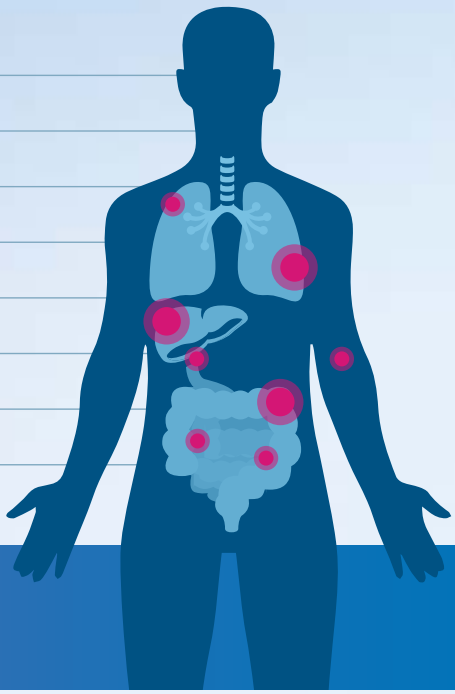
THE CHALLENGES OF MULTIORGAN cGVHD—IS YOUR THERAPY READY?

REZUROCK®
(belumosudil) tablets

42% of patients had ≥4 organs involved at the time of cGVHD diagnosis[1,a]

ORGAN INVOLVEMENT AT THE TIME OF DIAGNOSIS[1,a]

Skin	55%
Mouth	47%
Eyes	34%
Upper GI tract	24%
Lower GI tract	22%
Liver	22%
Lungs	20%
Esophagus	17%
Joints and fascia	17%



In addition to inflammation, patients frequently develop multiorgan fibrosis, which may further complicate cGVHD treatment.[2-4]

cGVHD, chronic graft-versus-host disease; GI, gastrointestinal.

[a]Based on an analysis of 93 charts of patients with cGVHD who received ≥3 lines of therapy.[1]

INDICATION

REZUROCK® (belumosudil) is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, REZUROCK can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with REZUROCK and for at least one week after the last dose

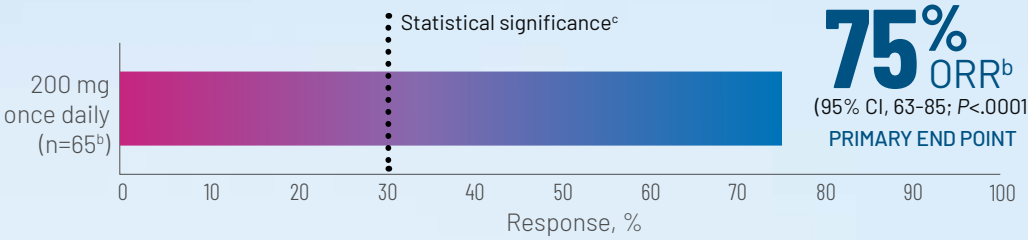
Please see additional Important Safety Information throughout.
Please see full Prescribing Information.

Help address diverse patient needs, including organ involvement[5]

REZUROCK® (belumosudil) tablets

REZUROCK: Clinically meaningful and statistically significant ORR in a real-world demographic of patients[5,6]

STATISTICALLY SIGNIFICANT ORR[a] FOLLOWING TREATMENT WITH REZUROCK 200 mg ONCE DAILY[5-7]



CR, n=4 (6%). PR, n=45 (69%).[1]

Study design: The ROCKstar study was an open-label phase 2 study comparing REZUROCK 200 mg once daily (n=66)[d] with REZUROCK 200 mg twice daily (n=66) in patients with cGVHD aged ≥12 years who received 2 to 5 prior lines of systemic therapy.[6]

ROCKstar study select baseline patient characteristics (200-mg once-daily arm): Median age of 53 years (range, 21-77); male, n=42 (64%); median of 3 prior lines of systemic therapy; median of 25 months (range, 2-162) from cGVHD diagnosis to enrollment; median prednisone-equivalent dose at enrollment of 0.20 mg/kg/d (range, 0.03-0.95); concomitant PPI use, n=33 (50%); ≥4 organs involved, n=33 (50%); previous aGVHD, n=42 (64%); refractory to prior line of systemic therapy, n=44 (79%)[e]; NIH-defined disease severity: n=46 (70%) severe, n=18 (27%) moderate, n=2 (3%) mild. Prior systemic therapies included corticosteroids (prednisone), n=65 (99%); tacrolimus, n=40 (61%); ECP, n=31 (47%); ibrutinib, n=22 (33%); and ruxolitinib, n=20 (30%).[6,8]

aGVHD, acute graft-versus-host disease; CR, complete response; ECP, extracorporeal photopheresis; FDA, US Food and Drug Administration; NIH, National Institutes of Health; ORR, overall response rate; PPI, proton pump inhibitor; PR, partial response.

[a]Proportion of patients who achieved CR or PR according to the 2014 NIH cGVHD Consensus Criteria.[5]
[b]Based on a final analysis by the FDA (n=65).
[c]Statistical significance was achieved if the lower bound of the 95% CI of ORR exceeded 30%.[6]
[d]The final FDA interpretation of the ROCKstar study omitted 1 patient from the REZUROCK 200-mg once-daily arm. As a result, there are minor differences between the ROCKstar publication, where n=66, and the Prescribing Information, where n=65.
[e]Denominator excludes patients with unknown status.[5]

IMPORTANT SAFETY INFORMATION (cont)

Adverse Reactions

- The most common (≥ 20%) adverse reactions, including laboratory abnormalities, were infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension

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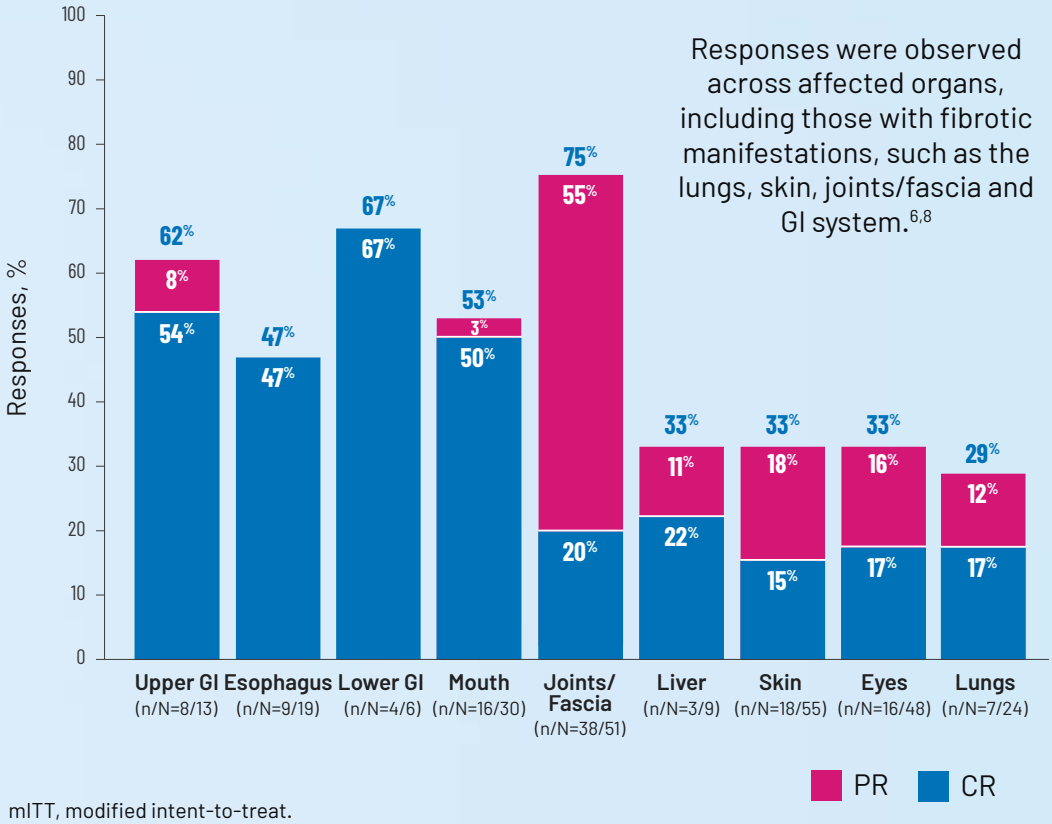
REZUROCK may be the answer to multiorgan threats

REZUROCK®
(belumosudil) tablets

Patients on REZUROCK saw PR and CR across multiple organs[6]

RESPONSES BY ORGAN SYSTEM WITH REZUROCK 200 mg ONCE DAILY IN THE mITT POPULATION (n=66)[8]



Responses were observed across affected organs, including those with fibrotic manifestations, such as the lungs, skin, joints/fascia and GI system.[6,8]

mITT, modified intent-to-treat.

IMPORTANT SAFETY INFORMATION (cont)

Adverse Reactions (cont)

- Permanent discontinuation of REZUROCK due to adverse reactions occurred in 18% of patients. The adverse reactions which resulted in permanent discontinuation of REZUROCK in > 3% of patients included nausea (4%). Adverse reactions leading to dose interruption occurred in 29% of patients. The adverse reactions leading to dose interruption in ≥ 2% were infections (11%), diarrhea (4%), and asthenia, dyspnea, hemorrhage, hypotension, liver function test abnormal, nausea, pyrexia, edema, and renal failure with (2% each)

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IMPORTANT SAFETY INFORMATION (cont)

Adverse Reactions (cont)

- Monitor total bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) at least monthly

Drug Interactions

- **Strong CYP3A Inducers:** Coadministration of REZUROCK with strong CYP3A inducers decreases belumosudil exposure, which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK to 200 mg twice daily when coadministered with strong CYP3A inducers
- **Proton Pump Inhibitors:** Coadministration of REZUROCK with proton pump inhibitors decreases belumosudil exposure, which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK to 200 mg twice daily when coadministered with proton pump inhibitors

Use in Specific Populations

- **Pregnancy:** Based on findings from animal studies and the mechanism of action, REZUROCK can cause fetal harm when administered to pregnant women. There are no available human data on REZUROCK use in pregnant women to evaluate for a drug-associated risk. Advise pregnant women and females of reproductive potential of the potential risk to the fetus
- **Lactation:** There are no data available on the presence of belumosudil or its metabolites in human milk or the effects on the breastfed child, or milk production. Because of the potential for serious adverse reactions from belumosudil in the breastfed child, advise lactating women not to breastfeed during treatment with REZUROCK and for at least one week after the last dose
- **Pediatric Use:** The safety and effectiveness of REZUROCK have been established in pediatric patients 12 years and older. The safety and effectiveness of REZUROCK in pediatric patients less than 12 years old have not been established
- **Geriatric Use:** Of the 186 patients with chronic GVHD in clinical studies of REZUROCK, 26% were 65 years and older. No clinically meaningful differences in safety or effectiveness of REZUROCK were observed in comparison to younger patients

References: 1. Data on file 1. Kadmon Pharmaceuticals, LLC; 2018. **2.** Jagasia MH, Greinix HT, Arora M, et al. National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease: I. The 2014 Diagnosis and Staging Working Group report. *Biol Blood Marrow Transplant*. 2015;21(3):389-401.e1. doi:10.1016/j.bbmt.2014.12.001 **3.** Flowers MED, Martin PJ. How we treat chronic graft-versus-host disease. *Blood*. 2015;125(4):606-615. doi:10.1182/blood-2014-08-551994 **4.** Kitko CL, White ES, Baird K. Fibrotic and sclerotic manifestations of chronic graft-versus-host disease. *Biol Blood Marrow Transplant*. 2012;18(1 suppl):S46-S52. doi:10.1016/j.bbmt.2011.10.021 **5.** REZUROCK. Package insert. Kadmon Pharmaceuticals, LLC; 2023. **6.** 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 **7.** Data on file 2. Kadmon Pharmaceuticals, LLC; 2021. **8.** Data on file 3. Kadmon Pharmaceuticals, LLC; 2021.

CLICK or **TAP** to connect with a representative and receive email updates about REZUROCK.

Please see additional Important Safety Information throughout.
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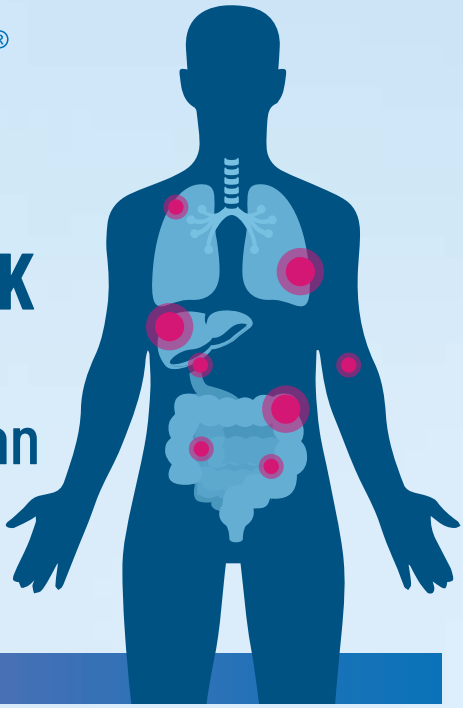

CONSIDER REZUROCK
for your appropriate patients with multiorgan involvement

IMPORTANT SAFETY INFORMATION (cont)

Use in Specific Populations (cont)

- **Renal and Hepatic Impairment:** Treatment with REZUROCK has not been studied in patients with pre-existing severe renal or hepatic impairment. For patients with pre-existing severe renal or hepatic impairment, consider the risks and potential benefits before initiating treatment with REZUROCK

You are encouraged to report side effects of prescription drugs to the FDA. Visit **www.FDA.gov/medwatch** or call **1-800-FDA-1088**. You may also contact Kadmon Pharmaceuticals, LLC, at **1-877-377-7862** to report side effects.

Please see additional Important Safety Information throughout.
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CLICK or **TAP** to visit REZUROCKhcp.com

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MAT-US-2305538-v1.0-08/2023