Trial record **1 of 1** for: tak-620-1019

Previous Study | Return to List | Next Study

A Study Comparing the Pharmacokinetics and Palatability of Two Candidate Pediatric Powder-for-Oral-Suspension Formulations of Maribavir to the Current Maribavir Tablet Formulation Administered in Healthy Adult Participants

ClinicalTrials.gov Identifier: NCT04131556

Recruitment Status : Terminated (The study was stopped because based on the planned interim analysis of the data of Part 1, palatability of both pediatric formulations was not acceptable.)
First Posted : October 18, 2019
Results First Posted : January 19, 2021
Last Update Posted : January 19, 2021

Sponsor:

Shire

Information provided by (Responsible Party):

Takeda (Shire)

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Healthy Volunteers
Intervention	Drug: Maribavir
Enrollment	20

Participant Flow

Go to

Recruitment Details	This study was conducted at single site in United States of America from 25 October 2019 (first participant first visit) and 06 January 2020 (last participant last visit).
Pre-assignment Details	This study was planned to be conducted in 2 parts: Part 1 and Part 2. However, study was terminated based on planned interim analysis of the data of Part 1, palatability of both pediatric formulations was not acceptable and therefore, Part 2 was not conducted. Participants were randomized to 1 of 6 sequences with treatment A, B and C. Baseline characteristics of participants were only analyzed and reported for overall study period, as planned, and not per treatment to avoid double-counting.

Arm/Group Title	Maribavir

▼ Arm/Group Description	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.
Period Title: **Overall Study**	
Started	20
Completed	18
Not Completed	2
Reason Not Completed	
Adverse Event	1
Withdrawal by Subject	1

Baseline Characteristics

Go to

Arm/Group Title	Maribavir
▼ Arm/Group Description	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.
Overall Number of Baseline Participants	20
▼ Baseline Analysis Population Description	Safety set 1 consisted of all participants who received at least 1 dose of maribavir in Part 1.

Age, Continuous Mean (Standard Deviation) Unit of measure: Years			
	Number Analyzed	20 participants	
		33.7 (8.90)	
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	20 participants	
	Female	12	60.0%
	Male	8	40.0%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	20 participants	
	Hispanic or Latino	17	85.0%
	Not Hispanic or Latino	3	15.0%
	Unknown or Not Reported	0	0.0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	20 participants	
	American Indian or Alaska Native	0	0.0%
	[illegible]	[illegible]	[illegible]

	Asian	0	0.0%
	Native Hawaiian or Other Pacific Islander	0	0.0%
	Black or African American	4	20.0%
	White	16	80.0%
	More than one race	0	0.0%
	Unknown or Not Reported	0	0.0%

Outcome Measures

Go to

1. Primary Outcome

Title	Part 1: Maximum Concentration (Cmax) Occurred at Time of Maximum Observed Concentration Sampled During a Dosing Interval (Tmax) of Maribavir in Plasma
▼ Description	Cmax defined as maximum concentration occurred at tmax of maribavir in plasma was reported. Geometric mean and geometric coefficient of variation percent (CV%) were reported.
Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Days 1, 4, and 7

▼ Outcome Measure Data

▼ Analysis Population Description

Pharmacokinetic (PK) set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C

▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: Micrograms per milliliter (mcg/mL)			
	10.7 (31.42%)	7.35 (46.92%)	6.84 (56.71%)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment B
	Comments	[Not Specified]
	Type of Statistical Test	Equivalence
	Comments	Equivalence analysis based on confidence intervals (CIs). If the 90% CIs of the geometric mean ratios were within (0.8, 1.25), bioequivalence between the two formulations (test powder for oral suspension versus reference tablet) was to be claimed. A linear mixed effect ANOVA model with treatment, period, sequence as fixed effects and participant within sequence as a random effect was used to fit to ln-transformed PK parameters.

Statistical Test of Hypothesis	P-Value	[Not Specified]
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	% Ratio of Geometric least square means
	Estimated Value	67.76
	Confidence Interval	(2-Sided) 90% 59.50 to 77.16
	Estimation Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment C
	Comments	[Not Specified]
	Type of Statistical Test	Equivalence
	Comments	Equivalence analysis based on confidence intervals (CIs). If the 90% CIs of the geometric mean ratios were within (0.8, 1.25), bioequivalence between the two formulations (test powder for oral suspension versus reference tablet) was to be claimed. A linear mixed effect ANOVA model with treatment, period, sequence as fixed effects and participant within sequence as a random effect was used to fit to ln-transformed PK parameters.
Statistical Test of Hypothesis	P-Value	[Not Specified]
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	% Ratio of Geometric least squares means

Estimation	Estimated Value	62.29
	Confidence Interval	(2-Sided) 90% 54.73 to 70.90
	Estimation Comments	[Not Specified]

2. Primary Outcome

Title	Part 1: Time of Maximum Observed Concentration Sampled During a Dosing Interval (Tmax) of Maribavir in Plasma
▼ Description	tmax defined as time of maximum observed concentration sampled during a dosing interval of maribavir in plasma were reported.
Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Days 1, 4, and 7

▼ Outcome Measure Data

▼ Analysis Population Description

PK set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Median (Full Range) Unit of Measure:			

Hour			
	1.00 (0.500 to 2.00)	3.00 (1.00 to 4.00)	2.00 (1.00 to 4.00)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment B
	Comments	Statistical analysis of tmax was performed using a nonparametric test. The median difference of tmax between treatments and 90% CIs of the median differences were calculated from Hodges-Lehman estimate, and p-value was produced from Wilcoxon signed rank test.
	Type of Statistical Test	Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<.001
	Comments	[Not Specified]
	Method	Wilcoxon signed rank test
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	1.25
	Confidence Interval	(2-Sided) 90% 0.75 to 1.75
	Estimation Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment C
	Comments	Statistical analysis of tmax was performed using a nonparametric test. The median difference of tmax between treatments and 90% CIs of the median

		differences were calculated from Hodges-Lehman estimate, and p-value was produced from Wilcoxon signed rank test.
	Type of Statistical Test	Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<.001
	Comments	[Not Specified]
	Method	Wilcoxon signed rank test
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	1.00
	Confidence Interval	(2-Sided) 90% 0.75 to 1.25
	Estimation Comments	[Not Specified]

3. Primary Outcome

Title	Part 1: Area Under the Curve From the Time of Dosing to the Last Measurable Concentration (AUC0-last) of Maribavir in Plasma
▼ Description	AUC0-last of maribavir in plasma was reported. Geometric mean and geometric coefficient of variation percent (CV%) were reported.
Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Days 1, 4, and 7

▼ Outcome Measure Data

▼ Analysis Population Description

PK set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately

treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: Hour*micrograms per milliliter (h*µg/mL)			
	50.1 (49.21%)	41.2 (55.09%)	39.1 (60.58%)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment B
	Comments	[Not Specified]
	Type of Statistical Test	Equivalence
	Comments	Equivalence analysis based on confidence intervals (CIs). If the 90% CIs of the geometric mean ratios were within (0.8, 1.25), bioequivalence between the two formulations (test powder for oral suspension versus reference tablet) was to be claimed. A linear mixed effect ANOVA model with treatment, period, sequence as

		claimed. A linear mixed effect ANOVA model with treatment, period, sequence as fixed effects and participant within sequence as a random effect was used to fit to ln-transformed PK parameters.
Statistical Test of Hypothesis	P-Value	[Not Specified]
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	% Ratio of Geometric least squares means
	Estimated Value	81.27
	Confidence Interval	(2-Sided) 90% 73.88 to 89.40
	Estimation Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment C
	Comments	[Not Specified]
	Type of Statistical Test	Equivalence
	Comments	Equivalence analysis based on confidence intervals (CIs). If the 90% CIs of the geometric mean ratios were within (0.8, 1.25), bioequivalence between the two formulations (test powder for oral suspension versus reference tablet) was to be claimed. A linear mixed effect ANOVA model with treatment, period, sequence as fixed effects and participant within sequence as a random effect was used to fit to ln-transformed PK parameters.
Statistical Test of Hypothesis	P-Value	[Not Specified]
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]

	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	% Ratio of Geometric least squares means
	Estimated Value	78.00
	Confidence Interval	(2-Sided) 90% 70.92 to 85.79
	Estimation Comments	[Not Specified]

4. Primary Outcome

Title	Area Under the Curve Extrapolated to Infinity, Calculated Using the Observed Value of the Last Non-Zero Concentration (AUC0-Inf) of Maribavir in Plasma
▼ Description	AUC0-Inf of maribavir in plasma was reported. Geometric mean and geometric coefficient of variation percent (CV%) were reported.
Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Days 1, 4, and 7

▼ Outcome Measure Data

▼ Analysis Population Description

PK set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants	18	19	20

Analyzed			

Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: h*µg/mL			
	52.5 (49.72%)	44.5 (56.26%)	42.4 (60.69%)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment B
	Comments	[Not Specified]
	Type of Statistical Test	Equivalence
	Comments	Equivalence analysis based on confidence intervals (CIs). If the 90% CIs of the geometric mean ratios were within (0.8, 1.25), bioequivalence between the two formulations (test powder for oral suspension versus reference tablet) was to be claimed. A linear mixed effect ANOVA model with treatment, period, sequence as fixed effects and participant within sequence as a random effect was used to fit to ln-transformed PK parameters.
Statistical Test of Hypothesis	P-Value	[Not Specified]
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	% Ratio of Geometric least squares means
	Estimated Value	83.52
	Confidence Interval	(2-Sided) 90%

		76.12 to 91.64
	Estimation Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment C
	Comments	[Not Specified]
	Type of Statistical Test	Equivalence
	Comments	Equivalence analysis based on confidence intervals (CIs). If the 90% CIs of the geometric mean ratios were within (0.8, 1.25), bioequivalence between the two formulations (test powder for oral suspension versus reference tablet) was to be claimed. A linear mixed effect ANOVA model with treatment, period, sequence as fixed effects and participant within sequence as a random effect was used to fit to ln-transformed PK parameters.
Statistical Test of Hypothesis	P-Value	[Not Specified]
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	% Ratio of Geometric least squares means
	Estimated Value	80.36
	Confidence Interval	(2-Sided) 90% 73.26 to 88.16
	Estimation Comments	[Not Specified]

5. Primary Outcome

Title	Part 1: Terminal Half-Life (t1/2) of Maribavir in Plasma
▼ Description	t1/2 of maribavir in plasma was reported.

Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Days 1, 4 and 7

▼ Outcome Measure Data

▼ Analysis Population Description

PK set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Median (Full Range) Unit of Measure: Hour			
	4.04 (1.33 to 8.07)	4.80 (1.90 to 11.6)	5.95 (1.36 to 10.1)

6. Primary Outcome

Title	Part 1: Apparent Total Body Clearance Following Extravascular Administration (CL/F) of Maribavir in Plasma
▼ Description	CL/F of maribavir in Plasma was reported.
Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Days 1, 4 and 7

▼ Outcome Measure Data

▼ Analysis Population Description

PK set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Mean (Standard Deviation) Unit of Measure: Liters per hour (L/h)			
	4.21 (1.99)	5.13 (2.82)	5.49 (3.29)

7. Primary Outcome

Title	Part 1: Delay Between the Time of Dosing and Time of Appearance of Plasma Concentration (Tlag) of Maribavir in Plasma
▼ Description	Tlag of maribavir in plasma was reported.
Time Frame	Pre-dose, 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 16, 20, 24 hours post-dose on Day 1, 4 and 7

▼ Outcome Measure Data

▼ Analysis Population Description

PK set 1 consisted of participants who received at least 1 dose of maribavir, did not vomit within 4 hours post dosing, and had at least 1 evaluable post-dose maribavir concentration value in Part 1. Data for the PK parameters were planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Median (Full Range) Unit of Measure: Hour			
	0.00 (0.00 to 0.250)	0.250 (0.00 to 0.500)	0.250 (0.00 to 0.500)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment B
	Comments	Statistical analysis of Tlag was performed using a nonparametric test. The median difference of Tlag between treatments and 90% CIs of the median differences were calculated from Hodges-Lehman estimate, and p-value was produced from Wilcoxon signed rank test.
	Type of Statistical Test	Other
	Comments	[Not Specified]

Statistical Test of Hypothesis	P-Value	0.006
	Comments	[Not Specified]
	Method	Wilcoxon signed rank test
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	0.13
	Confidence Interval	(2-Sided) 90% 0.13 to 0.25
	Estimation Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Treatment A, Treatment C
	Comments	Statistical analysis of Tlag was performed using a nonparametric test. The median difference of Tlag between treatments and 90% CIs of the median differences were calculated from Hodges-Lehman estimate, and p-value was produced from Wilcoxon signed rank test.
	Type of Statistical Test	Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.011
	Comments	[Not Specified]
	Method	Wilcoxon signed rank test
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	0.13
	Confidence Interval	(2-Sided) 90% 0.13 to 0.25

	Estimation Comments	[Not Specified]

8. Primary Outcome

Title	Part 1: Number of Participants With Responses to Palatability Assessment up to Day 7
▼ Description	The palatability was evaluated to identify, characterize and quantify the sensory attributes of products, e.g., basic tastes, texture and mouth feel and to assess the overall acceptability. Number of participants responded to palatability assessment up to Day 7 were reported.
Time Frame	Up to Day 7

▼ Outcome Measure Data

▼ Analysis Population Description
Safety set 1 consisted of all participants who received at least 1 dose of maribavir in Part 1. Data for the palatability was planned and analyzed based on unique treatment sequence A, B, C. Hence, data was reported separately.

Arm/Group Title	Treatment A	Treatment B	Treatment C
▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally on Day 1 or Day 4 or Day 7.	Participants received 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading on Day 1 or Day 4 or Day 7.	Participants received maribavir 200 mg powder for oral suspension with 36.1% drug loading on Day 1 or Day 4 or Day 7.
Overall Number of Participants Analyzed	18	19	20
Measure Type: Count of Participants Unit of Measure: Participants			

How this drug tasted to you?: Bitter	2	11.1%	14	73.7%	14	70.0%
How this drug tasted to you?: Salty	0	0.0%	0	0.0%	1	5.0%
How this drug tasted to you?: Sour	0	0.0%	1	5.3%	0	0.0%
How this drug tasted to you?: Sweet	0	0.0%	0	0.0%	0	0.0%
How this drug tasted to you?: Savory	0	0.0%	0	0.0%	0	0.0%
How this drug tasted to you?: No taste	16	88.9%	4	21.1%	5	25.0%
How strong was the taste?: Strong	0	0.0%	8	42.1%	8	40.0%
How strong was the taste?: Medium	1	5.6%	6	31.6%	3	15.0%
How strong was the taste?: Weak	1	5.6%	1	5.3%	4	20.0%
How strong was the taste?: no taste	16	88.9%	4	21.1%	5	25.0%
Did the drug have a rough or gritty texture?: No	18	100.0%	4	21.1%	4	20.0%
Did the drug have a rough or gritty texture?: Yes	0	0.0%	15	78.9%	16	80.0%
Was the drug easy	0	0.0%	0	0.0%	0	0.0%

to swallow?: No						
Was the drug easy to swallow?: Yes	18	100.0%	19	100.0%	20	100.0%
Overall taste & texture?: Agree	18	100.0%	10	52.6%	13	65.0%
Overall taste & texture?: Neither agree/disagree	0	0.0%	5	26.3%	4	20.0%
Overall taste & texture?: Disagree	0	0.0%	4	21.1%	3	15.0%

9. Secondary Outcome

Title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs)
▼ Description	An adverse event (AE) was any untoward medical occurrence in a clinical investigation participant administered a pharmaceutical product and that does not necessarily had a causal relationship with this treatment. A TEAE was an adverse event with a start date on or after the first dose of Investigational product (IP), or a start date before the date of the first dose of IP but increased in severity on or after the date of the first dose of IP. Number of participants with TEAEs were reported.
Time Frame	From start of study drug administration up to follow-up (Day 17)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety Set 1 consisted of all participants who received at least 1 dose of maribavir in Part 1.

Arm/Group Title	Maribavir

▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.
Overall Number of Participants Analyzed	20
Measure Type: Count of Participants Unit of Measure: Participants	
	3 15.0%

10. Secondary Outcome

Title	Number of Participants With Clinically Significant Changes in Vital Signs Reported as TEAEs
▼ Description	Vital sign assessments included systolic and diastolic blood pressure, pulse rate and body temperature. Any change in vital signs which were deemed clinically significant by the investigator were recorded as TEAE.
Time Frame	From start of study drug administration up to follow-up (Day 17)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety set 1 consisted of all participants who received at least 1 dose of maribavir in Part 1.

Arm/Group Title	Maribavir

▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.
Overall Number of Participants Analyzed	20
Measure Type: Count of Participants Unit of Measure: Participants	
	0 0.0%

11. Secondary Outcome

Title	Number of Participants With Clinically Significant Changes in Electrocardiogram (ECG) Reported as TEAEs
▼ Description	12-lead ECG were evaluated. Any change in ECG assessments which are deemed clinically significant by the investigator were reported as TEAE.
Time Frame	From start of study drug administration up to follow-up (Day 17)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety set 1 consisted of all participants who received at least 1 dose of maribavir in Part 1.

Arm/Group Title	Maribavir

▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.
Overall Number of Participants Analyzed	18
Measure Type: Count of Participants Unit of Measure: Participants	
	0 0.0%

12. Secondary Outcome

Title	Number of Participants With Clinically Significant Changes in Clinical Laboratory Results Reported as TEAEs
▼ Description	Clinical laboratory tests included biochemistry, hematology and urinalysis. Any change in clinical laboratory results which are deemed clinically significant by the investigator were reported as TEAE.
Time Frame	From start of study drug administration up to follow-up (Day 17)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety set 1 consisted of all participants who received at least 1 dose of maribavir in Part 1.

Arm/Group Title	Maribavir

▼ Arm/Group Description:	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.	
Overall Number of Participants Analyzed	18	
Measure Type: Count of Participants Unit of Measure: Participants		
	0	0.0%

Adverse Events

Go to

Time Frame	From start of study drug administration up to follow-up (Day 17)
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Maribavir
▼ Arm/Group Description	Participants received 200 milligrams (mg) of maribavir tablet orally (Treatment A) or 200 mg maribavir powder for oral suspension with 32.5 percent (%) drug loading (Treatment B) or maribavir 200 mg powder for oral suspension with 36.1% drug loading (Treatment C) on Day 1 or Day 4 or Day 7 in different sequences of ABC, BCA, CAB, CBA, ACB, and BAC.

All-Cause Mortality

	Maribavir	
	Affected / at Risk (%)	
Total	0/20 (0.00%)	

Serious Adverse Events

	Maribavir	
	Affected / at Risk (%)	# Events
Total	0/20 (0.00%)	

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%	
	Maribavir	
	Affected / at Risk (%)	# Events
Total	3/20 (15.00%)	
Gastrointestinal disorders		
Flatulence *[1]	1/20 (5.00%)	1
Investigations		
Liver function test increased *[1]	1/20 (5.00%)	1
Nervous system disorders		
Headache *[1]	1/20 (5.00%)	1

1 Term from vocabulary, MedDRA 22.1

* Indicates events were collected by non-systematic assessment

Limitations and Caveats

Go to

Sponsor terminated this study based on the planned interim analysis of the data of Part 1, palatability of both pediatric formulations was not acceptable.

More Information

Go to

Certain Agreements

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

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

If a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after Sponsor confirms there shall be no multicenter Study publication, the Institution and/or such Principal Investigator may publish the results from the Institution site individually.

Results Point of Contact

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Responsible Party:	Takeda (Shire)
ClinicalTrials.gov Identifier:	NCT04131556 History of Changes
Other Study ID Numbers:	**TAK-620-1019**
First Submitted:	October 17, 2019
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