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**REZUROCK**<sup>®</sup>  
(belumosudil) tablets

# ROCKSTAR STUDY

**Explore when considering REZUROCK** in the treatment of cGVHD for patients aged 12 years and older who have received at least two prior lines of systemic therapy.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to [UK-drugsafety@sanofi.com](mailto:UK-drugsafety@sanofi.com).

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# REZUROCK was evaluated in the pivotal ROCKstar (KD025-213) study for patients with cGVHD<sup>1</sup>

Patients received REZUROCK after failure of 2 to 5 previous lines of systemic therapy<sup>1</sup>

## Study design<sup>1</sup>

ROCKstar was a pivotal phase 2, open-label, non-controlled, randomized, multicenter study that evaluated the efficacy and safety of REZUROCK in patients with cGVHD after receiving 2 to 5 prior lines of systemic therapy.

## Treatment

Treatment consisted of REZUROCK 200 mg and was administered continuously until clinically significant progression of cGVHD or unacceptable toxicity.

## Primary end point

- Best ORR at any time, defined as the proportion of subjects who achieved CR or PR according to the 2014 NIH cGVHD Consensus Criteria<sup>1</sup>

## Prespecified key secondary end points (not powered to show statistical significance)

- Safety, DOR, TTR, LSS score, change in CS/CNI dose, FFS and OS<sup>1</sup>

cGVHD, chronic graft-versus-host disease; CNI, calcineurin inhibitor; CR, complete response; DOR, duration of response; FFS, failure-free survival; LSS, Lee Symptom Scale; NIH, National Institutes of Health; ORR, overall response rate; OS, overall survival; PR, partial response; TTR, time to response.

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2023. **3.** REZUROCK. Summary of Product Characteristics. **4.** Data on File. Sanofi. 2024. **5.** Lee SJ, Cutler C, Pavletic S, et al. Belumosudil for chronic graft-versus-host disease after 2 or more lines of systemic therapy: 3 year follow-up to the ROCKstar study. Poster presented at: Tandem Meetings; February 21, 2024; San Antonio, TX.

# Select ROCKstar study patient baseline characteristics<sup>1-5</sup>

Characteristics	2021 ROCKstar study 200 mg once daily (n=66) <sup>1-3,b</sup>	3-year follow-up 200 mg once daily (n=77) <sup>4,5,c</sup>
Median age, y (range)	53 (21-77)	53 (21-77)
Male, n (%)	42 (64)	49 (64)
Median prior lines of systemic therapy, n	3	3
Median time from cGVHD diagnosis to enrollment, mo (range)	25 (2-162)	25 (2-162)
Median prednisone-equivalent dose at enrollment, mg/kg/d (range)	0.20 (0.03-0.95)	0.18 (0.03-0.66)
Concomitant PPI use, n (%)	33 (50)	39 (51)
≥4 organs involved, n (%)	33 (50)	40 (52)
Previous aGVHD, n (%)	42 (64)	50 (65)
Refractory to prior line of systemic therapy, n (%)	44 (79)	50 (81)
<b>NIH-defined cGVHD severity, n (%)</b>		
Severe	46 (70)	56 (73)
Moderate	18 (27)	19 (25)
Mild	2 (3)	2 (3)

- The most common prior systemic therapy<sup>a</sup> was corticosteroids (98%), followed by calcineurin inhibitors (tacrolimus 62% and sirolimus 47%), ECP (48%), ibrutinib (34%) and ruxolitinib (29%)<sup>3</sup>

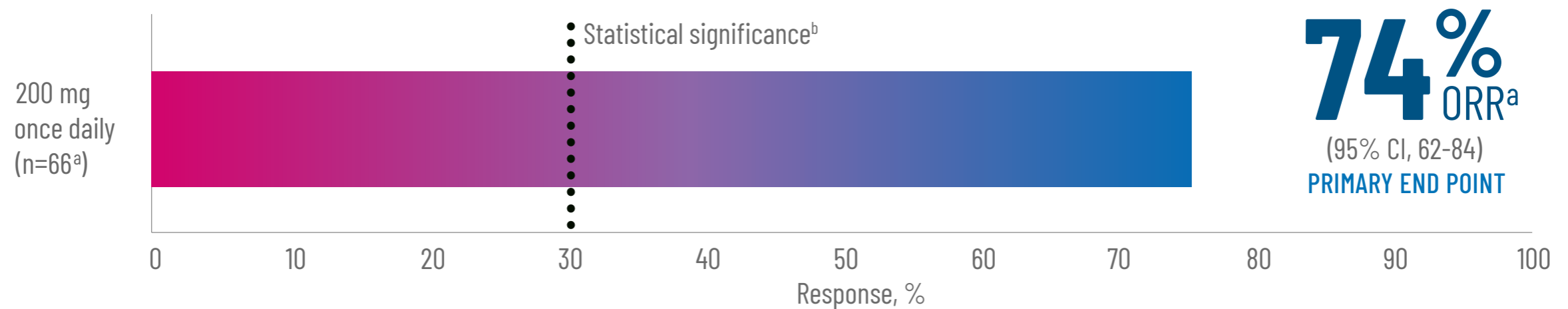
cGVHD, chronic graft-versus-host disease; NIH, National Institutes of Health; PPI, proton pump inhibitor; aGVHD, acute graft-versus-host disease; MHRA, Medicines and Healthcare Products Regulatory Agency.

<sup>a</sup>Some of these medicines do not have a licence in Great Britain for the treatment of cGvHD. <sup>b</sup>The final MHRA interpretation of the ROCKstar study omitted 1 patient from the REZUROCK200 mg once-daily arm. As a result, there are minor differences between the ROCKstar publication, where n=66, and the Summary of Product Characteristics, where n=65. <sup>c</sup>This analysis evaluated 152 participants in the mITT population (77 received belumosudil 200 mg once daily and 75 received belumosudil 200 mg twice daily), including 20 who were enrolled in a subsequent biomarker cohort after the August 19, 2020, ROCKstar publication data cutoff.<sup>5</sup>

**References:** **1.** Cutler C, Lee SJ, Arai S, *et al*; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138 (22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2023. **3.** REZUROCK. Summary of Product Characteristics. **4.** Data on File. Sanofi. 2024. **5.** Lee SJ, Cutler C, Pavletic S, *et al*. Belumosudil for chronic graft-versus-host disease after 2 or more lines of systemic therapy: 3 year follow-up to the ROCKstar study. Poster presented at: Tandem Meetings; February 21, 2024; San Antonio, TX.

# Clinically meaningful overall response rates<sup>1</sup>

## Statistically significant ORR<sup>a</sup> following treatment with REZUROCK 200 mg once daily<sup>1</sup>



**Primary end point:** Best ORR at any time, defined as the proportion of subjects who achieved CR or PR according to the 2014 NIH cGVHD Consensus Criteria<sup>1</sup>

**CR, n=4 (6%). PR, n=45 (68%)<sup>1</sup>**

**AFTER 3 YEARS OF TREATMENT WITH REZUROCK, THE BEST ORR<sup>c</sup> of 74% (95% CI, 63-83) was maintained in the 200-mg once-daily arm.<sup>2</sup>**

cGVHD, chronic graft-versus-host disease; CR, complete response; NIH, National Institutes of Health; mITT, modified intent-to-treat; ORR, overall response rate; PR, partial response.

<sup>a</sup>Based on mITT population (n=66).<sup>1</sup>

<sup>b</sup>Statistical significance was achieved if the lower bound of the 95% CI of ORR exceeded 30%.<sup>1</sup> Clopper Pearson interval (exact) method used for calculation of 95% CIs, and p values are adjusted through Hochberg method of multiplicity correction corresponding to the null hypothesis of ORR  $\leq$  30%.<sup>1</sup>

<sup>c</sup>Based on mITT population (n=77).<sup>3</sup>

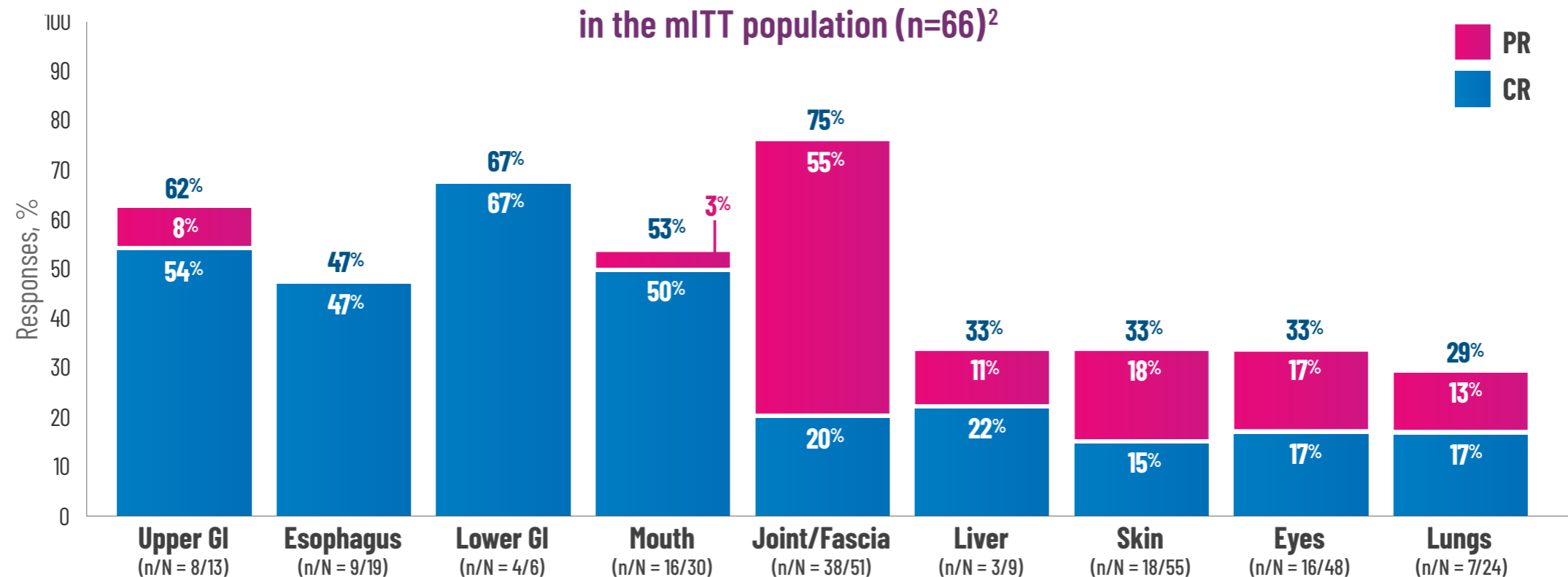
**References:** 1. Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. 2. Data on File. Sanofi. 2024.

# Response across all evaluated organs<sup>1,2</sup>

1-year data

3-year data

Responses by organ system<sup>a</sup> with REZUROCK 200 mg once daily in the mITT population (n=66)<sup>2</sup>



## Secondary end point: Response rate by organ system.<sup>1</sup>

CR, complete response; GI, gastrointestinal; mITT, modified intent-to-treat; PR, partial response.

<sup>a</sup>Primary end point was best ORR at any time, defined as the proportion of subjects who achieved CR or PR according to the 2014 NIH cGVHD Consensus Criteria.<sup>1</sup> CR defined as the resolution of all manifestations in each organ or site. PR defined as improvement in  $\geq 1$  organs or sites without progression in any other organ or site.<sup>3,4</sup>

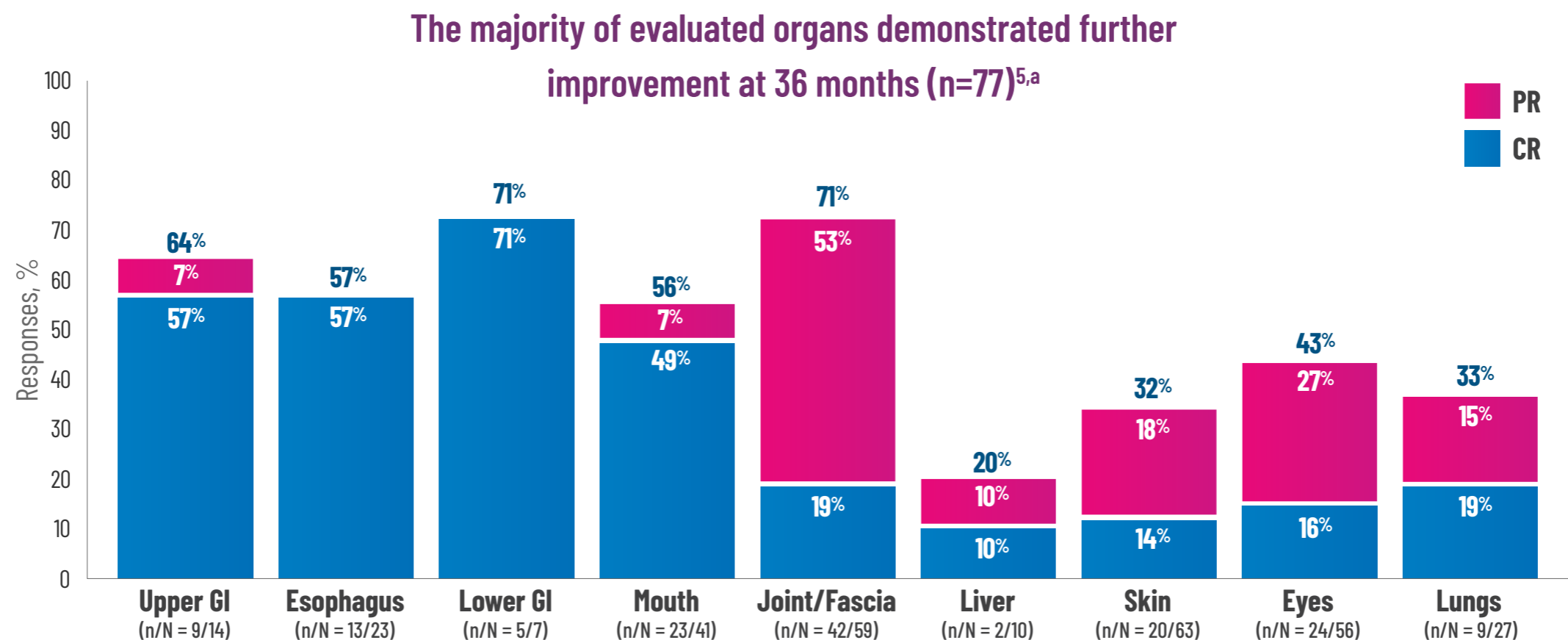
Percentages may not add up to the total due to rounding.

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. Supplementary Appendix. **3.** Lee SJ, Wolff D, Kitko C, et al. Measuring therapeutic response in chronic graft-versus-host disease. National Institutes of Health consensus development project on criteria for clinical trials in chronic graft-versus-host disease: IV. The 2014 Response Criteria Working Group report. *Biol Blood Marrow Transplant* 2015;21(6):984-999. doi:10.1016/j.bbmt.2015.02.025. **4.** REZUROCK. Summary of Product Characteristics. **5.** Data on File. Sanofi. 2024.

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# Most responses were seen **between 4 and 8 weeks**<sup>1</sup>

Cumulative response rates over time in the responder population with  
REZUROCK 200 mg once daily (n/N=48/66)<sup>1</sup>

**4.4 WEEKS**

Median time to response was 4.4 weeks  
(3.7-40.6)<sup>2</sup>

**100.3 WEEKS**

Median time from first response to the  
initiation of new systemic cGVHD therapy  
was 100.3 weeks (54.14-NA)<sup>1</sup>

**63% OF RESPONSES**

were observed between **weeks 4 and 8**<sup>1</sup>

**96% OF RESPONSES**

were observed by **weeks 24**<sup>1</sup>

After 3 years, the median DOR was

**69.9 WEEKS**<sup>3</sup>

# Responses were seen across all patient types<sup>1-3</sup>

## Best ORRs observed across key subgroups in the 200 mg once-daily arm<sup>1-3</sup>

The subgroups have limited numbers and were not powered for planned efficacy comparisons or inference. These are therefore exploratory.

1-year data

3-year data

### EARLIER REZUROCK INITIATION<sup>2</sup>

**86%**  
ORR

Defined as  
≤29-month duration  
of cGVHD before  
enrollment  
(n/N=30/35)

### SEVERE cGVHD<sup>2</sup>

**74%**  
ORR

(n/N=34/46)

### CHRONIC GVHD INVOLVING ≥4 ORGANS<sup>2</sup>

**70%**  
ORR

(n/N=23/33)

### >3 PRIOR LINES OF SYSTEMIC THERAPY<sup>2</sup>

**67%**  
ORR

(n/N=20/30)

cGVHD, chronic graft-versus-host disease; ORR, overall response rate.

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2023. **3.** Data on File. Sanofi. 2024. **4.** Chen Y-B. Highlights in graft-versus-host disease from the 2023 Tandem Meetings I Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR: commentary. *Clin Adv Hematol Oncol*. 2023;21 suppl 4(4):19-23.



# Responses were seen across all patient types<sup>1-3</sup>

## Best ORRs observed across key subgroups in the 200 mg once-daily arm<sup>1-3</sup>

The subgroups have limited numbers and were not powered for planned efficacy comparisons or inference. These are therefore exploratory.

1-year data

3-year data

WITHIN 36 MONTHS (n=77)<sup>3</sup>

**EARLIER REZUROCK  
INITIATION**

**83%**  
ORR

Defined as  
≤28-month duration  
of cGVHD before  
enrollment  
(n/N=34/41)

WITHIN 36 MONTHS (n=77)<sup>3</sup>

**SEVERE cGVHD**

**75%**  
ORR

(n/N=42/56)

WITHIN 36 MONTHS (n=77)<sup>3</sup>

**CHRONIC GVHD  
INVOLVING ≥4 ORGANS**

**75%**  
ORR

(n/N=30/40)

WITHIN 36 MONTHS (n=77)<sup>3</sup>

**>3 PRIOR LINES OF  
SYSTEMIC THERAPY**

**74%**  
ORR

(n/N=25/34)

**HOW SOON YOU TREAT MAY BE JUST AS IMPORTANT AS HOW YOU TREAT**

Earlier treatment of GVHD may offer better outcomes by preventing end-organ damage.<sup>4</sup>

cGVHD, chronic graft-versus-host disease; ORR, overall response rate.

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2023. **3.** Data on File. Sanofi. 2024. **4.** Chen Y-B. Highlights in graft-versus-host disease from the 2023 Tandem Meetings I Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR: commentary. *Clin Adv Hematol Oncol*. 2023;21 suppl 4(4):19-23.

# Change in QOL scores

## Improvements in patient-reported QOL<sup>1</sup>

≥7-point reduction in LSS summary score with REZUROCK 200 mg once daily in the mITT population in an exploratory analysis<sup>1</sup>

- Both responders (69%) and non responders (29%) had improved QOL scores<sup>1</sup>

The Lee Symptom Scale (LSS) is a 30-item, 7-subscale symptom scale and QOL measurement tool that evaluates the AEs of cGVHD in the categories of skin, vitality, lung, nutritional status, psychological functioning, eye and mouth.<sup>2</sup>

These were not tested for statistical significance.

**59%**

(n/N=39/66)

**12 MONTHS<sup>1,a</sup>**

**58%**

(n/N=45/77)

**36 MONTHS<sup>3,b</sup>**

AE, adverse event; cGVHD, chronic graft-versus-host disease; LSS, Lee Symptom Scale; mITT, modified intent-to-treat; QOL, quality of life.

<sup>a</sup>Based on mITT population (n=66).<sup>1</sup>

<sup>b</sup>Based on mITT population (n=77).<sup>3</sup>

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Lee SJ, Cook EF, Soiffer R, Antin JH. Development and validation of a scale to measure symptoms of chronic graft-versus-host disease. *Biol Blood Marrow Transplant*. 2002;8(8):444-452. doi:10.1053/bbmt.2002.v8.pm12234170. **3.** Data on File. Sanofi. 2024.

# Change in dependence on CS and CNI therapies

## Change in use of CS and CNI therapies<sup>1, 2, 4</sup>

This data is descriptive.

1-year data<sup>a</sup>

3-year data<sup>b</sup>

**CS reductions and discontinuations were observed in the 200-mg once-daily arm<sup>1</sup>**

**64%** (n/N=42/66) of patients reduced their **CS DOSE**.

**20%** (n/N=13/66) of patients **DISCONTINUED CS THERAPY** during treatment with REZUROCK.

**CNI reductions and discontinuations were observed in the 200-mg once-daily arm<sup>4</sup>**

**29%** (n/N=7/24) of patients reduced their **CNI DOSE**.

**8%** (n/N=2/24) of patients successfully **DISCONTINUED CNI THERAPY**.

CNI, calcineurin inhibitor; CR, complete response; CS, corticosteroid; mITT, modified intent-to-treat; PR, partial response.

<sup>a</sup>Based on mITT population (n=66).<sup>1,3</sup>

<sup>b</sup>Based on mITT population (n=77).<sup>4</sup>

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2023. **3.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. Supplementary Appendix. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **4.** Data on File. Sanofi. 2024.

# Change in dependence on CS and CNI therapies

## Change in use of CS and CNI therapies<sup>1, 2, 4</sup>

This data is descriptive.

1-year data<sup>a</sup>

3-year data<sup>b</sup>

Higher rates of CS reductions and discontinuations were observed in the 200-mg once-daily arm over 3 years<sup>4</sup>

**65%** (n/N=50/76) of patients reduced their **CS DOSE**.

**27%** (n/N=21/73) of patients **DISCONTINUED CS THERAPY** during treatment with REZUROCK.

Higher rates of CNI reductions and discontinuations were observed in the 200-mg once-daily arm over 3 years<sup>4</sup>

**47%** (n/N=15/32) of patients reduced their **CNI DOSE**.

**22%** (n/N=7/32) of patients successfully **DISCONTINUED CNI THERAPY**.

CNI, calcineurin inhibitor; CR, complete response; CS, corticosteroid; mITT, modified intent-to-treat; PR, partial response.

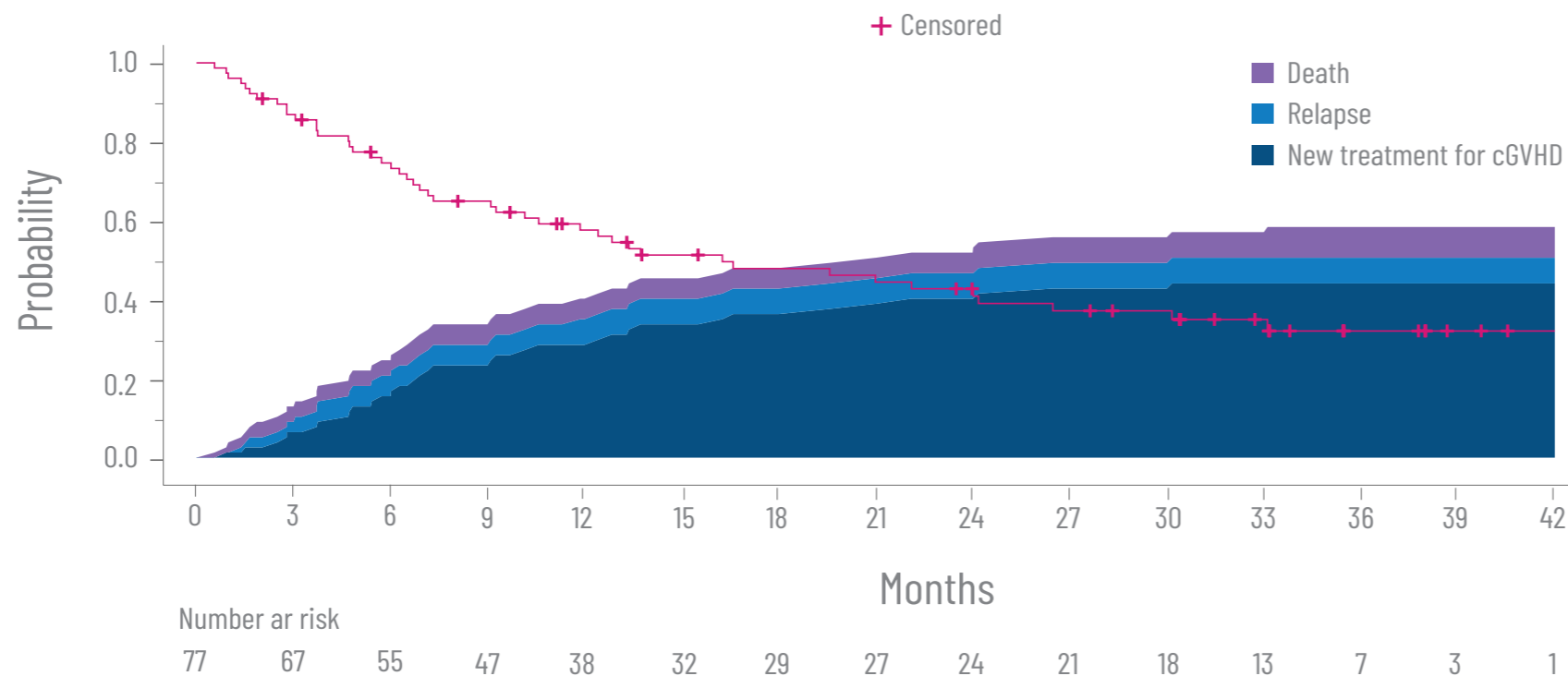
<sup>a</sup>Based on mITT population (n=66).<sup>1,3</sup>

<sup>b</sup>Based on mITT population (n=77).<sup>4</sup>

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2023. **3.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. Supplementary Appendix. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **4.** Data on File. Sanofi. 2024.

# FFS rates with REZUROCK

## FFS<sup>a</sup> with REZUROCK 200 mg once daily in the mITT population<sup>2</sup>



**FFS was maintained throughout the 36-month period.<sup>2</sup>**

The FFS rate was

**73%**

(95% CI, 61-83) at 6 months.<sup>1</sup>

**57%**

(95% CI, 44-68) at 12 months.<sup>1</sup>

**42%**

(n/N=32/77) at 36 months.<sup>2</sup>

**Secondary end point:** FFS, defined as the absence of relapse, nonrelapse mortality or a need for additional systemic therapy.<sup>1</sup>

Adapted from Data on File, Sanofi<sup>2</sup>

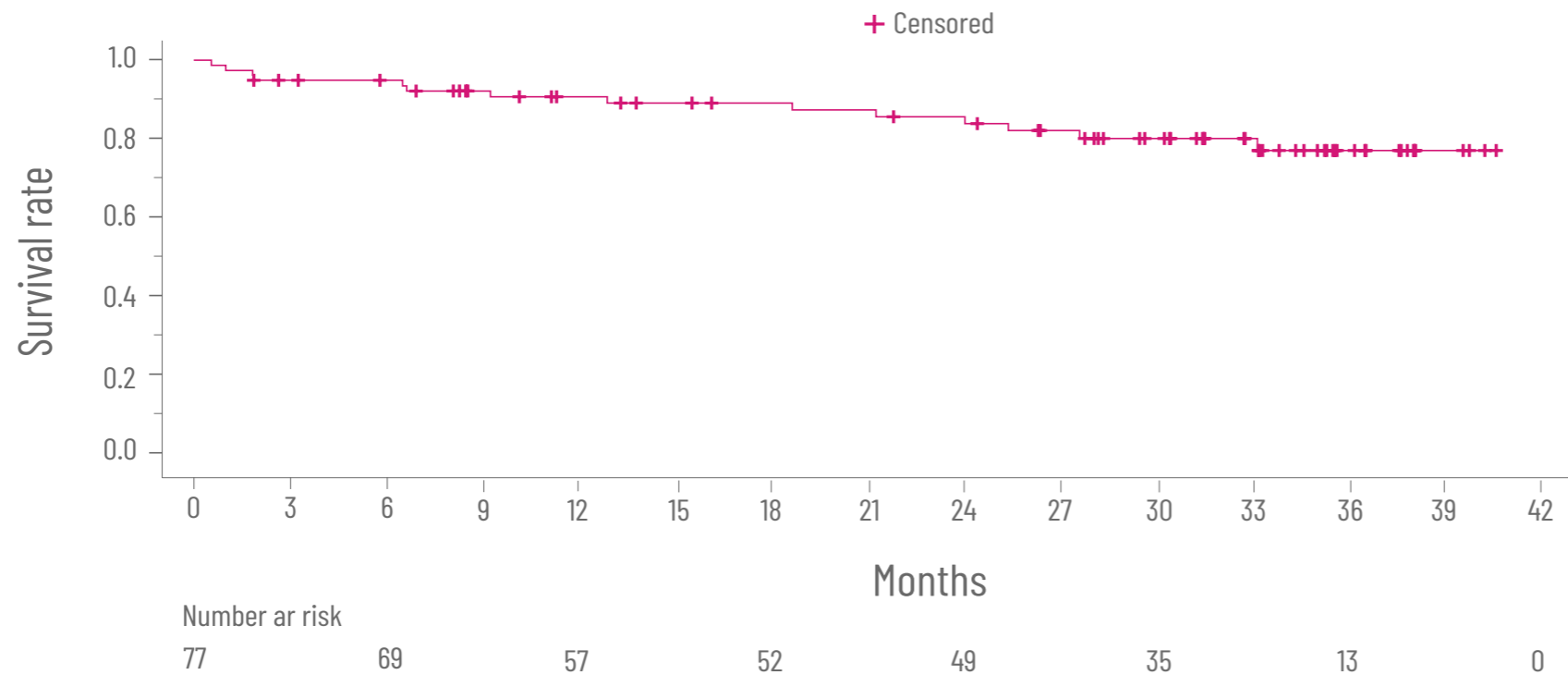
cGVHD, chronic graft-versus-host disease; FFS, failure-free survival; mITT, modified intent-to-treat.

<sup>a</sup>Kaplan-Meier curve of estimated FFS.

**References:** **1.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021. **2.** Data on File. Sanofi. 2024.

# Estimated OS rates with REZUROCK

## OS<sup>a</sup> with REZUROCK 200 mg once daily in the mITT population<sup>1</sup>



The estimated 2-year OS rate was

**86%**

(95% CI, 75-92).<sup>1</sup>

**Secondary end point:** OS, defined as the time from the first dose of REZUROCK to the date of death due to any cause.<sup>2,3</sup>

Adapted from Data on File, Sanofi.<sup>1</sup>

mITT, modified intent-to-treat; OS, overall survival.

<sup>a</sup>Kaplan-Meier curve of estimated OS.

**References:** **1.** Data on File. Sanofi. 2024. **2.** Data on File. Sanofi. 2023. **3.** Cutler C, Lee SJ, Arai S, et al; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*. 2021;138 (22):2278-2289. doi:10.1182/blood.2021012021.

# The ROCKstar study: safety and tolerability profile<sup>1</sup>

**AEs were overall consistent with those expected in patients with cGVHD receiving corticosteroids and other immunosuppressants.**

Data up to 19 August 2020 included.<sup>1</sup>

- There was 1 reported case of Epstein-Barr virus and 1 reported case of CMV reactivation

Commonly reported AEs, n (%)	REZUROCK 200 mg QD (n=66)	REZUROCK 200 mg BID (n=66)	Overall (N=132)
<b>All grades in ≥20% of patients</b>			
Fatigue	<b>30 (46)</b>	20 (30)	50 (38)
Diarrhoea	<b>23 (35)</b>	21 (32)	44 (33)
Nausea	<b>23 (35)</b>	18 (27)	41 (31)
Cough	<b>20 (30)</b>	17 (26)	37 (28)
Upper respiratory tract infection	<b>17 (26)</b>	18 (27)	35 (27)
Dyspnea	<b>21 (32)</b>	12 (18)	33 (25)
Headache	<b>13 (20)</b>	18 (27)	31 (24)
Peripheral edema	<b>17 (26)</b>	13 (20)	30 (23)
Vomiting	<b>18 (27)</b>	10 (15)	28 (21)
Muscle spasms	<b>13 (20)</b>	13 (20)	26 (20)
<b>Grade ≥3 in ≥5% of patients</b>			
Pneumonia	<b>6 (9)</b>	4 (6)	10 (8)
Hypertension	<b>4 (6)</b>	4 (6)	8 (6)
Hyperglycemia	<b>3 (5)</b>	3 (5)	6 (5)

Safety overview	REZUROCK 200 mg QD (n=66)	REZUROCK 200 mg BID (n=66)	Overall (N=132)
Median duration of treatment, mo	<b>9.4</b>	11.8	10.4
Any AE, n (%)	<b>65 (99)</b>	66 (100)	131 (99)
Grade ≥3 AEs, n (%)	<b>37 (56)</b>	34 (52)	71 (54)
SAEs, n (%)	<b>27 (41)</b>	23 (35)	50 (38)
<b>Drug-related AEs, n (%)</b>			
Any related AE	<b>49 (74)</b>	40 (61)	89 (67)
Related SAEs	<b>5 (8)</b>	2 (3)	7 (5)
Deaths <sup>a</sup> , n (%)	<b>8 (12)</b>	6 (9)	14 (11)

<sup>a</sup>Six subjects died during long-term follow-up (>28 days after the last dose).

**According to the Summary of Product Characteristics, the dosage of REZUROCK should be increased to 200 mg twice daily when co-administered with strong CYP3A inducers or proton pump inhibitors (PPIs).**

AE, adverse event; cGVHD, chronic graft-versus-host disease; CMV, cytomegalovirus.