 (1.22%)	1/156 (0.64%)
Neutropenia	3/164 (1.83%)	9/156 (5.77%)
Thrombocytopenia	0/164 (0%)	1/156 (0.64%)
Cardiac disorders		
Acute Coronary Syndrome	0/164 (0%)	2/156 (1.28%)
Angina Pectoris	0/164 (0%)	1/156 (0.64%)
Arrhythmia	1/164 (0.61%)	1/156 (0.64%)
Arrhythmia Supraventricular	1/164 (0.61%)	0/156 (0%)
Cardiac Failure	1/164 (0.61%)	0/156 (0%)
Mitral Valve Disease	1/164 (0.61%)	0/156 (0%)
Myocardial Infarction	0/164 (0%)	2/156 (1.28%)
Pericardial Effusion	1/164 (0.61%)	0/156 (0%)
Tachycardia	1/164 (0.61%)	0/156 (0%)
Congenital, familial and genetic disorders		

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Hereditary Haemorrhagic Telangiectasia	0/164 (0%)	1/156 (0.64%)
Renal Arteriovenous Malformation	0/164 (0%)	1/156 (0.64%)
Endocrine disorders		
Hyperparathyroidism	1/164 (0.61%)	0/156 (0%)
Gastrointestinal disorders		
Abdominal Pain	1/164 (0.61%)	3/156 (1.92%)
Abdominal Pain Upper	0/164 (0%)	1/156 (0.64%)
Colitis	0/164 (0%)	1/156 (0.64%)
Constipation	1/164 (0.61%)	0/156 (0%)
Diarrhoea	2/164 (1.22%)	4/156 (2.56%)
Gastric Ulcer	0/164 (0%)	1/156 (0.64%)
Gastrooesophageal Reflux Disease	0/164 (0%)	1/156 (0.64%)
Impaired Gastric Emptying	0/164 (0%)	1/156 (0.64%)
Inguinal Hernia	0/164 (0%)	1/156 (0.64%)
Intestinal Ischaemia	1/164 (0.61%)	0/156 (0%)
Large Intestine Perforation	0/164 (0%)	1/156 (0.64%)
Mouth Ulceration	1/164 (0.61%)	0/156 (0%)
Oral Pain	1/164 (0.61%)	0/156 (0%)
Pancreatitis	2/164 (1.22%)	0/156 (0%)
Pancreatitis Acute	1/164 (0.61%)	0/156 (0%)
Small Intestinal Obstruction	0/164 (0%)	1/156 (0.64%)
General disorders		
Asthenia	0/164 (0%)	1/156 (0.64%)
Catheter Related Complication	0/164 (0%)	1/156 (0.64%)
Catheter Site Discharge	1/164 (0.61%)	0/156 (0%)
Chest Pain	0/164 (0%)	2/156 (1.28%)

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Impaired Healing	0/164 (0%)	2/156 (1.28%)
Malaise	0/164 (0%)	2/156 (1.28%)
Multi-organ Failure	1/164 (0.61%)	0/156 (0%)
Non-cardiac Chest Pain	0/164 (0%)	1/156 (0.64%)
Oedema Peripheral	0/164 (0%)	1/156 (0.64%)
Pyrexia	3/164 (1.83%)	4/156 (2.56%)
Immune system disorders		
Food Allergy	1/164 (0.61%)	0/156 (0%)
Kidney Transplant Rejection	3/164 (1.83%)	0/156 (0%)
Transplant Rejection	11/164 (6.71%)	8/156 (5.13%)
Infections and infestations		
Abscess Limb	0/164 (0%)	1/156 (0.64%)
Bacterial Infection	1/164 (0.61%)	0/156 (0%)
Bronchopneumonia	1/164 (0.61%)	0/156 (0%)
Campylobacter Infection	1/164 (0.61%)	0/156 (0%)
Cellulitis	1/164 (0.61%)	0/156 (0%)
Cytomegalovirus Colitis	1/164 (0.61%)	0/156 (0%)
Cytomegalovirus Hepatitis	1/164 (0.61%)	0/156 (0%)
Cytomegalovirus Infection	21/164 (12.8%)	5/156 (3.21%)
Cytomegalovirus Syndrome	12/164 (7.32%)	1/156 (0.64%)
Cytomegalovirus Viraemia	2/164 (1.22%)	0/156 (0%)
Erysipelas	0/164 (0%)	1/156 (0.64%)
Escherichia Sepsis	0/164 (0%)	1/156 (0.64%)
Escherichia Urinary Tract Infection	0/164 (0%)	1/156 (0.64%)
Febrile Infection	0/164 (0%)	1/156 (0.64%)
Folliculitis	1/164 (0.61%)	0/156 (0%)

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Gastroenteritis	2/164 (1.22%)	3/156 (1.92%)
Klebsiella Infection	1/164 (0.61%)	0/156 (0%)
Lung Infection Pseudomonal	0/164 (0%)	1/156 (0.64%)
Mediastinitis	0/164 (0%)	1/156 (0.64%)
Perirectal Abscess	1/164 (0.61%)	0/156 (0%)
Pneumonia	1/164 (0.61%)	2/156 (1.28%)
Pneumonia Streptococcal	1/164 (0.61%)	0/156 (0%)
Pyelonephritis	0/164 (0%)	1/156 (0.64%)
Pyelonephritis Acute	2/164 (1.22%)	2/156 (1.28%)
Sepsis	1/164 (0.61%)	3/156 (1.92%)
Septic Shock	1/164 (0.61%)	0/156 (0%)
Subcutaneous Abscess	1/164 (0.61%)	0/156 (0%)
Upper Respiratory Tract Infection	0/164 (0%)	1/156 (0.64%)
Urinary Tract Infection	7/164 (4.27%)	10/156 (6.41%)
Urosepsis	1/164 (0.61%)	0/156 (0%)
Wound Infection	1/164 (0.61%)	1/156 (0.64%)
Injury, poisoning and procedural complications		
Complications of Transplant Surgery	1/164 (0.61%)	0/156 (0%)
Complications of Transplanted Kidney	2/164 (1.22%)	1/156 (0.64%)
Contusion	0/164 (0%)	1/156 (0.64%)
Graft Dysfunction	0/164 (0%)	2/156 (1.28%)
Hip Fracture	1/164 (0.61%)	0/156 (0%)
Medical Device Complication	0/164 (0%)	1/156 (0.64%)
Overdose	1/164 (0.61%)	0/156 (0%)
Post Procedural Fistula	1/164 (0.61%)	0/156 (0%)
Ureteric Anastomosis Complication	0/164 (0%)	1/156 (0.64%)

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Wound Dehiscence	1/164 (0.61%)	0/156 (0%)
Wound Secretion	0/164 (0%)	1/156 (0.64%)
Investigations		
Blood Creatinine Increased	10/164 (6.1%)	8/156 (5.13%)
Metabolism and nutrition disorders		
Dehydration	4/164 (2.44%)	1/156 (0.64%)
Diabetes Mellitus	0/164 (0%)	2/156 (1.28%)
Diabetes Mellitus Inadequate Control	1/164 (0.61%)	0/156 (0%)
Diabetic Ketoacidosis	1/164 (0.61%)	0/156 (0%)
Hyperglycaemia	1/164 (0.61%)	0/156 (0%)
Hyperkalaemia	1/164 (0.61%)	1/156 (0.64%)
Hypoglycaemia	0/164 (0%)	1/156 (0.64%)
Hyponatraemia	0/164 (0%)	1/156 (0.64%)
Musculoskeletal and connective tissue disorders		
Arthralgia	0/164 (0%)	1/156 (0.64%)
Groin Pain	0/164 (0%)	1/156 (0.64%)
Muscle Haemorrhage	1/164 (0.61%)	1/156 (0.64%)
Muscular Weakness	0/164 (0%)	1/156 (0.64%)
Nervous system disorders		
Cerebrovascular Accident	1/164 (0.61%)	0/156 (0%)
Clonus	0/164 (0%)	1/156 (0.64%)
Neuropathy Peripheral	0/164 (0%)	1/156 (0.64%)
Tremor	0/164 (0%)	1/156 (0.64%)
Renal and urinary disorders		
Haematuria	1/164 (0.61%)	1/156 (0.64%)
Hydronephrosis	1/164 (0.61%)	0/156 (0%)

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Renal Artery Stenosis	1/164 (0.61%)	0/156 (0%)
Renal Failure	0/164 (0%)	1/156 (0.64%)
Renal Failure Acute	4/164 (2.44%)	2/156 (1.28%)
Renal Impairment	3/164 (1.83%)	2/156 (1.28%)
Renal Tubular Disorder	0/164 (0%)	1/156 (0.64%)
Renal Tubular Necrosis	0/164 (0%)	1/156 (0.64%)
Renal Vein Thrombosis	1/164 (0.61%)	0/156 (0%)
Ureteric Obstruction	1/164 (0.61%)	1/156 (0.64%)
Ureteric Stenosis	1/164 (0.61%)	1/156 (0.64%)
Reproductive system and breast disorders		
Benign Prostatic Hyperplasia	1/164 (0.61%)	1/156 (0.64%)
Respiratory, thoracic and mediastinal disorders		
Acute Pulmonary Oedema	0/164 (0%)	1/156 (0.64%)
Lung Disorder	1/164 (0.61%)	2/156 (1.28%)
Pulmonary Embolism	1/164 (0.61%)	1/156 (0.64%)
Pulmonary Oedema	1/164 (0.61%)	0/156 (0%)
Respiratory Failure	0/164 (0%)	1/156 (0.64%)
Surgical and medical procedures		
Ureteral Stent Removal	1/164 (0.61%)	0/156 (0%)
Vascular disorders		
Arterial Stenosis	1/164 (0.61%)	0/156 (0%)
Deep Vein Thrombosis	2/164 (1.22%)	1/156 (0.64%)
Haemorrhage	1/164 (0.61%)	0/156 (0%)
Hypotension	2/164 (1.22%)	0/156 (0%)
Iliac Artery Stenosis	1/164 (0.61%)	0/156 (0%)
Lymphocele	2/164 (1.22%)	3/156 (1.92%)

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Phlebitis	2/164 (1.22%)	0/156 (0%)
Shock Haemorrhagic	1/164 (0.61%)	0/156 (0%)
Venous Thrombosis	0/164 (0%)	1/156 (0.64%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Total	133/164 (81.1%)	141/156 (90.38%)
Blood and lymphatic system disorders		
Anaemia	29/164 (17.68%)	24/156 (15.38%)
Leukopenia	41/164 (25%)	58/156 (37.18%)
Neutropenia	22/164 (13.41%)	16/156 (10.26%)
Thrombocytopenia	6/164 (3.66%)	8/156 (5.13%)
Gastrointestinal disorders		
Abdominal Pain	12/164 (7.32%)	8/156 (5.13%)
Abdominal Pain Upper	7/164 (4.27%)	8/156 (5.13%)
Constipation	24/164 (14.63%)	14/156 (8.97%)
Diarrhoea	41/164 (25%)	48/156 (30.77%)
Dyspepsia	3/164 (1.83%)	11/156 (7.05%)
Nausea	18/164 (10.98%)	17/156 (10.9%)
Vomiting	6/164 (3.66%)	10/156 (6.41%)
General disorders		
Fatigue	7/164 (4.27%)	14/156 (8.97%)
Oedema Peripheral	35/164 (21.34%)	30/156 (19.23%)
Pyrexia	17/164 (10.37%)	10/156 (6.41%)
Infections and infestations		

	Valganciclovir up to 100 Days	Valganciclovir up to 200 Days
	Affected/At Risk (%)	Affected/At Risk (%)
Nasopharyngitis	17/164 (10.37%)	12/156 (7.69%)
Upper Respiratory Tract Infection	14/164 (8.54%)	14/156 (8.97%)
Urinary Tract Infection	20/164 (12.2%)	29/156 (18.59%)
Investigations		
Blood Creatinine Increased	11/164 (6.71%)	9/156 (5.77%)
Metabolism and nutrition disorders		
Hyperkalaemia	20/164 (12.2%)	14/156 (8.97%)
Hypomagnesaemia	17/164 (10.37%)	10/156 (6.41%)
Hypophosphataemia	20/164 (12.2%)	18/156 (11.54%)
Nervous system disorders		
Headache	16/164 (9.76%)	9/156 (5.77%)
Tremor	19/164 (11.59%)	25/156 (16.03%)
Psychiatric disorders		
Insomnia	12/164 (7.32%)	10/156 (6.41%)
Renal and urinary disorders		
Haematuria	7/164 (4.27%)	9/156 (5.77%)
Respiratory, thoracic and mediastinal disorders		
Cough	17/164 (10.37%)	7/156 (4.49%)
Dyspnoea	9/164 (5.49%)	6/156 (3.85%)
Oropharyngeal Pain	6/164 (3.66%)	8/156 (5.13%)
Skin and subcutaneous tissue disorders		
Rash	9/164 (5.49%)	5/156 (3.21%)
Vascular disorders		
Hypertension	21/164 (12.8%)	19/156 (12.18%)
Hypotension	10/164 (6.1%)	3/156 (1.92%)

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.

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