Clinical trial results:
A Randomized, Placebo-Controlled, Phase 2 Study of HB-101, a Bivalent Cytomegalovirus (CMV) Vaccine, in CMV-Seronegative Recipient (R-) Patients Awaiting Kidney Transplantation from Living CMV-Seropositive Donors (D+)

Summary

EudraCT number	2017-005047-32
Trial protocol	DK BE FR AT NO DE NL
Global end of trial date	22 June 2022
Results information	
Result version number	v1 (current)
This version publication date	08 July 2023
First version publication date	08 July 2023

Trial information

Trial identification	
Sponsor protocol code	H-100-002
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03629080
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Hookipa Biotech GmbH
Sponsor organisation address	Helmut-Qualtinger-Gasse 2, Vienna, Austria, 1030
Public contact	General Contact, Hookipa Biotech GmbH, +43 18906360, office@hookipapharma.com
Scientific contact	General Contact, Hookipa Biotech GmbH, +43 18906360, office@hookipapharma.com

Notes:

Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 May 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 June 2022
Global end of trial reached?	Yes
Global end of trial date	22 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1.To assess the safety and reactogenicity of HB-101.

2.To assess the immunogenicity of HB-101.

Protection of trial subjects:

All considerations regarding the protection of human subjects were carried out in accordance with the protocol, GCP, ICH Guidelines, the ethical principles that have their origin in the Declaration of Helsinki, and all applicable regulatory requirements. The investigator (according to applicable regulatory requirements) or a person designated by the investigator and under the investigator's responsibility fully informed patients of all pertinent aspects of the clinical trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 50
Country: Number of subjects enrolled	Norway: 1
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	France: 11
Country: Number of subjects enrolled	Germany: 6
Worldwide total number of subjects	83
EEA total number of subjects	19

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	71
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Overall, 90 patients were screened. Seven (7.8%) patients were screen-failed and 83 (92.2%) were subsequently randomized/enrolled. The reasons for screen failure were withdrawal by patient (4 [4.4%] patients), failure to meet inclusion/exclusion criteria (2 [2.2%] patients), and other (1 [1.1%]. The study was conducted at 26 global sites.

Pre-assignment

Screening details:

Male and female patients 18 years of age or older who were eligible to undergo kidney transplantation from a living donor. Groups 1 and 2: CMV immunoglobulin G (IgG) seronegative (-) patients receiving a kidney from CMV IgG seropositive (+) donors. Group 3: CMV IgG (+) patients receiving a kidney from CMV IgG (+) or CMV IgG (-) donors.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The study was double-blinded for Groups 1 and 2; patients and Investigators were blinded to study treatment. The Sponsor study team members were unblinded after each patient received their last dose of study drug and underwent his/her kidney transplantation. Medpace, the Investigator, and study site personnel remained blinded for the entire study with the exception of the study site pharmacist who prepared the study drug for administration. Group 3 was open label; no randomization or blinding.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: Arm 1a: HB-101 vaccine preemptive

Arm description:

Group 1: The preemptive group (CMV seronegative) was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients were monitored per preemptive institutional standards.
Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Arm type	Experimental
Investigational medicinal product name	HB-101
Investigational medicinal product code	HK1-HgB and HK1-Hpp65
Other name	rLCMV vector (HK1) encoding human CMV glycoprotein B (gB) and phosphoprotein 65 kD (Hpp65)
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

HB-101 uses replication-deficient lymphocytic choriomeningitis virus (rLCMV) as a vector for a bivalent recombinant vaccine against human cytomegalovirus (HCMV). One vector expresses the pp65 protein of HCMV, and one expresses a truncated gB protein of HCMV. HB-101 was produced pre-diluted and ready-to-use.
HB-101 is formulated at 1.2 E8 focus-forming units/mL. The product is filled in 2 mL single-dose vials containing 0.7 mL of vaccine. The volume of administration of 1 dose of HB-101 is 1.0 mL.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant. Patients enrolled had to have a

kidney transplantation planned between 2 and 4 months after the first injection of study drug. This was to ensure that patients received at least 2 doses of HB-101.

Arm title	Group 1: Arm 1b: Placebo preemptive

Arm description:

Group 1: The preemptive group (CMV seronegative) was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients were monitored per preemptive institutional standards.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.
Three intramuscular doses of placebo were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

Saline (0.9% w/v NaCl) as a ready-to-use solution for intramuscular injection was used as the placebo. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant. Patients enrolled had to have a kidney transplantation planned between 2 and 4 months after the first injection of the placebo.

Arm title	Group 2: Arm 2a: HB-101 vaccine prophylactic

Arm description:

Group 2 - The prophylactic group was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients received 3 to 6 months of anti-viral prophylaxis following institutional standards.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Arm type	Experimental
Investigational medicinal product name	HB-101
Investigational medicinal product code	HK1-HgB and HK1-Hpp65
Other name	rLCMV vector (HK1) encoding human CMV glycoprotein B (gB) and phosphoprotein 65 kD (Hpp65)
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

HB-101 uses replication-deficient lymphocytic choriomeningitis virus (rLCMV) as a vector for a bivalent recombinant vaccine against human cytomegalovirus (HCMV). One vector expresses the pp65 protein of HCMV, and one expresses a truncated gB protein of HCMV. HB-101 was produced pre-diluted and ready-to-use.
HB-101 is formulated at 1.2 E8 focus-forming units/mL. The product is filled in 2 mL single-dose vials containing 0.7 mL of vaccine. The volume of administration of 1 dose of HB-101 is 1.0 mL.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant. Patients enrolled had to have a

kidney transplantation planned between 2 and 4 months after the first injection of study drug. This was to ensure that patients received at least 2 doses of HB-101.

Arm title	Group 2: Arm 2b: Placebo prophylactic

Arm description:

Group 2 - The prophylactic group was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients received 3 to 6 months of anti-viral prophylaxis following institutional standards.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant. Three intramuscular doses of placebo were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

Saline (0.9% w/v NaCl) as a ready-to-use solution for intramuscular injection was used as the placebo. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant. Patients enrolled had to have a kidney transplantation planned between 2 and 4 months after the first injection of the placebo.

Arm title	Group 3: HB-101 vaccine: CMV (+) patients: preemptive

Arm description:

Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.
The ITT Population included all patients who were enrolled in the study. For Group 3, enrollment was defined as receiving at least 1 dose of study drug.
The mITT Population included all ITT Population patients who received a kidney transplant and at least 2 doses of study drug prior to kidney transplant.
For this arm, "study completion" means that the patient was included in the mITT Population.

Arm type	Experimental
Investigational medicinal product name	HB-101
Investigational medicinal product code	HK1-HgB and HK1-Hpp65
Other name	rLCMV vector (HK1) encoding human CMV glycoprotein B (gB) and phosphoprotein 65 kD (Hpp65)
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

HB-101 uses replication-deficient lymphocytic choriomeningitis virus (rLCMV) as a vector for a bivalent recombinant vaccine against human cytomegalovirus (HCMV). One vector expresses the pp65 protein of HCMV, and one expresses a truncated gB protein of HCMV. HB-101 was produced pre-diluted and ready-to-use.
HB-101 is formulated at 1.2 E8 focus-forming units/mL. The product is filled in 2 mL single-dose vials containing 0.7 mL of vaccine. The volume of administration of 1 dose of HB-101 is 1.0 mL.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant. Patients enrolled had to have a kidney transplantation planned between 2 and 4 months after the first injection of study drug. This was to ensure that patients received at least 2 doses of HB-101.

Arm title	Group 3: HB-101 vaccine: CMV (+) patients: prophylactic

Arm description:

Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.
The ITT Population included all patients who were enrolled in the study. For Group 3, enrollment was defined as receiving at least 1 dose of study drug.
The mITT Population included all ITT Population patients who received a kidney transplant and at least 2 doses of study drug prior to kidney transplant.
For this arm, "study completion" means that the patient was included in the mITT Population.

Arm type	Experimental
Investigational medicinal product name	HB-101
Investigational medicinal product code	HK1-HgB and HK1-Hpp65
Other name	rLCMV vector (HK1) encoding human CMV glycoprotein B (gB) and phosphoprotein 65 kD (Hpp65)
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

HB-101 uses replication-deficient lymphocytic choriomeningitis virus (rLCMV) as a vector for a bivalent recombinant vaccine against human cytomegalovirus (HCMV). One vector expresses the pp65 protein of HCMV, and one expresses a truncated gB protein of HCMV. HB-101 was produced pre-diluted and ready-to-use.
HB-101 is formulated at 1.2 E8 focus-forming units/mL. The product is filled in 2 mL single-dose vials containing 0.7 mL of vaccine. The volume of administration of 1 dose of HB-101 is 1.0 mL.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant. Patients enrolled had to have a kidney transplantation planned between 2 and 4 months after the first injection of study drug. This was to ensure that patients received at least 2 doses of HB-101.

Number of subjects in period 1	Group 1: Arm 1a: HB-101 vaccine preemptive	Group 1: Arm 1b: Placebo preemptive	Group 2: Arm 2a: HB-101 vaccine prophylactic
Started	12	5	35
Completed	10	4	22
Not completed	2	1	13
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	-	1	2
Physician decision	-	-	1
Kidney transplant was delayed	-	-	3
Adverse event, non-fatal	-	-	1
Kidney transplant was delayed	-	-	-
Other	1	-	2
Did not receive at least 2 doses of study drug	-	-	-
Failure to comply with Protocol requirements	1	-	1
Lost to follow-up	-	-	2

Number of subjects in period 1	Group 2: Arm 2b: Placebo prophylactic	Group 3: HB-101 vaccine: CMV (+) patients: preemptive	Group 3: HB-101 vaccine: CMV (+) patients: prophylactic

Started	17	4	10
Completed	16	3	6
Not completed	1	1	4
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	-
Physician decision	-	-	-
Kidney transplant was delayed	-	-	-
Adverse event, non-fatal	-	-	-
Kidney transplant was delayed	-	1	3
Other	-	-	-
Did not receive at least 2 doses of study drug	-	-	1
Failure to comply with Protocol requirements	-	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Group 1: Arm 1a: HB-101 vaccine preemptive

Reporting group description:

Group 1: The preemptive group (CMV seronegative) was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients were monitored per preemptive institutional standards.
Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 1: Arm 1b: Placebo preemptive

Reporting group description:

Group 1: The preemptive group (CMV seronegative) was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients were monitored per preemptive institutional standards.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.
Three intramuscular doses of placebo were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 2: Arm 2a: HB-101 vaccine prophylactic

Reporting group description:

Group 2 - The prophylactic group was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients received 3 to 6 months of anti-viral prophylaxis following institutional standards.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 2: Arm 2b: Placebo prophylactic

Reporting group description:

Group 2 - The prophylactic group was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients received 3 to 6 months of anti-viral prophylaxis following institutional standards.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.
Three intramuscular doses of placebo were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 3: HB-101 vaccine: CMV (+) patients: preemptive

Reporting group description:

Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.
The ITT Population included all patients who were enrolled in the study. For Group 3, enrollment was

defined as receiving at least 1 dose of study drug.
The mITT Population included all ITT Population patients who received a kidney transplant and at least 2 doses of study drug prior to kidney transplant.
For this arm, "study completion" means that the patient was included in the mITT Population.

Reporting group title	Group 3: HB-101 vaccine: CMV (+) patients: prophylactic

Reporting group description:

Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.
The ITT Population included all patients who were enrolled in the study. For Group 3, enrollment was defined as receiving at least 1 dose of study drug.
The mITT Population included all ITT Population patients who received a kidney transplant and at least 2 doses of study drug prior to kidney transplant.
For this arm, "study completion" means that the patient was included in the mITT Population.

Reporting group values	Group 1: Arm 1a: HB-101 vaccine preemptive	Group 1: Arm 1b: Placebo preemptive	Group 2: Arm 2a: HB-101 vaccine prophylactic
Number of subjects	12	5	35
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	9	2	31
From 65-84 years	3	3	4
85 years and over	0	0	0
Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a maximum of 69 years.			
Units: years			
arithmetic mean	47.5	63.6	47.3
standard deviation	± 15.17	± 9.45	± 15.13
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	4	0	6
Male	8	5	29

Reporting group values	Group 2: Arm 2b: Placebo prophylactic	Group 3: HB-101 vaccine: CMV (+) patients: preemptive	Group 3: HB-101 vaccine: CMV (+) patients: prophylactic
Number of subjects	17	4	10
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	4	9
From 65-84 years	1	0	1
85 years and over	0	0	0
Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a maximum of 69 years.			
Units: years			
arithmetic mean	45.5	48.3	49.5
standard deviation	± 13.99	± 6.99	± 11.92
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	6	1	7
Male	11	3	3

Reporting group values	Total		
Number of subjects	83		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	71		
From 65-84 years	12		
85 years and over	0		

Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a maximum of 69 years.			
Units: years arithmetic mean standard deviation	- 		
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	24		
Male	59		

Subject analysis sets

Subject analysis set title	Safety Population Arm 1a: HB-101: Preemptive
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.

Subject analysis set title	Safety Population Arm 2a: HB-101: Prophylactic
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Safety Population Arm 1b: Placebo: Preemptive
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.

Subject analysis set title	Safety Population Arm 2b: Placebo: Prophylactic
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Safety Population Group 3: HB-101: CMV (+): Preemptive
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.

Subject analysis set title	Safety Population Group 3: HB-101: CMV (+): Prophylactic
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.

Subject analysis set title	Immunogenicity Population Arm 1a: HB-101: Preemptive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all ITT Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.

Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Arm 1b: Placebo: Preemptive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Arm 2a: HB-101: Prophylactic
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Arm 2b: Placebo: Prophylactic
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Group 3: HB-101: CMV (+) preemptive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.

Subject analysis set title	Immunogenicity Population Group 3 HB-101: CMV (+) Prophylactic

Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.

Reporting group values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive
Number of subjects	11	34	4
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	8	30	1
From 65-84 years	3	4	3
85 years and over	0	0	0
Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a maximum of 69 years.			
Units: years			
arithmetic mean	46.90	47.08	66.25
standard deviation	± 15.76	± 15.29	± 8.26
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	3	6	1
Male	8	28	3

Reporting group values	Safety Population Arm 2b: Placebo: Prophylactic	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic
Number of subjects	17	4	10
Age categorical Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	4	9
From 65-84 years	1	0	1
85 years and over	0	0	0
Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a maximum of 69 years.			
Units: years			
arithmetic mean	45.82	48.25	49.50
standard deviation	± 14.05	± 6.99	± 11.91
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	6	1	3
Male	11	3	7

Reporting group values	Immunogenicity Population Arm 1a: HB-101: Preemptive	Immunogenicity Population Arm 1b: Placebo: Preemptive	Immunogenicity Population Arm 2a: HB-101: Prophylactic
Number of subjects	11	4	27
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	9	1	25
From 65-84 years	2	3	2
85 years and over	0	0	0
Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a			

maximum of 69 years.			
Units: years			
arithmetic mean	45.72	65.50	44.66
standard deviation	± 14.55	± 9.74	± 15.62
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	4	0	4
Male	7	4	23

Reporting group values	Immunogenicity Population Arm 2b: Placebo: Prophylactic	Immunogenicity Population Group 3: HB-101: CMV (+) preemptive	Immunogenicity Population Group 3 HB-101: CMV (+) Prophylactic
Number of subjects	13	3	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	12	3	7
From 65-84 years	1	0	1
85 years and over	0	0	0
Age continuous			
ITT Population: For the 47 patients randomized to HB-101 in Groups 1 and 2, the mean age (standard deviation [SD]) was 47.4 (14.97) years with a minimum of 20 and a maximum of 70 years. Of the 22 patients randomized to placebo in Groups 1 and 2, the mean age (SD) was 49.6 (15.04) years with a minimum of 24 and a maximum of 72 years. For the 14 patients in Group 3, the mean age (SD) was 49.1 (10.49) years with a minimum of 35 and a maximum of 69 years.			
Units: years			
arithmetic mean	48.38	49.33	51.00
standard deviation	± 13.90	± 8.14	± 12.21
Gender categorical			
ITT Population: Of the 47 patients randomized to HB-101 in Groups 1 and 2, 37 (78.7%) were male and 10 (21.3%) were female. Of the 22 patients randomized to placebo in Groups 1 and 2, 16 (72.7%) were male and 6 (27.3%) were female. Of the 14 patients in Group 3, 10 (71.4%) were male and 4 (28.6%) were female.			
Units: Subjects			
Female	5	1	3
Male	8	2	5

End points

End points reporting groups

Reporting group title	Group 1: Arm 1a: HB-101 vaccine preemptive

Reporting group description:

Group 1: The preemptive group (CMV seronegative) was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients were monitored per preemptive institutional standards.
Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 1: Arm 1b: Placebo preemptive

Reporting group description:

Group 1: The preemptive group (CMV seronegative) was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients were monitored per preemptive institutional standards.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.
Three intramuscular doses of placebo were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 2: Arm 2a: HB-101 vaccine prophylactic

Reporting group description:

Group 2 - The prophylactic group was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients received 3 to 6 months of anti-viral prophylaxis following institutional standards.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.
Three intramuscular doses of study drug were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 2: Arm 2b: Placebo prophylactic

Reporting group description:

Group 2 - The prophylactic group was randomized in a 2:1 ratio (HB-101:placebo) to receive either HB-101 or placebo before transplant. Post-transplant patients received 3 to 6 months of anti-viral prophylaxis following institutional standards.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.
Three intramuscular doses of placebo were to be administered. The ideal dosing schedule for the 3 doses was planned for 0, 1, and 3 months prior to kidney transplant.
The Intent-to-Treat (ITT) Population includes all patients who were enrolled. For Group 1 and Group 2, enrolled is defined as being randomized and patients were analyzed by their randomized treatment group.

Reporting group title	Group 3: HB-101 vaccine: CMV (+) patients: preemptive

Reporting group description:

Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.
The ITT Population included all patients who were enrolled in the study. For Group 3, enrollment was

defined as receiving at least 1 dose of study drug.
The mITT Population included all ITT Population patients who received a kidney transplant and at least 2 doses of study drug prior to kidney transplant.
For this arm, "study completion" means that the patient was included in the mITT Population.

Reporting group title	Group 3: HB-101 vaccine: CMV (+) patients: prophylactic

Reporting group description:

Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.
The ITT Population included all patients who were enrolled in the study. For Group 3, enrollment was defined as receiving at least 1 dose of study drug.
The mITT Population included all ITT Population patients who received a kidney transplant and at least 2 doses of study drug prior to kidney transplant.
For this arm, "study completion" means that the patient was included in the mITT Population.

Subject analysis set title	Safety Population Arm 1a: HB-101: Preemptive
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.

Subject analysis set title	Safety Population Arm 2a: HB-101: Prophylactic
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Safety Population Arm 1b: Placebo: Preemptive
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.

Subject analysis set title	Safety Population Arm 2b: Placebo: Prophylactic
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Safety Population Group 3: HB-101: CMV (+): Preemptive
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.

Subject analysis set title	Safety Population Group 3: HB-101: CMV (+): Prophylactic
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.

Subject analysis set title	Immunogenicity Population Arm 1a: HB-101: Preemptive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all ITT Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.

Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Arm 1b: Placebo: Preemptive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Arm 2a: HB-101: Prophylactic
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Arm 2b: Placebo: Prophylactic
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.

Subject analysis set title	Immunogenicity Population Group 3: HB-101: CMV (+) preemptive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.

Subject analysis set title	Immunogenicity Population Group 3 HB-101: CMV (+) Prophylactic
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The Immunogenicity Population included all Intent-to-Treat (ITT) Population patients who received at least 1 dose of study drug and who had at least 1 post-dose immunogenicity measurement.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.

Primary: Safety: Incidence and severity of AEs and SAEs

End point title	Safety: Incidence and severity of AEs and SAEs[1]

End point description:

Groups 1 and 2: Overall, 42 (63.6%) patients reported AEs during the pre-transplant period. Overall, 13 (19.7%) patients experienced a TEAE related to study drug pre-transplant and 2 (3.0%) patients experienced TEAEs related to study drug of Grade 3 or higher. Overall, 29 (64.4%) patients in the HB-101 treatment group reported TEAEs post-transplant: 6 (54.5%) patients who received preemptive care and 23 (67.6%) patients who received prophylactic treatment. There were 19 (42.2%) patients in the HB-101 treatment group who experienced SAEs and 19 (42.2%) patients who experienced treatment-emergent SAEs.
Group 3: Overall, 8 (57.1%) patients reported AEs and 3 (21.4%) patients experienced a TEAE related to study drug during the pre-transplant period.
Overall, 9 (64.3%) patients reported TEAEs post-transplant: 3 (75.0%) patients who received preemptive care and 6 (60.0%) patients who received prophylactic treatment.

End point type	Primary

End point timeframe:

Adverse events (AEs) were captured from the date of informed consent through study completion (15 months).A treatment-emergent AE (TEAE) was defined as an AE with a start date and time on or after the first administration of study drug.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Safety assessments were were summarized by descriptive statistics. However, AEs were captured from the date of informed consent through study completion. All AEs were coded to SOC and PT using the MedDRA version 22.0 and analyzed using the Safety Population. This information can be found in the "Adverse Events" section.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	34	4	17
Units: patients	11	34	4	17

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	10		
Units: patients	4	10		

Statistical analyses

No statistical analyses for this end point

Primary: Safety: Body temperature

End point title	Safety: Body temperature[2]

End point description:

Oral body temperature was measured in degrees Celsius prior to study drug administrations and seven days after.

RESULTS: The results express the change from baseline to Dose 3. There were no clinically meaningful changes in the median values for body temperature assessment from baseline.

End point type	Primary

End point timeframe:

Change from Baseline to Dose 3. Three (3) months.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Vital signs including height, weight, systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature were summarized by descriptive statistics for each treatment group.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	12	1	7
Units: celsius temperature				
arithmetic mean (standard deviation)	-0.0 (± 0.4)	0.2 (± 0.6)	-0.1 (± 0.0)	-0.3 (± 0.26)

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: celsius temperature				
arithmetic mean (standard deviation)	-0.2 (± 0.57)	0.6 (± 0.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Safety: Respiratory rate

End point title	Safety: Respiratory rate[3]

End point description:

Respiration rate in breaths per minute was measured prior to study drug administration and seven days after.

RESULTS: The results express the change from baseline to Dose 3. There were no clinically meaningful changes in the median values for respiratory rate assessment from baseline.

End point type	Primary

End point timeframe:

Change from Baseline to Dose 3. Three (3) months.

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Vital signs including height, weight, systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature were summarized by descriptive statistics for each

treatment group.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	11	1	7
Units: breaths/minute				
arithmetic mean (standard deviation)	0.5 (± 5.26)	0.2 (± 2.56)	0.0 (± 0.0)	-0.6 (± 2.70)

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: breaths/minute				
arithmetic mean (standard deviation)	-4.0 (± 8.49)	2.0 (± 0.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Safety: Diastolic blood pressure

End point title	Safety: Diastolic blood pressure[4]

End point description:

Diastolic Blood Pressure was measured in millimeters of mercury (mmHg) prior to study drug administration and seven days after.

RESULTS: There were no clinically meaningful changes in the median values for diastolic or systolic blood pressure assessments from baseline.

End point type	Primary

End point timeframe:

Change from Baseline to Dose 3.
Three (3) months.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Vital signs including height, weight, systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature were summarized by descriptive statistics for each treatment group.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	13	1	7
Units: mmHg				
arithmetic mean (standard deviation)	0.5 (± 5.74)	2.6 (± 9.55)	2.0 (± 0.0)	1.3 (± 6.47)

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: mmHg				
arithmetic mean (standard deviation)	6.0 (± 0.0)	6.0 (± 0.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Safety: Systolic Blood Pressure

End point title	Safety: Systolic Blood Pressure[5]

End point description:

Systolic Blood Pressure was measured in millimeters of mercury (mmHg) prior to study drug administration and seven days after.

RESULTS: The results express the change from baseline to Dose 3. There were no clinically meaningful changes in the median values for systolic blood pressure assessments from baseline.

End point type	Primary

End point timeframe:

Change from Baseline to Dose 3. Three (3) months.

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Vital signs including height, weight, systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature were summarized by descriptive statistics for each treatment group.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	13	1	7
Units: mmHg				
arithmetic mean (standard deviation)	-5.5 (± 12.61)	5.4 (± 14.36)	11.0 (± 0.0)	2.7 (± 19.81)

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: mmHg				
arithmetic mean (standard deviation)	2.0 (± 2.83)	5.0 (± 0.0)		

Statistical analyses

No statistical analyses for this end point

Primary: CMV neutralizing antibody titers (NTAs) at day of Transplant for 2 doses

End point title	CMV neutralizing antibody titers (NTAs) at day of Transplant for 2 doses[6]

End point description:

GMT=geometric mean titer (defined as the antilog10 of the mean of log10 values). The CMV neut parameter underwent all tests and summaries of the other parameters with the addition of a 95% confidence interval of the geometric mean titer.
Overall, 12 patients treated with HB-101 had positive CMV titers on the day of transplant: 2 (33.3%) patients who received 2 doses of HB-101 and preemptive care; 1 (50.0%) patient who received 3 doses of HB-101 and preemptive care; 4 (26.7%) patients who received 2 doses of HB-101 and prophylactic treatment; and 5 (100.0%) patients who received 3 doses of HB-101 and prophylactic treatment.
Compared to placebo, more patients treated with HB-101 had positive CMV titers on the day of transplant. Patients who received 3 doses of HB-101 and prophylactic treatment had statistically significant higher CMV titers compared to placebo (p=0.0022) on the day of transplant.

End point type	Primary

End point timeframe:

Day of transplant. Three (3) months.

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: CMV neutralizing antibody titers (NTAs) at day of transplant for 2 doses were summarized by descriptive statistics for each treatment group.

End point values	Immunogenicity Population Arm 1a: HB-101: Preemptive	Immunogenicity Population Arm 1b: Placebo: Preemptive	Immunogenicity Population Arm 2a: HB-101: Prophylactic	Immunogenicity Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	2	15	7
Units: log10 virus neutralising unit(s)				
geometric mean (confidence interval 95%)	6.1 (3.0 to 12.3)	4 (4 to 4)	6.6 (4.0 to 10.9)	5.8 (2.4 to 14.0)

End point values	Immunogenicit	Immunogenicit		

	y Population Group 3: HB-101: CMV (+) preemptive	y Population Group 3 HB-101: CMV (+) Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1	4		
Units: log10 virus neutralising unit(s)				
geometric mean (confidence interval 95%)	314.0 (314.0 to 314.0)	375.0 (228.1 to 615.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Reactogenicity: Local - Injection site reactions

End point title	Reactogenicity: Local - Injection site reactions[7]

End point description:

Incidence and severity of localized injection site reactions were summarized by symptom type and by injection site and symptom type for the Safety Population.
Group 1 and 2: The majority of local injection site reactions did not receive a Grade (mild, moderate, or severe); however, of those that did receive a Grade, the majority were mild. There were no severe or life threatening injection site reactions reported. The majority of local injection site reactions between patients who received HB-101 were comparable to patients who received placebo. There were more patients that reported mild tenderness in the HB-101 treatment group versus the placebo treatment group (5 [11.1%] patients versus 1 [4.8%] patient, respectively).
Group 3: The majority of local injection site reactions did not receive a Grade (mild, moderate, or severe); however, of those that did receive a Grade, the majority were mild. There were no severe or life threatening injection site reactions reported.

End point type	Primary

End point timeframe:

Potential signs/symptoms of reactogenicity were assessed after each study drug administration. Fifteen (15) months.

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: For assessing the safety and reactogenicity of HB-101, the incidence and severity of localized or generalized injection site reactions were summarized by descriptive statistics, by symptom type and by injection site and symptom type for the Safety Population.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	34	4	17
Units: patients	2	9	0	4

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	10		

Units: patients	4	5		

Statistical analyses

No statistical analyses for this end point

Primary: Reactogenicity: General- Injection site reactions

End point title	Reactogenicity: General- Injection site reactions[8]

End point description:

The incidence and severity of generalized injection site reactions were summarized by symptom type and by injection site and symptom type for the Safety Population.
Group 1 and 2: The majority of systemic (general) injection site reactions did not receive a Grade (mild, moderate, or severe); however, of those that did receive a Grade, the majority were mild. There were no severe or life threatening injection site reactions.
Overall, there were more patients that reported systemic (general) injection site reactions to study drug in the HB-101 treatment group versus the placebo treatment group.

Group 3: The majority of systemic (general) injection site reactions did not receive a Grade (mild, moderate, or severe); however, of those that did receive a Grade, the majority were mild. There were no severe or life threatening injection site reactions.

End point type	Primary

End point timeframe:

Potential signs/symptoms of reactogenicity were assessed after each study drug administration. Fifteen (15) months.

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: For assessing the safety and reactogenicity of HB-101, the incidence and severity of localized or generalized injection site reactions were summarized by descriptive statistics, by symptom type and by injection site and symptom type for the Safety Population.

End point values	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	34	4	17
Units: patients	2	9	0	4

End point values	Safety Population Group 3: HB-101: CMV (+): Preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	10		
Units: patients	4	5		

Statistical analyses

No statistical analyses for this end point

Primary: CMV neutralizing antibody titers (NTAs) at day of Transplant for 3 doses

End point title	CMV neutralizing antibody titers (NTAs) at day of Transplant for 3 doses[9]

End point description:

GMT=geometric mean titer (defined as the antilog10 of the mean of log10 values). The CMV neut parameter underwent all tests and summaries of the other parameters with the addition of a 95% confidence interval of the geometric mean titer.
Overall, 12 patients treated with HB-101 had positive CMV titers on the day of transplant: 2 (33.3%) patients who received 2 doses of HB-101 and preemptive care; 1 (50.0%) patient who received 3 doses of HB-101 and preemptive care; 4 (26.7%) patients who received 2 doses of HB-101 and prophylactic treatment; and 5 (100.0%) patients who received 3 doses of HB-101 and prophylactic treatment.
Compared to placebo, more patients treated with HB-101 had positive CMV titers on the day of transplant. Patients who received 3 doses of HB-101 and prophylactic treatment had statistically significant higher CMV titers compared to placebo (p=0.0022) on the day of transplant.

End point type	Primary

End point timeframe:

Day of transplant. Three (3) months.

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: CMV neutralizing antibody titers (NTAs) at day of transplant for 3 doses were summarized by descriptive statistics for each treatment group.

End point values	Immunogenicity Population Arm 1a: HB-101: Preemptive	Immunogenicity Population Arm 1b: Placebo: Preemptive	Immunogenicity Population Arm 2a: HB-101: Prophylactic	Immunogenicity Population Arm 2b: Placebo: Prophylactic
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	2	5	6
Units: log10 virus neutralising unit(s)				
geometric mean (confidence interval 95%)	11.7 (0.0 to 999)	4.0 (4.0 to 4.0)	26.9 (13.7 to 52.8)	4.0 (4.0 to 4.0)

End point values	Immunogenicity Population Group 3: HB-101: CMV (+) preemptive	Immunogenicity Population Group 3 HB-101: CMV (+) Prophylactic		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: log10 virus neutralising unit(s)				
geometric mean (confidence interval 95%)	334.7 (0.0 to 999)	464.0 (464.0 to 464.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All adverse events (AEs) were recorded from the time of the first injection of study drug up through 30 days after the last injection. Only AEs considered by the Investigator to be related to study drug were recorded from 31 days to End of Study Visit.

Adverse event reporting additional description:

Listings are presented specifically for non serious treatment-emergent AEs (TEAEs) and serious TEAEs occurred pre- and post-transplant in the Safety Population.
The Safety Population includes all patients in the Intent-to-Treat (ITT) Population who received any study drug and were analyzed by their actual treatment group.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Safety Population Arm 1a: HB-101: Preemptive

Reporting group description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 1a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive HB-101 before transplant, and monitoring after transplant.

Reporting group title	Safety Population Arm 1b: Placebo: Preemptive

Reporting group description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 1b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor randomized to receive placebo before transplant, and monitoring after transplant.

Reporting group title	Safety Population Arm 2a: HB-101: Prophylactic

Reporting group description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 2a: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive HB-101 before transplant, and anti-viral prophylaxis and monitoring after transplant.

Reporting group title	Safety Population Arm 2b: Placebo: Prophylactic

Reporting group description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Arm 2b: CMV seronegative (-) patients awaiting kidney transplant from a CMV seropositive (+) living donor to receive placebo before transplant, and anti-viral prophylaxis and monitoring after transplant.

Reporting group title	Safety Population Group 3: HB-101: CMV (+) patient: preemptive

Reporting group description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant CMV management followed preemptive care as defined at study enrollment by the Investigator and institutional standards.

Reporting group title	Safety Population Group 3: HB-101: CMV (+): Prophylactic

Reporting group description:

The Safety Population included all patients in the Intent-to-Treat (ITT) Population who received any study drug.
Adult CMV seropositive (+) patients awaiting kidney transplant from a CMV seropositive (+) or CMV seronegative (-) living donor were enrolled into Group 3. Post-transplant patients received anti-viral prophylaxis following institutional standards.

Serious adverse events	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 11 (45.45%)	2 / 4 (50.00%)	14 / 34 (41.18%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	2 / 11 (18.18%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant rejection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HLA marker study positive			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	3 / 34 (8.82%)
occurrences causally related to treatment / all	1 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Bicuspid aortic valve			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial infarction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary ostial stenosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular injury			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperparathyroidism tertiary			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Neuropathic arthropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
corona virus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus viraemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 4 (25.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastritis viral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Safety Population Arm 2b: Placebo: Prophylactic	Safety Population Group 3: HB-101: CMV (+) patient: preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 17 (29.41%)	2 / 4 (50.00%)	2 / 10 (20.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant rejection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	2 / 10 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea paroxysmal nocturnal			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HLA marker study positive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Bicuspid aortic valve			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary ostial stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperparathyroidism tertiary			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Neuropathic arthropathy			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rheumatoid arthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
corona virus infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus viraemia			
subjects affected / exposed	3 / 17 (17.65%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Safety Population Arm 1a: HB-101: Preemptive	Safety Population Arm 1b: Placebo: Preemptive	Safety Population Arm 2a: HB-101: Prophylactic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 11 (54.55%)	3 / 4 (75.00%)	23 / 34 (67.65%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 11 (9.09%)	2 / 4 (50.00%)	2 / 34 (5.88%)
occurrences (all)	1	2	2
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Pallor			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Skin cyst excision			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	4 / 34 (11.76%)
occurrences (all)	0	0	4
Influenza like illness			
subjects affected / exposed	2 / 11 (18.18%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
Pyrexia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	2 / 34 (5.88%)
occurrences (all)	0	2	3
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
Feeling hot			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Swelling			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Vessel puncture site pruritus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Kidney transplant rejection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Rales			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Sleep apnoea syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
Investigations			
Blood creatine increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
Cytomegalovirus test positive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2

BK polyomavirus test			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Blood glucose increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Blood immunoglobulin A increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
HLA marker study positive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Crossmatch incompatible			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Donor specific antibody present			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Procedural pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	4 / 34 (11.76%)
occurrences (all)	0	1	4
Complications of transplanted kidney			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Delayed graft function			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Incision site pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Post procedural discharge			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Transplantation complication			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Vascular graft stenosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Left ventricular hypertrophy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Ventricular extrasystoles			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	1 / 34 (2.94%)
occurrences (all)	0	2	1
Tremor			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
Dysaesthesia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 4 (25.00%)	2 / 34 (5.88%)
occurrences (all)	1	1	2
Leukopenia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Nephrogenic anaemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Pancytopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Meniere's disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Eye disorders			
Scleritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Xanthopsia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 11 (18.18%)	2 / 4 (50.00%)	1 / 34 (2.94%)
occurrences (all)	4	2	1
Nausea			
subjects affected / exposed	2 / 11 (18.18%)	1 / 4 (25.00%)	2 / 34 (5.88%)
occurrences (all)	2	1	2
Diarrhoea			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	3 / 34 (8.82%)
occurrences (all)	1	0	3
Vomiting			
subjects affected / exposed	3 / 11 (27.27%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	3	0	0
Dyspepsia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatocellular injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Cholestasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
pruritus generalised			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Purpura senile			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Renal pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Renal impairment			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Urethral spasm			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Muscular weakness			

subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	2 / 34 (5.88%)
occurrences (all)	0	1	2
Nasopharyngitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Cytomegalovirus infection			
subjects affected / exposed	3 / 11 (27.27%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	8	0	0
Bacteraemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Coronavirus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

Escherichia urinary tract infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Haematoma infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Pseudomonas infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Hyperkalaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Hypocalcaemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	4
Gout			
subjects affected / exposed	0 / 11 (0.00%)	1 / 4 (25.00%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Calcium deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Safety Population Arm 2b: Placebo: Prophylactic	Safety Population Group 3: HB-101: CMV (+) patient: preemptive	Safety Population Group 3: HB-101: CMV (+): Prophylactic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 17 (70.59%)	3 / 4 (75.00%)	6 / 10 (60.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Skin papilloma			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 17 (17.65%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Skin cyst excision			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 17 (5.88%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Feeling hot			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hyperthermia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pruritus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Kidney transplant rejection			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood creatine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus test positive			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
BK polyomavirus test			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin A increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
HLA marker study positive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Urine output decreased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Crossmatch incompatible			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Donor specific antibody present			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Complications of transplanted kidney			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Delayed graft function			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Incision site pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Post procedural discharge			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Transplantation complication			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular graft stenosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	2 / 17 (11.76%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Tremor			
subjects affected / exposed	2 / 17 (11.76%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 17 (0.00%)	2 / 4 (50.00%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Paraesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 17 (17.65%)	3 / 4 (75.00%)	0 / 10 (0.00%)
occurrences (all)	3	3	0
Leukopenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nephrogenic anaemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Meniere's disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Scleritis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Xanthopsia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	2 / 10 (20.00%)
occurrences (all)	0	1	3
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Dyspepsia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hepatocellular injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cholestasis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
pruritus generalised			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Purpura senile			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Oliguria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Urethral spasm			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hyperparathyroidism secondary			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	2 / 17 (11.76%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Flank pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 4 (50.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	2 / 10 (20.00%)
occurrences (all)	0	1	2
Infections and infestations			
Cytomegalovirus viraemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	1 / 17 (5.88%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Epididymitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Escherichia urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haematoma infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	2 / 17 (11.76%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Metabolic acidosis			
subjects affected / exposed	1 / 17 (5.88%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 4 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Calcium deficiency			
subjects affected / exposed	0 / 17 (0.00%)	2 / 4 (50.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Folate deficiency			
subjects affected / exposed	0 / 17 (0.00%)	1 / 4 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 June 2019	Global Protocol Amendment 1 (Version 4.0) dated 26 June 2019 was developed to respond to regulatory feedback and investigational site feedback. The key changes are summarized below: - The language describing the study design was modified throughout the study Protocol to provide further clarity on how much time should have been scheduled between study drug injections and when additional study drug injections should have been administered; - The maximum allowed number of patients receiving additional study drug injections was capped at 10 patients (less than 10% of planned sample size); - A window of ±2 days was added to the minimum of 7 days that was planned between the last dose of study drug and transplantation; - Language was also added throughout the study Protocol to specify procedures for patients who received a kidney from a deceased donor or patients who were paired with a CMV seronegative (-) donor; - New sections were added to define the end of the study and the early study termination; - The definition of abstinence and a clarification note were added to Inclusion Criterion 8 describing contraception use; - Inclusion Criterion 7 was deleted due to redundancy with Inclusion Criterion 9; - Language was added to describe how to handle a patient who had a false positive pregnancy test; - Exclusion Criterion 17 was added to exclude patients who received Cytogam® in their post transplant prophylaxis regimen; - A new section was added to describe the procedures for discontinuation of study drug and language was added to the withdrawal criteria to describe procedures for withdrawal of consent and discontinuation of study drug; - The study assessments were updated to allow for the study visit occurring 7 days after study drug administration to be conducted via phone call, in the event that the patient cannot return to the site; - A new section was added to clarify the procedures for the CMR PCR testing (locally versus centrally).
07 November 2019	Global Protocol Amendment 2 (Version 5.0) dated 07 November 2019 was developed to incorporate the following: - Addition of an open-label Group 3 to the study design that included patients who were CMV seropositive (+) awaiting a kidney transplant from a CMV seropositive (+) or seronegative (-) living donor; -- Patients enrolled in Group 3 received open-label HB-101 and were followed with a post transplant CMV management strategy per institutional standard (either preemptive or prophylactic care);- -- Safety and reactogenicity, immunogenicity, and efficacy of HB-101 were assessed in Group 3 patients. Study drug dosing and all assessments for Group 3 were the same as for Groups 1 and 2 per existing schedules for dosing and procedures; and -- The safety, immunogenicity, and efficacy data collected from this patient population were to provide critical information for the registration trial based on the broad population of patients who are at intermediate and high risk of developing clinically significant CMV infections post-transplantation. - Inclusion of a urine sample in addition to serum sample for pregnancy tests to be acceptable.

09 December 2020	Global Protocol Amendment 3 (Version 6.0) dated 09 December 2020 was developed to incorporate the following: - HLA sensitization was added as a risk related to administration of vaccines based on the Sponsor's understanding of the risk of HLA sensitization posed by the investigational CMV vaccine HB-101 and to offer a recommendation to mitigate this risk. Additionally, patients' HLA genotypes were considered during Screening. -- To minimize the risk of HLA sensitizations in patients enrolled, the Protocol was amended to enroll only those patients who had no risk or low risk of sensitization owing to tolerance against the r relevant HLA epitopes. - Assessment of additional immunogenicity parameters of HB-101 by CMV ICS pp65 and CMV ICS gB assays were moved from secondary to exploratory endpoints. - Assessment of LCMV neutralizing antibody and LCMV NP-specific ELISPOT were moved from secondary to exploratory endpoints.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported