Clinical trial results:
A Long-term Follow-up of Study 64041575RSV2004 to Evaluate the Impact of Lumicitabine (JNJ-64041575) on the Incidence of Asthma and/or Wheezing in Infants and Children with a History of Respiratory Syncytial Virus Infection

Summary

EudraCT number	2016-002095-26
Trial protocol	GB FR ES DE BE PT FI SK IE IT
Global end of trial date	13 April 2020

Results information

Result version number	v1 (current)
This version publication date	25 October 2020
First version publication date	25 October 2020

Trial information

Trial identification

Sponsor protocol code	64041575RSV2002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03332459
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen- Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen- Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen- Cilag International NV, ClinicalTrialsEU@its.jnj.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	13 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 April 2020
Global end of trial reached?	Yes
Global end of trial date	13 April 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study was to evaluate the incidence of the clinical diagnosis of asthma and the frequency of wheezing in infants and children who were treated with lumicitabine or placebo in Study 64041575RSV2004 during the follow-up period and within 2 years after the respiratory syncytial virus (RSV) infection.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Safety evaluations were based on the monitoring of adverse events (AEs) and serious adverse events (SAEs) throughout the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 January 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	Japan: 7
Worldwide total number of subjects	7
EEA total number of subjects	0

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)	6
Children (2-11 years)	1
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Only subjects previously enrolled in study 64041575RSV2004 (EudraCT ID: 2017-001862-56) were eligible to enroll in this study. Only 7 subjects were enrolled in study 64041575RSV2004 before the study 64041575RSV2004 was prematurely terminated.

Pre-assignment

Screening details:

Total of 7 subjects were enrolled in this study from study 64041575RSV2004 and completed this study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received placebo for the treatment of Respiratory Syncytial Virus (RSV) infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of placebo, frequency and type of respiratory infections and medical resource usage.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects who received placebo in a feeding Phase 2 study (64041575RSV2004) were observed. No study drug was administered in this study.

Arm title	Lumicitabine 40/20 mg/kg regimen

Arm description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 40/20 milligrams per kilograms (mg/kg) for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.

Arm type	Experimental
Investigational medicinal product name	Lumicitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects who received lumicitabine 40/20 mg/kg regimen in a feeding Phase 2 study (64041575RSV2004) were observed. No study drug was administered in this study.

Arm title	Lumicitabine 60/40 mg/kg regimen

Arm description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 60/40 mg/kg for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.

Arm type	Experimental
Investigational medicinal product name	Lumicitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects who received lumicitabine 60/40 mg/kg regimen in a feeding Phase 2 study (64041575RSV2004) were observed. No study drug was administered in this study.

Number of subjects in period 1	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen
Started	3	1	3
Completed	3	1	3

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received placebo for the treatment of Respiratory Syncytial Virus (RSV) infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of placebo, frequency and type of respiratory infections and medical resource usage.	
Reporting group title	Lumicitabine 40/20 mg/kg regimen
Reporting group description:	
Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 40/20 milligrams per kilograms (mg/kg) for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.	
Reporting group title	Lumicitabine 60/40 mg/kg regimen
Reporting group description:	
Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 60/40 mg/kg for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.	

Reporting group values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen
Number of subjects	3	1	3
Title for AgeCategorical			
Units: subjects			
Infants And Toddlers	2	1	3
children	1	0	0
Title for AgeContinuous			
Here '99999' indicates that the data was not estimated due to only single subject was analyzed.			
Units: months			
arithmetic mean	16	17	6.3
standard deviation	± 13.08	± 99999	± 2.52
Title for Gender			
Units: subjects			
Female	0	0	1
Male	3	1	2

Reporting group values	Total		
Number of subjects	7		
Title for AgeCategorical			
Units: subjects			
Infants And Toddlers	6		
children	1		
Title for AgeContinuous			
Here '99999' indicates that the data was not estimated due to only single subject was analyzed.			
Units: months			
arithmetic mean			
standard deviation	-		

Title for Gender Units: subjects			
Female	1		
Male	6		

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received placebo for the treatment of Respiratory Syncytial Virus (RSV) infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of placebo, frequency and type of respiratory infections and medical resource usage.

Reporting group title	Lumicitabine 40/20 mg/kg regimen

Reporting group description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 40/20 milligrams per kilograms (mg/kg) for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.

Reporting group title	Lumicitabine 60/40 mg/kg regimen

Reporting group description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 60/40 mg/kg for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.

Primary: Percentage of Subjects With Asthma After Respiratory Syncytial Virus (RSV) Infection

End point title	Percentage of Subjects With Asthma After Respiratory Syncytial Virus (RSV) Infection[1]

End point description:

Percentage of subjects with asthma as diagnosed by a physician was reported. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this long term follow up (LTFU) study.

End point type	Primary

End point timeframe:

Up to 2 Years

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: Descriptive statistics were done, no inferential statistical analyses were performed.

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0 to 56.15)	0 (0 to 79.35)	0 (0 to 56.15)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Wheezing Days in Subjects Within the First 2 Years After RSV Infection

End point title	Percentage of Wheezing Days in Subjects Within the First 2 Years After RSV Infection[2]

End point description:

Percentage of days with wheezing in subjects within the first 2 Years after RSV infection based on information reported by the parent/caregiver was reported. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this LTFU study. Here '99999' indicates that the standard deviation was not evaluable as no wheezing day was observed in the specified group.

End point type	Primary

End point timeframe:

Up to 2 Years

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: Descriptive statistics were done, no inferential statistical analyses were performed.

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Percentage of Wheezing Days				
arithmetic mean (standard deviation)	0.03 (± 0.058)	0.00 (± 99999)	2.53 (± 4.388)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Wheezing Days in Subjects per Month After RSV Infection

End point title	Percentage of Wheezing Days in Subjects per Month After RSV Infection

End point description:

Percentage of wheezing days in subjects per month after RSV infection based on information reported by the parent/caregiver was reported. All Enrolled analysis set included all subjects from the 64041575RSV2004 study who were enrolled in this LTFU study. Here '99999' indicates that the standard deviation was not evaluable as no wheezing day was observed in the specified group.

End point type	Secondary

End point timeframe:

Up to 2 Years

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Percentage of Wheezing Days				
arithmetic mean (standard deviation)				

Month 1	1.00 (± 1.732)	0.00 (± 99999)	1.00 (± 1.732)	
Month 2	0.00 (± 0.000)	0.00 (± 99999)	1.00 (± 1.732)	
Month 3	0.00 (± 0.000)	0.00 (± 99999)	5.67 (± 9.815)	
Month 4	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 5	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 6	0.00 (± 0.000)	0.00 (± 99999)	2.00 (± 3.464)	
Month 7	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 8	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 9	0.00 (± 0.000)	0.00 (± 99999)	4.33 (± 7.506)	
Month 10	0.00 (± 0.000)	0.00 (± 99999)	3.33 (± 5.774)	
Month 11	0.00 (± 0.000)	0.00 (± 99999)	5.00 (± 8.660)	
Month 12	0.00 (± 0.000)	0.00 (± 99999)	5.67 (± 9.815)	
Month 13	0.00 (± 0.000)	0.00 (± 99999)	6.33 (± 10.970)	
Month 14	0.00 (± 0.000)	0.00 (± 99999)	4.33 (± 7.506)	
Month 15	0.00 (± 0.000)	0.00 (± 99999)	6.00 (± 10.392)	
Month 16	0.00 (± 0.000)	0.00 (± 99999)	7.67 (± 13.279)	
Month 17	0.00 (± 0.000)	0.00 (± 99999)	4.00 (± 6.928)	
Month 18	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 19	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 20	0.00 (± 0.000)	0.00 (± 99999)	1.00 (± 1.732)	
Month 21	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 22	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 23	0.00 (± 0.000)	0.00 (± 99999)	4.00 (± 6.928)	
Month 24	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Wheezing Episodes in Subjects per Month After the RSV Infection

End point title	Number of Wheezing Episodes in Subjects per Month After the RSV Infection

End point description:

Number of wheezing episodes in subjects per month after the RSV infection based on information reported by the parent/caregiver was reported. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this LTFU study. Here '99999' indicates that the standard deviation was not evaluable as no wheezing episodes were observed in the specified group.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Episodes				
arithmetic mean (standard deviation)				
Month 1	0.33 (± 0.577)	0.00 (± 99999)	0.33 (± 0.577)	
Month 2	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 3	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 4	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 5	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 6	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 7	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 8	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 9	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 10	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 11	0.00 (± 0.000)	0.00 (± 99999)	1.00 (± 1.732)	
Month 12	0.00 (± 0.000)	0.00 (± 99999)	1.00 (± 1.732)	
Month 13	0.00 (± 0.000)	0.00 (± 99999)	1.00 (± 1.732)	
Month 14	0.00 (± 0.000)	0.00 (± 99999)	0.67 (± 1.155)	
Month 15	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 16	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 17	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 18	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 19	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 20	0.00 (± 0.000)	0.00 (± 99999)	0.33 (± 0.577)	
Month 21	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 22	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	
Month 23	0.00 (± 0.000)	0.00 (± 99999)	0.67 (± 1.155)	
Month 24	0.00 (± 0.000)	0.00 (± 99999)	0.00 (± 0.000)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Reportable Adverse Events (AEs)

End point title	Number of Subjects With Reportable Adverse Events (AEs)

End point description:

Number of subjects with reportable AEs was reported. The following AEs were considered reportable (within the context of this study): Respiratory illness AEs, including subsequent RSV infections, adverse events considered at least possibly related to study treatment (lumicitabine or placebo, as received in Study 64041575RSV2004), and serious adverse events. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this LTFU study.

End point type	Secondary

End point timeframe:

Up to 2 Years

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Subjects	3	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events (SAEs)

End point title	Number of Subjects With Serious Adverse Events (SAEs)

End point description:

SAE is any AE that results in: death, persistent or significant disability/incapacity, requires inpatient hospitalization or prolongation of existing hospitalization, is life-threatening experience, is a congenital anomaly/birth defect and may jeopardize subject and/or may require medical or surgical intervention to prevent one of the outcomes listed above. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this LTFU study.

End point type	Secondary

End point timeframe:

Up to 2 years

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Subjects	0	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Respiratory Infections per Subject

End point title	Number of Respiratory Infections per Subject

End point description:

The number of respiratory infections among subjects, based on information reported by the parent/caregiver was reported. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this LTFU study. Here '99999' indicates that the standard deviation was not estimable as only one subject was analyzed for the respective arm.

End point type	Secondary

End point timeframe:

Up to 2 Years

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Infections per Subject				
arithmetic mean (standard deviation)	10.7 (± 4.62)	6.0 (± 99999)	19.5 (± 6.36)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Medical Encounters

End point title	Number of Subjects with Medical Encounters

End point description:

Number of subjects with medical encounters (Hospital inpatient department visits, hospital outpatient department visits, medical practitioner office visits) was reported based on information reported by the parent/caregiver. All Enrolled analysis set included all subjects from 64041575RSV2004 study who were enrolled in this LTFU study.

End point type	Secondary

End point timeframe:

Up to 2 Years

End point values	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	3	
Units: Subjects				
Hospital Inpatient Department	0	0	1	
Hospital Outpatient Department	3	1	2	
Medical Practitioner Office	2	1	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 2 years

Adverse event reporting additional description:

Reportable AEs (Respiratory illness AEs, including subsequent RSV infections, AEs considered at least possibly related to study treatment [lumicitabine or placebo, as received in Study 64041575RSV2004], and serious adverse events) reported below. All Enrolled analysis set: all subjects from 64041575RSV2004 study enrolled in this LTFU study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received placebo for the treatment of Respiratory Syncytial Virus (RSV) infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of placebo, frequency and type of respiratory infections and medical resource usage.

Reporting group title	Lumicitabine 40/20 mg/kg regimen

Reporting group description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 40/20 milligrams per kilograms (mg/kg) for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.

Reporting group title	Lumicitabine 60/40 mg/kg regimen

Reporting group description:

Subjects who completed the last planned study-related visit in a feeding Phase 2 study (64041575RSV2004), in which they received lumicitabine 60/40 mg/kg for the treatment of RSV infection, and who agreed to participate in this follow-up study were assessed for the incidence of the clinical diagnosis of asthma, frequency of wheezing, long-term safety of lumicitabine, frequency and type of respiratory infections and medical resource usage.

Serious adverse events	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
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			
Exanthema Subitum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Norovirus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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	Placebo	Lumicitabine 40/20 mg/kg regimen	Lumicitabine 60/40 mg/kg regimen
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	1 / 1 (100.00%)	2 / 3 (66.67%)
Respiratory, thoracic and mediastinal disorders			
Rhinitis Allergic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Upper Respiratory Tract Inflammation			

subjects affected / exposed	2 / 3 (66.67%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Wheezing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	12
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	2 / 3 (66.67%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Adenovirus Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	2 / 3 (66.67%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	7	2	3
Enterocolitis Viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Exanthema Subitum			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	15
Pharyngitis			
subjects affected / exposed	2 / 3 (66.67%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	8	2	1
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 6	1 / 1 (100.00%) 2	1 / 3 (33.33%) 7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to the limited number of subjects enrolled in this study (n=7), no meaningful conclusions can be made.

Notes: