In **cGVHD**, where inflammation and fibrosis coexist[1,2]

# OPEN THEIR WORLD TO POSSIBILITIES WITH REZUROCK

For patients with cGVHD aged ≥12 years,
**REACH FOR REZUROCK as soon as any 2 systemic therapies fail[1]**

Patient portrayal.

cGVHD, chronic graft-versus-host disease; STAT3, signal transducer and activator of transcription 3; STAT5, signal transducer and activator of transcription 5; Th17, type 17 helper T [cell]; Treg, regulatory T [cell].

## MECHANISM OF ACTION

Belumosudil downregulated pro-inflammatory responses via regulation of STAT3/STAT5 phosphorylation and shifting Th17/Treg balance in ex vivo or in vitro human T-cell assays. Belumosudil also inhibited aberrant profibrotic signaling in vitro. In vivo, belumosudil demonstrated activity in animal models of cGVHD. The mechanism of action of belumosudil in cGVHD is not fully understood.[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 one week after the last dose

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

REZUROCK®
(belumosudil) tablets

# **cGVHD presents multiple challenges** for patients who have already suffered so much[1,3-5]

## cGVHD is a common and serious complication that affects about half of alloHCT recipients[6]

- cGVHD is a widespread immune reaction involving donor B and T cells and is characterized by the presence of inflammatory and fibrotic manifestations[2,7]
- aGVHD is characterized by inflammation and primarily involves the skin, GI tract and liver. Unlike aGVHD, cGVHD also involves fibrosis across multiple organ systems[2,7]
- The burden of cGVHD is multifaceted, with patients experiencing poor QOL and progressive disability[3,8]
- Immunosuppressive therapy plays an important role, but is not always effective in addressing the disease[4,9,10]

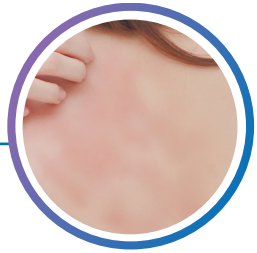
**cGVHD affects immune homeostasis, throwing the immune system out of balance.[2]**

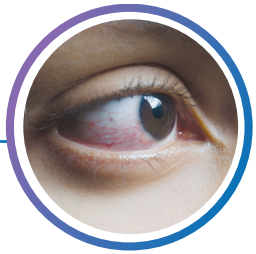
## Patients with cGVHD can develop multiorgan manifestations in the[11]


aGVHD, acute graft-versus-host disease; alloHCT, allogeneic hematopoietic cell transplant; GI, gastrointestinal; QOL, quality of life.

## cGVHD affects each patient differently[9,11]; however, it typically presents as

- Skin rashes and lesions[10,12-14]
- Skin thickening or tightening[10,12-14]
- Joint stiffness and loss of mobility and dexterity[10,12]
- Impaired lung function[10]
- Nausea, vomiting, diarrhea or loss of appetite[9,10]
- General decline in health, including fatigue[15,16]
- Ocular dysfunction[10,15]
- Abnormal liver function, measured by various tests[10]





Patient portrayal.

**HEAR FROM PATIENTS WITH cGVHD**

**CLICK or TAP** to access videos of patients with cGVHD talking about their condition.

# **REZUROCK works differently** by targeting both the inflammatory and fibrotic processes of cGVHD[1,17,18]

REZUROCK® (belumosudil) tablets

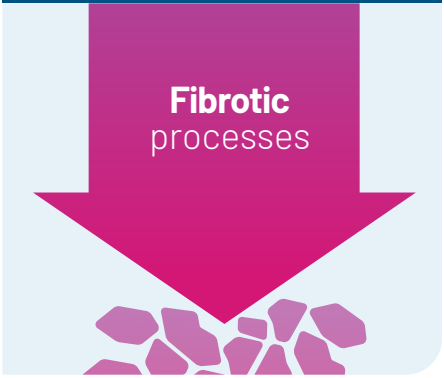
As an oral selective ROCK2 inhibitor, REZUROCK is an innovative treatment designed to **restore immune homeostasis** and **downregulate the fibrotic processes** of cGVHD.[1,17,18]

**Reduces inflammation via its immunomodulatory effect[17,19]**


**Downregulates** pro-inflammatory Tfh and Th17 cells[17,19]

**Upregulates** Treg cells, restoring immune homeostasis[20]

**Downregulates fibrosis[18,21]**




**Prevents** upregulation of profibrotic genes and processes[21]

To learn more about the MOA of REZUROCK, visit **REZUROCKhcp.com**.
The MOA video for patients and caregivers is available at **REZUROCK.com**.

The mechanism of action of belumosudil in cGVHD is not fully understood.

MOA, mechanism of action; ROCK2, rho-associated coiled-coil–containing protein kinase-2; Tfh, follicular helper T [cell].

## 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

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

# What your patients **should know** about REZUROCK study results

REZUROCK® (belumosudil) tablets

Your patients and their caregivers may have questions about REZUROCK. This information may be helpful for establishing treatment expectations.

## Clinically meaningful[a] responses were seen in the pivotal ROCKstar study (n=66).[22,b,c]

- Statistically significant ORR[d] of 75% (primary end point; 95% CI, 63-85; *P*<.0001) with the 200-mg once-daily dose in a broad range of patients[1,11,22,e,f]
- 63% of responses were observed between weeks 4 and 8[11]
- 94% of responses were observed by week 24[11]
- Some patients may take longer to respond, especially those with more severe disease and organ involvement with fibrotic manifestations[9,22]

## Patients saw improvement across multiple organs, including the[11]

- Skin
- Eyes
- Mouth
- Lower and upper GI tract
- Esophagus
- Joints/fascia
- Liver
- Lungs

## Some patients had a reduced need for corticosteroids and other immunosuppressants.[11,22]

## REZUROCK can be used in patients after failure of any 2 prior systemic therapies.[1]

**52% (n/N=34/65) of patients[f] reported clinically meaningful improvements in QOL (95% CI, 40-65)**

(≥7-point reduction in LSS[g] summary score) with REZUROCK 200 mg once daily in an exploratory analysis.[1,11,h]

- Both responders (61%) and nonresponders[i] (25%) had improved QOL scores[11]

Visit **REZUROCKhcp.com** to learn more.

AE, adverse event; CR, complete response; FDA, US Food and Drug Administration; LSS, Lee Symptom Scale; NIH, National Institutes of Health; ORR, overall response rate; PR, partial response.

[a]Clinically meaningful was defined as a ≥30% ORR.[22]
[b]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.
[c]The ROCKstar study was an open-label phase 2 study comparing REZUROCK 200 mg once daily (n=66) 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. Prespecified key secondary end points were not powered to show statistical significance.[1,22,b]
[d]ORR was defined as the proportion of patients who achieved CR or PR according to the 2014 NIH cGVHD Consensus Criteria.[1,22]
[e]Statistical significance was achieved if the lower bound of the 95% CI of ORR exceeded 30%.[22]
[f]Based on a final analysis by the FDA as seen through cycle 7 day 1 (n=65).[1]
[g]The 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.[23]
[h]An exploratory analysis provides a better understanding of a problem but is not proof. It is difficult to measure QOL because every person is different and will have a unique experience with treatment.
[i]Nonresponders were defined as patients with CR or PR in ≥1 organ, accompanied by progression in another organ (considered progression); outcomes that did not meet the criteria for CR, PR, progression or mixed response; or progression in ≥1 organ or site without a response in any other organ or site.[11]

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

# REZUROCK was well tolerated in patients with cGVHD[1]

REZUROCK® (belumosudil) tablets

## Safety was evaluated across 2 clinical studies[1]

### Consider the safety profile of REZUROCK in patients with cGVHD who often receive immunosuppressive therapy.

- Fatal adverse reaction was reported in 1 patient with severe nausea, vomiting, diarrhea and multiorgan failure[1]
- 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%)[1]
- 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[1]
- There were no reports of CMV infection in both the ROCKstar and the foundational, dose-finding KD025-208 studies, and only 1 report of CMV reactivation in total[22,24]
- In the ROCKstar and KD025-208 clinical studies of REZUROCK, grade ≥3 cytopenias were reported in <4% and 4% of patients, respectively[22,24]

**MOST PATIENTS WERE ABLE TO MAINTAIN TREATMENT WITH REZUROCK 200 mg ONCE DAILY (n=83)[1]**

**9.2 MONTHS**

Patients had a median duration of treatment of 9.2 months (range, 0.5-44.7 months).

Patient portrayal.

CMV, cytomegalovirus.

[a]Data included results from a dose-finding multicenter study of REZUROCK for the treatment of patients with cGVHD (N=54) who had received 1 to 3 prior lines of systemic therapy and required additional treatment. REZUROCK was administered by mouth at 200 mg once daily, 200 mg twice daily or 400 mg once daily.[24]

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

# Safety results across 2 clinical studies pooled for analysis[1]

REZUROCK® (belumosudil) tablets

## NONLABORATORY ADVERSE REACTIONS IN ≥10% OF PATIENTS WITH cGVHD TREATED WITH REZUROCK 200 mg ONCE DAILY (n=83)[1,b]

| | | All grades, % | Grades 3-4, % |
|---|---|---|---|
| Infections and infestations | Infection (pathogen not specified) | 53 | 16 |
| | Viral infection | 19 | 4 |
| | Bacterial infection | 16 | 4 |
| General disorders and administration site conditions | Asthenia | 46 | 4 |
| | Edema | 27 | 1 |
| | Pyrexia | 18 | 1 |
| Gastrointestinal | Nausea | 42 | 4 |
| | Diarrhea | 35 | 5 |
| | Abdominal pain | 22 | 1 |
| | Dysphagia | 16 | 0 |
| Respiratory, thoracic and mediastinal | Dyspnea | 33 | 5 |
| | Cough | 30 | 0 |
| | Nasal congestion | 12 | 0 |
| Vascular | Hemorrhage | 23 | 5 |
| | Hypertension | 21 | 7 |
| Musculoskeletal and connective tissue | Musculoskeletal pain | 22 | 4 |
| | Muscle spasm | 17 | 0 |
| | Arthralgia | 15 | 2 |
| Nervous system | Headache | 21 | 0 |
| Metabolism and nutrition | Decreased appetite | 17 | 1 |
| Skin and subcutaneous | Rash | 12 | 0 |
| | Pruritus | 11 | 0 |

[a]Data included results from a dose-finding multicenter study of REZUROCK for the treatment of patients with cGVHD (N=54) who had received 1 to 3 prior lines of systemic therapy and required additional treatment. REZUROCK was administered by mouth at 200 mg once daily, 200 mg twice daily or 400 mg once daily.[24]

[b]Please see Table 2 of the REZUROCK Prescribing Information for complete details on nonlaboratory adverse reactions.

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

# REZUROCK: Convenient once-daily oral tablet for your patients with cGVHD[1]

REZUROCK® (belumosudil) tablets

## The recommended dose of REZUROCK is 200 mg once daily administered orally[1]

Inform patients that the REZUROCK tablets should be swallowed whole with a glass of water **without cutting, crushing or chewing the tablets**.

Advise patients to take REZUROCK at approximately the **same time each day** with a meal. It is important for patients to understand that **a meal is not a snack**, and that it is about the same amount of calories as they might have for lunch or dinner.

If the patient misses a dose of REZUROCK, instruct the patient **not to take extra doses** to make up for the missed dose.

**Monitor total bilirubin, AST and ALT** at least monthly (see full Prescribing Information for more details on when to hold or discontinue REZUROCK due to hepatotoxicity or other adverse reactions).

If patients are **taking proton pump inhibitors** (eg, rabeprazole) **or strong CYP3A inducers** (eg, rifampin), increase the dosage of REZUROCK to 200 mg twice daily.

## Effect of REZUROCK on other drugs

- **BCRP Substrates:** Avoid concomitant use with drugs that are BCRP substrates (eg, rosuvastatin) where possible. If used together, monitor patients more frequently for adverse reactions and decrease the BCRP substrates dosage(s) in accordance with the respective Prescribing Information
- **OATP1B1 Substrates:** If used together, monitor patients more frequently for adverse reactions of these substrates (eg, rosuvastatin) and decrease the OATP1B1 substrates dosage(s) in accordance with the respective Prescribing Information
- **Certain CYP1A2, CYP3A, P-gp or UGT1A1 Substrates:** Avoid concomitant use of REZUROCK with drugs that are sensitive CYP1A2 substrates (eg, caffeine), sensitive CYP3A substrates (eg, midazolam), UGT1A1 substrates (eg, raltegravir) or P-gp substrates (eg, dabigatran), for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the substrates dosage(s) in accordance with the respective Prescribing Information

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BCRP, breast cancer resistance protein; CYP1A2, cytochrome P450 family 1 subfamily A member 2; CYP3A, cytochrome P450 family 3 subfamily A; OATP1B1, organic anion transporting polypeptide 1B1; P-gp, P-glycoprotein; UGT1A1, uridine diphosphate glucuronosyltransferase family 1 member A1.

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


Patient portrayal.

Not actual size.

Store REZUROCK tablets at room temperature (68 °F-77 °F [20 °C-25 °C]) in the original container.[1]

REZUROCK should be dispensed to the patient in the original container only. Store in original container to protect from moisture. Replace cap securely each time after opening. Do not discard desiccant.[1]

Each pale-yellow, oblong, 200-mg tablet is debossed with "KDM" on one side and "200" on the other side.[1]

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## 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)

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

# Important Safety Information

REZUROCK®
(belumosudil) tablets

## 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 one week after the last dose

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

### Drug Interactions

- **Proton Pump Inhibitors:** Belumosudil exhibits pH-dependent solubility. Concomitant use of REZUROCK with proton pump inhibitors decreases belumosudil exposure, which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK when used concomitantly with proton pump inhibitors
- **Strong CYP3A Inducers:** Belumosudil is a CYP3A substrate. Concomitant use of REZUROCK with strong CYP3A inducers decreases belumosudil exposure which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK when used concomitantly with strong CYP3A inducers
- **BCRP and OATP1B1 Substrates:** Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions and decrease the BCRP substrates dosage(s) in accordance with the respective Prescribing Information.

  Belumosudil is a BCRP inhibitor. Concomitant use of REZUROCK with BCRP substrates increases their plasma concentrations, which may increase the risk of adverse reactions related to these substrates.

  Belumosudil is an OATP1B1 inhibitor. Concomitant use of REZUROCK with OATP1B1 substrates may increase their plasma concentrations. Monitor patients more frequently for adverse reactions of these substrates and decrease the OATP1B1 substrates dosage(s) in accordance with the respective Prescribing Information

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

# Important Safety Information (cont)

REZUROCK® (belumosudil) tablets

### Drug Interactions (cont)

- **Certain CYP1A2 and CYP3A Substrates:** Avoid concomitant use of REZUROCK with drugs that are sensitive CYP1A2 or CYP3A substrates, for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the CYP1A2 or CYP3A substrate dosage(s) in accordance with the respective Prescribing Information. Belumosudil is a CYP1A2 and CYP3A inhibitor. Concomitant use of REZUROCK with sensitive CYP1A2 substrates (e.g., caffeine) or CYP3A substrates (e.g., midazolam) is predicted to increase CYP1A2 or CYP3A substrate exposure, which may increase the risk of adverse reactions related to these substrates
- **Certain UGT1A1 Substrates:** Avoid concomitant use of REZUROCK with drugs that are UGT1A1 substrates, for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the UGT1A1 substrates dosage(s) in accordance with the respective Prescribing Information. Belumosudil is a UGT1A1 inhibitor. Concomitant use of REZUROCK with a UGT1A1 substrate decreased plasma concentrations of the glucuronide metabolite of the UGT1A1 substrate. Concomitant use of belumosudil with other UGT1A1 substrates may increase their plasma concentrations, which may increase the risk of adverse reactions related to these substrates
- **Certain P-gp Substrates:** Avoid concomitant use of REZUROCK with drugs that are P-gp substrates, for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the P-gp substrates dosage(s) in accordance with the respective Prescribing Information. Belumosudil is a P-gp inhibitor. Concomitant use of REZUROCK with P-gp substrates increased their plasma concentrations, which may increase the risk of adverse reactions related to these substrates

### Use in Specific Populations

- **Pregnancy:** 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 one week after the last dose
- **Pediatric Use:** 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
- **Renal Impairment:** Treatment with REZUROCK has not been studied in patients with pre-existing severe renal impairment. For patients with pre-existing severe renal impairment, consider the risks and potential benefits before initiating treatment with REZUROCK
- **Hepatic Impairment:** Avoid use in patients with moderate hepatic impairment (Child-Pugh B) or severe hepatic impairment (Child-Pugh C) without liver GVHD. No dose adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A)

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

# MyROCK ASSIST™

Enroll patients in MyROCK ASSIST so our specialists can determine which programs are available to patients.

## INSURANCE

Navigating coverage and providing insurance assistance

## CO-PAY

Co-pay savings program[a] for commercially or privately insured patients

## ACCESS

Providing a free 30-day supply of REZUROCK to eligible patients who experience delays or gaps in their insurance coverage

**For full Terms and Conditions, and to enroll patients in MyROCK ASSIST, please visit MyROCKASSIST.com or call 1-844-523-6661, Monday through Friday, 8 AM–8 PM ET.**

Patient portrayal.

[a]Patient Terms and Conditions: The MyROCK ASSIST Commercial Co-pay Savings Program provides co-pay/coinsurance support for out-of-pocket costs on REZUROCK® (belumosudil) tablets prescriptions. A yearly maximum benefit applies. Limit one 30-day supply per 30 days. This program is not health insurance. This program is for commercially or privately insured patients only; uninsured or cash-paying patients are not eligible. Patients are not eligible if prescriptions are paid, in whole or in part, by any state- or federally funded programs, including, but not limited to, Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, TriCare, private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs, or where prohibited by law. The co-pay program may not be combined with any other rebate, coupon or offer. Sanofi reserves the right to rescind, revoke or amend this offer at any time without further notice. Any savings provided by the program may vary depending on patients' out-of-pocket costs. This program is intended to help patients afford REZUROCK. Patients may have insurance plans that attempt to dilute the impact of the assistance available under the program. In those situations, the program may change its terms. Card is valid through December 31 of the year of activation. On January 1 of the following year, the card automatically resets and is subject to annual limits if the prescription benefit remains the same. A representative of Sanofi may contact the patient for follow up on any adverse event that may be reported. Upon registration, patients receive all program details.

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

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MAT-US-2204988-v5.0-03/2026

REZUROCK®
(belumosudil) tablets