NCCN PREFERRED CATEGORY 1

Ripretinib (QINLOCK®) is **THE ONLY** recommended 4th-line therapy for advanced GIST[1]*

MANAGING PATIENTS ON QINLOCK® (ripretinib)

A guide to adverse reactions, dosing, and administration

GIST=gastrointestinal stromal tumor; NCCN®=National Comprehensive Cancer Network®.

*Preferred 4th-line therapy (Category 1) for unresectable or metastatic disease.[1]

INDICATION

QINLOCK is a kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

SELECT SAFETY INFORMATION

There are no contraindications for QINLOCK.

Palmar-plantar erythrodysesthesia syndrome (PPES): In INVICTUS, Grade 1-2 PPES occurred in 21% of the 85 patients who received QINLOCK. PPES led to dose discontinuationin 1.2% of patients, dose interruption in 2.4% of patients,and dose reduction in 1.2% of patients. Based on severity, withhold QINLOCK and then resume at same or reduced dose.

Please see additional Safety Information throughout and accompanying full Prescribing Information, including Patient Information.

QINLOCK® (ripretinib) 50 mg tablets

QINLOCKHCP.com

QINLOCK® (ripretinib) DEMONSTRATED POWERFUL PFS RESULTS[2]

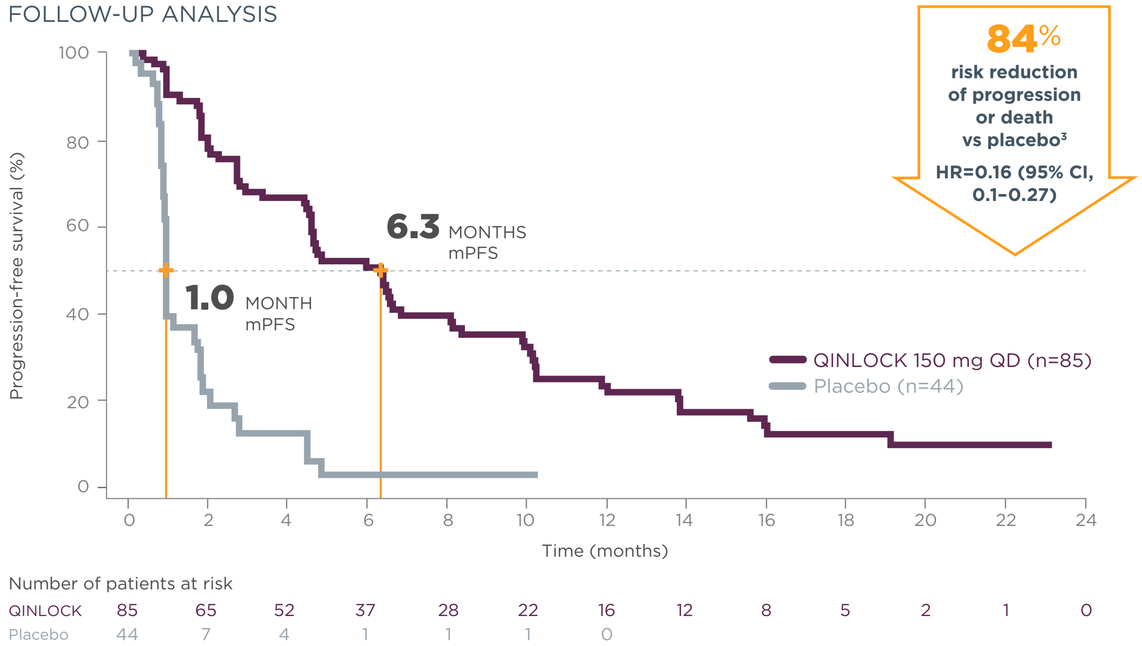
QINLOCK provided superior median PFS vs placebo in the primary analysis of the Phase 3 INVICTUS study[2]

PRIMARY ENDPOINT: PFS

- 6.3 months vs 1.0 month (HR=0.15 [95% CI, 0.09-0.25]; *P*<0.0001)[2]

QINLOCK demonstrated consistent PFS results after 9 months of additional follow-up[3]*

FOLLOW-UP ANALYSIS



Number of patients at risk

QINLOCK	85	65	52	37	28	22	16	12	8	5	2	1	0
Placebo	44	7	4	1	1	1	0						

Clinically meaningful improvement in objective response rate (ORR) by BICR

KEY SECONDARY ENDPOINT: ORR

PRIMARY ANALYSIS

9.4% QINLOCK **vs. 0.0%** Placebo
(*P*=0.0504)[2,4†]

- 66% of QINLOCK-treated patients experienced stable disease ≥6 weeks vs 20% with placebo (exploratory analysis)[4]

FOLLOW-UP ANALYSIS

11.8% QINLOCK **vs. 0.0%** Placebo[3*]

- Median duration of response was 14.5 months with QINLOCK vs NE with placebo[3]

Study design: INVICTUS was a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial in 129 patients who had received ≥3 prior anticancer therapies for advanced GIST. The primary endpoint was PFS based on BICR using modified RECIST 1.1 criteria. The key secondary endpoint was ORR based on BICR. Additional secondary endpoints included OS, quality of life, and safety. Participants were randomized 2:1 to receive 150 mg QD QINLOCK (n=85) or placebo (n=44). Treatment continued until disease progression or unacceptable toxicity. At disease progression, placebo patients could cross over to QINLOCK. After the primary analysis data cutoff date (May 31, 2019), 9 months of additional follow-up was conducted (March 9, 2020).[2-4‡]

†All responses were partial responses.

‡44 patients were randomized to placebo but one did not receive treatment.

BICR=blinded independent central review; CI=confidence interval; HR=hazard ratio; mPFS=median progression-free survival; NE=not estimable; OS=overall survival; PFS=progression-free survival; QD=once a day; RECIST=response evaluation criteria in solid tumors.

*The follow-up analyses were conducted approximately 9 months from the data cutoff date in the primary analysis and were not powered to show statistical significance.[3]

SELECT SAFETY INFORMATION

New Primary Cutaneous Malignancies: In INVICTUS, cutaneous squamous cell carcinoma (cuSCC) occurred in 4.7% of the 85 patients who received QINLOCK with a median time to event of 4.6 months (range 3.8 to 6 months). In the pooled safety population, cuSCC and keratoacanthoma occurred in 7% and 1.9% of 351 patients, respectively.

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets

QINLOCK® (ripretinib) WAS ASSOCIATED WITH CLINICALLY MEANINGFUL OVERALL SURVIVAL[2]

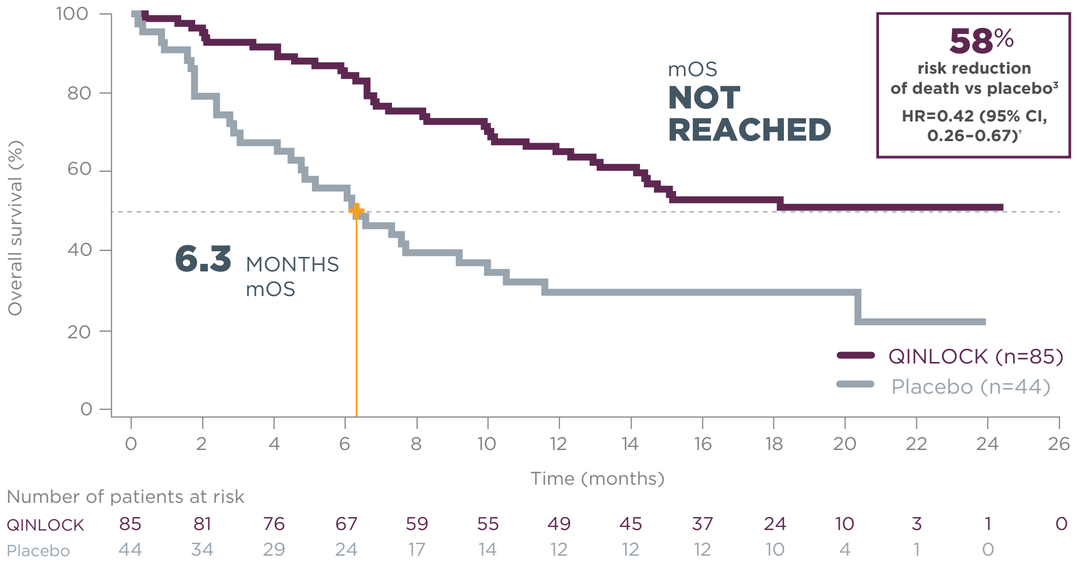
QINLOCK overall survival (OS) vs placebo in the primary analysis[2,4*]

SECONDARY ENDPOINT: OS

- 15.1 months vs 6.6 months (HR=0.36 [95% CI, 0.21-0.62])[2,4*]

QINLOCK median OS not reached after 9 months of additional follow-up[3†]

FOLLOW-UP ANALYSIS



Number of patients at risk

QINLOCK	85	81	76	67	59	55	49	45	37	24	10	3	1	0
Placebo	44	34	29	24	17	14	12	12	12	10	4	1	0	

mOS=median overall survival.

OS data include all time periods. Placebo curve includes patients who crossed over to QINLOCK treatment.

Estimated OS after 9 months of additional follow-up[3]

Estimated landmark OS	QINLOCK (n=85)	Placebo (n=44)
6-months OS (95% CI)	**84.3%** (74.5–90.6)	**55.9%** (39.9–69.2)
12-months OS (95% CI)	**65.1%** (53.6–74.5)	**29.7%** (16.8–43.7)
18-months OS (95% CI)	**53.0%** (41.3–63.3)	**29.7%** (16.8–43.7)
24-months OS (95% CI)	**50.6%** (38.5–61.4)	**NE** (NE–NE)

Data will continue to mature as additional patient follow-up is conducted and these estimates are therefore subject to inherent limitations.

*OS was a secondary endpoint in the INVICTUS trial. OS was not evaluated for statistical significance as a result of the sequential testing procedure used for the secondary endpoints of ORR and OS.[2,4]

†The follow-up analysis was conducted approximately 9 months from the data cutoff date in the primary analysis and was not powered to show statistical significance.[3]

NCCN PREFERRED CATEGORY 1

Ripretinib (QINLOCK®) is **THE ONLY therapy recommended** for 4th-line advanced GIST by the National Comprehensive Cancer Network® (NCCN®)[1]

SELECT SAFETY INFORMATION

In INVICTUS, melanoma occurred in 2.4% of the 85 patients who received QINLOCK. In the pooled safety population, melanoma occurred in 0.9% of 351 patients. Perform dermatologic evaluations when initiating QINLOCK and routinely during treatment. Manage suspicious skin lesions with excision and dermatopathologic evaluation. Continue QINLOCK at the same dose.

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets

SAFETY ESTABLISHED ACROSS A BROAD RANGE OF PATIENTS IN THE INVICTUS TRIAL PRIMARY ANALYSIS[2,4]

Serious adverse reactions

- Serious adverse reactions occurring in >2% of patients were abdominal pain (4.7%), anemia (3.5%), nausea (2.4%) and vomiting (2.4%)[2]

Rates of dose modifications due to adverse reactions were similar between QINLOCK® (ripretinib) and placebo

Dose modifications due to adverse reactions

	QINLOCK (n=85)[2]	Placebo (n=43)[5*†]
Discontinuation	**8%**	12%
Dose reduction	**7%**	2%
Dose interruption	**24%**	21%

- Safety findings after 9 months of additional follow-up were generally consistent with the primary analysis[3]

The overall rates of grade 3/4 adverse reactions were similar between QINLOCK and placebo (49.4% and 44.2%, respectively)[5]

Adverse reactions reported in ≥10% of patients who received QINLOCK[2‡]

	QINLOCK (n=85)		Placebo (n=43)[†]	
	Grades 1–4	Grades 3–4	Grades 1–4	Grades 3–4
Skin and subcutaneous tissue				
Alopecia	52%	NA[§]	4.7%	NA[§]
Palmar-plantar erythrodysesthesia syndrome	21%	0	0	0
Dry skin	13%	0	7%	0
Pruritus	11%	0	4.7%	0
General				
Fatigue	42%	3.5%	23%	2.3%
Peripheral edema	17%	1.2%	7%	0
Asthenia	13%	1.2%	14%	4.7%
Gastrointestinal				
Nausea	39%	3.5%	12%	0
Abdominal pain	36%	7%	30%	4.7%
Constipation	34%	1.2%	19%	0
Diarrhea	28%	1.2%	14%	2.3%
Vomiting	21%	3.5%	7%	0
Stomatitis	11%	0	0	0

NA=not applicable.

*Placebo values represent dose modifications for treatment-emergent adverse events.[5]

†44 patients were randomized to placebo, but 1 did not receive treatment.[5]

‡In the double-blind treatment period of INVICTUS.

§There is no grade 3 or 4 alopecia as per Common Terminology Criteria for Adverse Events (CTCAE) v4.03.[6]

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets

SAFETY ESTABLISHED ACROSS A BROAD RANGE OF PATIENTS IN THE INVICTUS TRIAL PRIMARY ANALYSIS[2,4]

Adverse reactions reported in ≥10% of patients who received QINLOCK® (ripretinib), cont'd[2]*

	QINLOCK (n=85)		Placebo (n=43)†	
	Grades 1–4	Grades 3–4	Grades 1–4	Grades 3–4
Musculoskeletal and connective tissue				
Myalgia	32%	1.2%	12%	0
Arthralgia	18%	0	4.7%	0
Muscle spasms	15%	0	4.7%	0
Metabolism and nutrition				
Decreased appetite	27%	1.2%	21%	2.3%
Investigations				
Decreased weight	19%	0	12%	0
Nervous system				
Headache	19%	0	4.7%	0
Vascular				
Hypertension	14%	7%	4.7%	0
Respiratory, thoracic and mediastinal				
Dyspnea	13%	0	0	0

*In the double-blind treatment period of INVICTUS.
†44 patients were randomized to placebo, but 1 did not receive treatment.[5]

The most common Grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase (7%) and decreased phosphate (5%)[2]

- There were no Grade 4 laboratory abnormalities associated with QINLOCK

EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer 30-item; EQ-5D-5L VAS=EuroQol 5 Dimension 5 Level visual analogue scale.

Please see additional Safety Information throughout.

QINLOCK quality of life (QOL) results[4]

SECONDARY ENDPOINT: QOL
PRIMARY ANALYSIS (PRESPECIFIED ANALYSIS)

Clinically relevant differences were observed between QINLOCK and placebo in the following prespecified QOL assessments[4]

Self-reported health

Physical function

Role function

Assessments were made on Cycle 1, Day 1 (baseline) and Cycle 2, Day 1 (28 days later).

- Comparisons were only made out to Cycle 2, Day 1 for QINLOCK (n=71) and placebo (n=32) due to the low number of placebo patients with completed assessments after this point

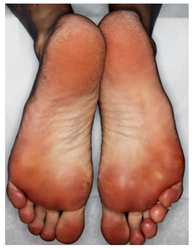
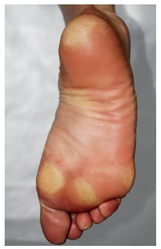
Self-reported health was evaluated using the EQ-5D-5L VAS; physical function and role function were evaluated using the EORTC QLQ-C30.

Detailed information on the above QOL analysis and results is available here ▶

QINLOCK® (ripretinib) 50 mg tablets

PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME (PPES)

PPES occurred in 21.2% of patients treated with QINLOCK® (ripretinib), the majority of which was Grade 1 (mild)[7]

Severity[6]		Rate Among QINLOCK-treated Patients[8]*
Grade 1 Minimal skin changes or dermatitis (eg, erythema, edema, or hyperkeratosis) without pain.	 Photo of actual QINLOCK patient†	12.9%
Grade 2 Skin changes (eg, peeling, blisters, bleeding, edema, or hyperkeratosis) with pain; limiting instrumental activities of daily life (ADL).	 Photo of actual QINLOCK patient†	8.2%
Grade 3 Severe skin changes (eg, peeling, blisters, bleeding, edema, or hyperkeratosis) with pain; limiting self-care ADL.	There were no cases of Grade 3 PPES in INVICTUS	0%

*From primary analysis.
†Illustrative photos of PPES observed in QINLOCK-treated patients (Grade 1 and Grade 2 PPES shown, as graded by expert oncodermatologist).
Source: CTCAE version 4.03 used in the INVICTUS trial.[8]

Please see additional Safety Information throughout.

Time to onset and maximum severity of PPES occurred almost simultaneously[7]

- Median time to first occurrence: 1.9 months
- Median time to worst severity grade: 1.9 months

This indicates that PPES generally did not worsen over time[7]

Mild to moderate PPES (Grades 1–2) was observed in the INVICTUS trial. It is likely that any PPES experienced with QINLOCK will be mild to moderate, based on the occurrence of PPES in INVICTUS[2,8]

- After 9 months of additional follow-up, the rate and grades of PPES were generally consistent in QINLOCK-treated patients (22%; Grades 1 or 2)[3]

QINLOCK® (ripretinib) 50 mg tablets

PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME (PPES)

Managing QINLOCK® (ripretinib) patients experiencing PPES

Severity[6]	How to Manage[2]
Grade 1	**No dose modifications recommended.** Consider supportive care (see opposite).
Grade 2	**Dose modification recommended:** • Withhold QINLOCK until Grade ≤1 or baseline. If recovered within 7 days, resume QINLOCK at same dose; otherwise resume at reduced dose* • Consider re-escalating QINLOCK if maintained at Grade ≤1 or baseline for at least 28 days • If PPES recurs, withhold QINLOCK until Grade ≤1 or baseline and then resume QINLOCK at a reduced dose regardless of time to improvement*
Grade 3	**Dose modification recommended**: • Withhold QINLOCK for at least 7 days or until Grade ≤1 or baseline (maximum 28 days). Resume QINLOCK at a reduced dose* • Consider re-escalating QINLOCK if maintained at Grade ≤1 or baseline for at least 28 days

*The recommended dose reduction for adverse reactions is QINLOCK 100 mg orally once daily.[2]

One patient (1.2%) had a dose reduction and one patient (1.2%) discontinued QINLOCK due to PPES in INVICTUS[2,8]

DOSE MODIFICATIONS DUE TO PPES IN THE INVICTUS STUDY[2]

Dose interruption	Dose reduction	Discontinuation
2.4%	1.2%	1.2%

Supportive care for PPES

NOTE: The below are general tips and suggestions of supportive care for patients experiencing PPES. They are not specific to QINLOCK or the INVICTUS study.

Consider advising patients to:

- Avoid hot water and hand products containing alcohol[9,10]
- Wear thick cotton gloves and/or socks at night[9,10]
- Use moisturizing creams, creams containing urea, or topical soothing ointments[9,11]

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets

HYPERTENSION

Hypertension occurred in 14.1% of patients treated with QINLOCK® (ripretinib)[2,5]

- Grade 3 hypertension was reported in 7.1% of QINLOCK-treated patients[2,5]

Severity[6]	Rate Among QINLOCK-treated Patients[8]*
Grade 1 Systolic BP 120–139 mm Hg or diastolic BP 80–89 mm Hg.	**2.4%**
Grade 2 Systolic BP 140–159 mm Hg or diastolic BP 90–99 mm Hg; medical intervention indicated; recurrent or persistent (≥24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg if previously WNL; monotherapy indicated.	**4.7%**
Grade 3 Systolic BP ≥160 mm Hg or diastolic BP ≥100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy than previously used indicated.	**7.1%**
Grade 4 Life-threatening consequences (eg, malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated.	**0%**

*From primary analysis.

Source: CTCAE version 4.03 used in the INVICTUS trial.[8]

WNL=within normal limits.

- After 9 months of additional follow-up, hypertension occurred in 15% of patients. Grades 3–4 hypertension was reported in 7% of QINLOCK-treated patients[3]

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets

HYPERTENSION

Managing QINLOCK® (ripretinib) patients experiencing hypertension

Severity[6]	How to Manage[2]
Grade 1	No dosing modifications recommended.
Grade 2	
Grade 3	**Dose modification recommended:** • If symptomatic, withhold QINLOCK until symptoms have resolved and blood pressure is controlled • If blood pressure is controlled to Grade ≤1 or baseline, resume QINLOCK at the same dose; otherwise, resume QINLOCK at reduced dose* • If Grade 3 hypertension recurs, withhold QINLOCK until symptoms have resolved and blood pressure is controlled. Resume QINLOCK at a reduced dose*
Grade 4	While there were no cases of Grade 4 hypertension in the INVICTUS study, discontinue QINLOCK if it occurs.

*The recommended dose reduction for adverse reactions is QINLOCK 100 mg orally once daily.[2]

No patients dose modified or discontinued QINLOCK due to hypertension in INVICTUS[8]

DOSE MODIFICATIONS DUE TO HYPERTENSION IN THE INVICTUS STUDY[8]

Dose interruption	Dose reduction	Discontinuation
0 %	0%	0%

Please see additional Safety Information throughout.

Do not initiate QINLOCK in patients with uncontrolled hypertension[2]

- Adequately control blood pressure prior to initiating QINLOCK
- Monitor blood pressure as clinically indicated
- Initiate or adjust antihypertensive therapy as appropriate

Advise patients on QINLOCK to:

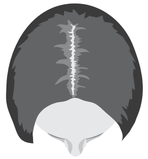
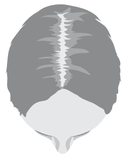
- Undergo routine blood pressure monitoring[2]
- Contact their healthcare provider immediately if they experience changes in blood pressure

QINLOCK® (ripretinib) 50 mg tablets

ALOPECIA

Alopecia occurred in 51.8% of patients treated with QINLOCK® (ripretinib), the majority of which was Grade 1 (mild)[7]

- Alopecia was defined to include hair thinning, not just complete hair loss[2]

Severity[6]		Rate Among QINLOCK-treated Patients[8]*
Grade 1 Hair loss of <50% of normal not obvious from a distance. May require different hairstyle but not a wig or hair piece.	BASELINE  GRADE 1   *For illustrative purposes*	40.0%
Grade 2 Hair loss of ≥50% normal that is apparent to others; a wig or hair piece is necessary; associated with psychosocial impact.	BASELINE   GRADE 2   *For illustrative purposes*	11.8%

*From primary analysis.

Source: CTCAE version 4.03 used in the INVICTUS trial.[8]

Please see additional Safety Information throughout.

Time to onset and maximum severity of alopecia occurred almost simultaneously[7]

- Median time to first occurrence: 1.9 months
- Median time to worst severity grade: 2.1 months

This indicates that alopecia generally did not worsen over time[7]

- After 9 months of additional follow-up, alopecia occurred in 52% of QINLOCK-treated patients[3]

QINLOCK® (ripretinib) 50 mg tablets

ALOPECIA

Dose modifications are not recommended for patients who experience alopecia while taking QINLOCK® (ripretinib)[2]

- Instead, consider supportive care (see opposite)

One patient (1.2%) had a dose reduction and no patients discontinued QINLOCK due to alopecia in INVICTUS[8]

DOSE MODIFICATIONS DUE TO ALOPECIA IN THE INVICTUS STUDY[8]

Dose interruption	Dose reduction	Discontinuation
1.2%	1.2%	0%

Supportive care for alopecia

NOTE: The below are general tips and suggestions of supportive care for patients experiencing alopecia. They are not specific to QINLOCK or the INVICTUS study.

Consider recommending that patients:

- **Talk about it** with a counselor, friend, family member or someone going through a similar experience[12]
- **With the help of a hair stylist,** find a cut and style that optimizes body and coverage[12]
- **Talk to a dermatologist** who specializes in hair loss about helpful treatments
  - The American Hair Research Society, a nonprofit organization composed of physicians, scientists, and industry partners, is also a good resource. Patients can visit americanhairresearchsociety.org for more information
- **Use a gentle, fragrance-free shampoo** to clean hair and scalp. Gently pat hair dry and use a soft brush. Use sun protection on the scalp when outdoors, and cover the head during cold weather. Avoid blow drying hair with excessive heat, and curling or straightening hair with chemicals[12]
- **Consider a wig, scarf, or turban**: Purchase the wig before hair falls out to ensure a good match. Visit a full-service wig salon that specializes in hair loss, and save the receipt for potential insurance and medical tax deductions[12,13]
- **Consider use of hair powders or fibers**, or scalp micropigmentation[14]

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets

QINLOCK® (ripretinib) IS DOSED ONCE DAILY, WITH OR WITHOUT FOOD[2]

The recommended dose of QINLOCK is 150 mg[2]

(3 x 50 mg tablets)

Dosed once daily | **No known dietary restrictions**

QINLOCK should be taken at the same time each day[2]

- Advise patients to take all 3 tablets in one sitting, and to swallow tablets whole
- In the event of a missed dose, advise patients to take a replacement dose only if it is within 8 hours of the missed dose
- If the patient vomits after taking a dose, advise him or her not take an additional dose until the next scheduled dose

Mutational testing is not required to administer QINLOCK[2]

SELECT SAFETY INFORMATION

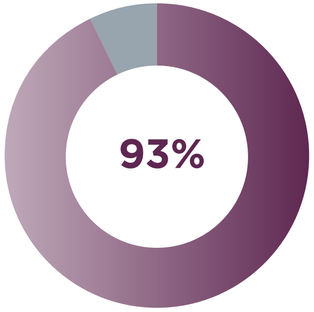
Hypertension: In INVICTUS, Grade 1-3 hypertension occurred in 14% of the 85 patients who received QINLOCK, including Grade 3 hypertension in 7% of patients. Do not initiate QINLOCK in patients with uncontrolled hypertension. Monitor blood pressure as clinically indicated. Based on severity, withhold QINLOCK and then resume at same or reduced dose or permanently discontinue.

Please see additional Safety Information throughout.

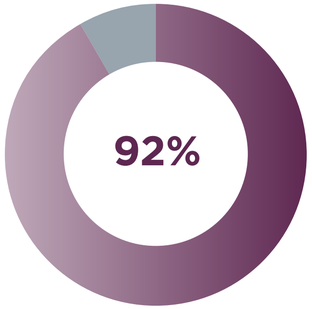
QINLOCK® (ripretinib) 50 mg tablets

DOSE QINLOCK® (ripretinib) WITH CONFIDENCE

Most QINLOCK-treated patients were able to start and stay on the full indicated dose



did not experience a dose reduction due to an adverse reaction[2]*



did not discontinue QINLOCK due to an adverse reaction[2]*

*In the primary analysis.[2]

There were no Grade 4 laboratory abnormalities reported with QINLOCK[2]

Select laboratory abnormalities (≥10%) worsening from baseline in GIST patients who received QINLOCK with a difference of >5% compared to placebo[2]

	QINLOCK (n=85)†		Placebo (n=43)†	
	Grades 1–4	Grades 3–4‡	Grades 1–4	Grades 3–4
Hematology				
Increased activated partial thromboplastin time	35%	0	9%	0
Increased INR	21%	3.8%	15%	0
Decreased neutrophil count	10%	0	2.5%	0
Chemistry				
Increased lipase	32%	7%	13%	8%
Decreased phosphate	26%	4.9%	2.5%	0
Increased triglycerides	26%	2.4%	23%	0
Decreased calcium	23%	0	8%	0
Increased blood bilirubin	22%	0	5%	2.5%
Increased CPK	21%	1.2%	10%	0
Decreased sodium	17%	2.4%	10%	2.5%
Increased creatinine	16%	0	18%	0
Increased serum amylase	13%	1.2%	5%	0
Increased ALT	12%	1.2%	5%	0

ALT=alanine aminotransferase; CPK=creatine phosphokinase; INR=international normalized ratio.

†The denominator used to calculate the rate varied from 82 to 83 for QINLOCK and 39 to 40 for placebo based on the number of patients with a baseline value and at least one post-treatment value.

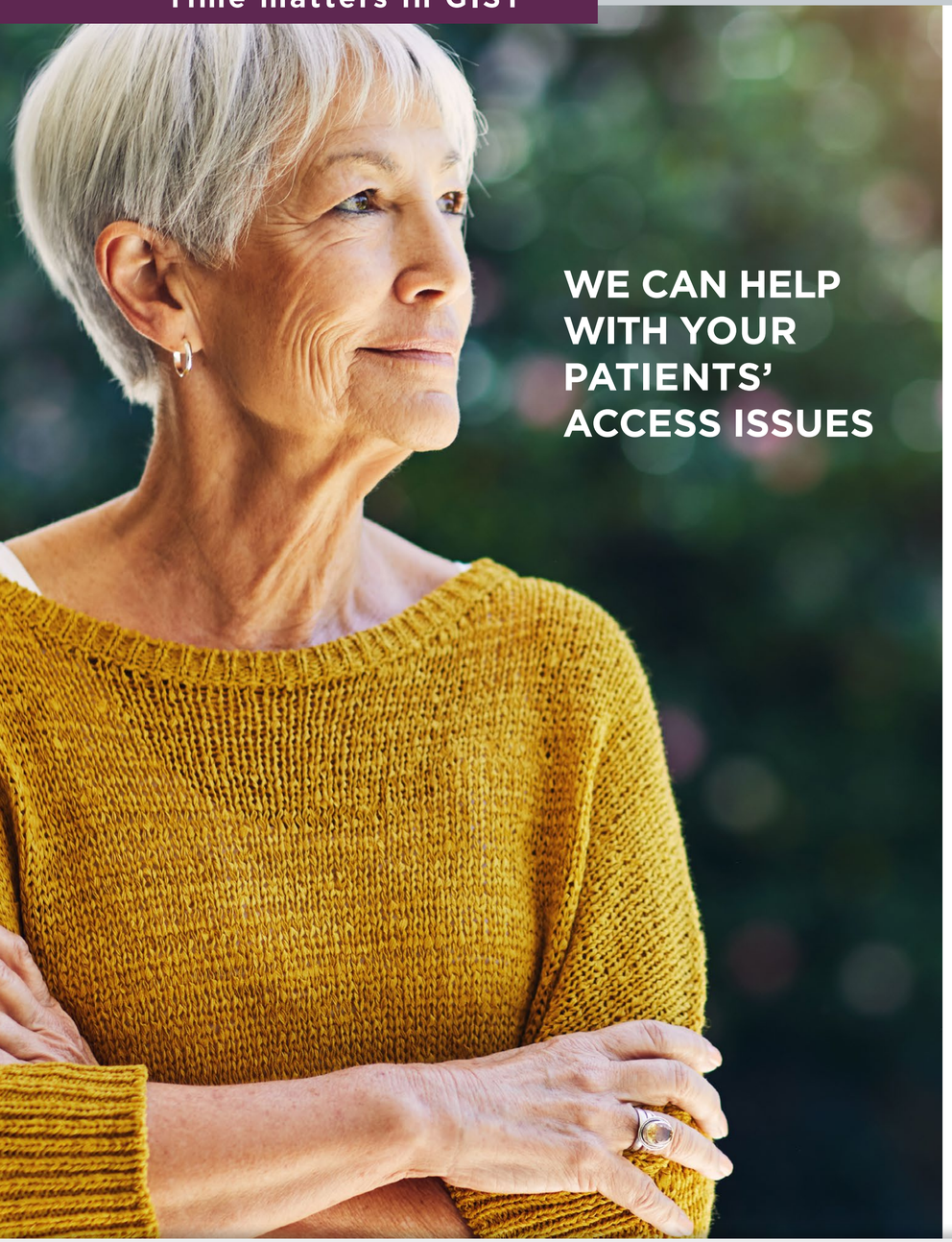
‡Only includes Grade 3 laboratory abnormalities.

SELECT SAFETY INFORMATION

Cardiac Dysfunction: In INVICTUS, cardiac failure occurred in 1.2% of the 85 patients who received QINLOCK. In the pooled safety population, cardiac dysfunction (including cardiac failure, acute left ventricular failure, diastolic dysfunction, and ventricular hypertrophy) occurred in 1.7% of 351 patients, including Grade 3 adverse reactions in 1.1% of patients.

Please see additional Safety Information throughout.

QINLOCK® (ripretinib) 50 mg tablets



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- **Temporary supply programs:** to help patients start on QINLOCK® (ripretinib) if a coverage decision is delayed, or stay on therapy if coverage changes*

Financial help for patients with different types of insurance, or no insurance at all

- As little as $0 per month for eligible patients with commercial insurance*
- Referral to foundations and other funding sources
- Free medication for eligible patients who aren't covered for QINLOCK*

*Terms and conditions apply.

To get started, contact a dedicated Case Manager at
1-833-4DACCES (1-833-432-2237) Monday–Friday 8AM–8PM ET
or visit **DecipheraAccessPoint.com**

QINLOCK is available through the following specialty pharmacy providers

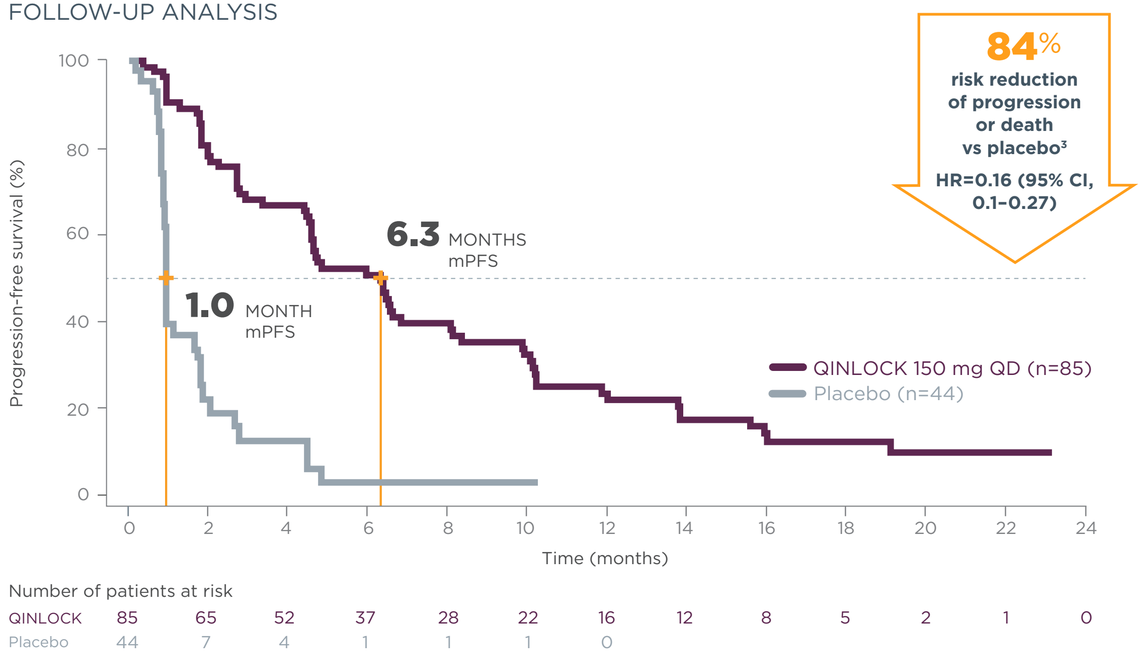
Specialty Pharmacy	Website	Telephone/Fax Number	
Biologics by McKesson	biologics.mckesson.com	**T:** 800-850-4306	**F:** 800-823-4506
US Bioservices	www.usbioservices.com	**T:** 877-757-0667	**F:** 888-899-0067
PANTHERx	www.pantherxrare.com	**T:** 833-711-8824	**F:** 866-242-6915

QINLOCK® (ripretinib) 50 mg tablets

THE FIRST AND ONLY SWITCH-CONTROL KINASE INHIBITOR THAT PROVIDES POWERFUL AND CONSISTENT PFS RESULTS IN ADVANCED GIST[2,3,15]

QINLOCK demonstrated superior median PFS vs placebo in the primary analysis (6.3 months vs 1.0 month *P*<0.0001) and provided consistent PFS results after 9 months of additional follow-up[2,3*]

FOLLOW-UP ANALYSIS



*Follow-up analyses were not powered to show statistical significance.[3]

†Not evaluated for statistical significance as a result of the sequential testing procedure used for the secondary endpoints of ORR and OS.[2,4]

NCCN PREFERRED CATEGORY 1

Ripretinib (QINLOCK®) is **THE ONLY therapy recommended** for 4th-line advanced GIST by the National Comprehensive Cancer Network® (NCCN®)[1]

Clinically meaningful ORR and OS results

- ORR in primary analysis: 9.4% with QINLOCK vs 0% with placebo (*P*=0.0504)[2,4]
  - Follow-up analysis: 11.8% with QINLOCK vs 0% with placebo[3*]
- Median OS in primary analysis: 15.1 months with QINLOCK vs 6.6 months with placebo[2,4†]
  - Follow-up analysis: Not reached with QINLOCK vs 6.3 months with placebo[3*]

Serious and common adverse reactions

- Serious adverse reactions occurring in >2% of patients were abdominal pain (4.7%), anemia (3.5%), nausea (2.4%), and vomiting (2.4%)[2]
- The most common adverse reactions (≥20%) were alopecia (52%), fatigue (42%), nausea (39%), abdominal pain (36%), constipation (34%), myalgia (32%), diarrhea (28%), decreased appetite (27%), PPES (21%), and vomiting (21%). The most common Grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase (7%) and decreased phosphate (5%)[2]
- Safety findings were generally consistent after 9 months of additional follow-up[3]

Dose QINLOCK with confidence—most patients were able to start and stay on the full indicated dose in the primary analysis

- 93% did not have their dose reduced due to an adverse reaction[2]
- 92% did not discontinue treatment due to an adverse reaction[2]

Mutational testing is not required to administer QINLOCK[2]

Visit QINLOCKHCP.com to learn more

Please see additional Safety Information throughout and accompanying full Prescribing Information, including Patient Information.

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IMPORTANT SAFETY INFORMATION

There are no contraindications for QINLOCK.

Palmar-plantar erythrodysesthesia syndrome (PPES): In INVICTUS, Grade 1-2 PPES occurred in 21% of the 85 patients who received QINLOCK. PPES led to dose discontinuation in 1.2% of patients, dose interruption in 2.4% of patients, and dose reduction in 1.2% of patients. Based on severity, withhold QINLOCK and then resume at same or reduced dose.

New Primary Cutaneous Malignancies: In INVICTUS, cutaneous squamous cell carcinoma (cuSCC) occurred in 4.7% of the 85 patients who received QINLOCK with a median time to event of 4.6 months (range 3.8 to 6 months). In the pooled safety population, cuSCC and keratoacanthoma occurred in 7% and 1.9% of 351 patients, respectively. In INVICTUS, melanoma occurred in 2.4% of the 85 patients who received QINLOCK. In the pooled safety population, melanoma occurred in 0.9% of 351 patients. Perform dermatologic evaluations when initiating QINLOCK and routinely during treatment. Manage suspicious skin lesions with excision and dermatopathologic evaluation. Continue QINLOCK at the same dose.

Hypertension: In INVICTUS, Grade 1-3 hypertension occurred in 14% of the 85 patients who received QINLOCK, including Grade 3 hypertension in 7% of patients. Do not initiate QINLOCK in patients with uncontrolled hypertension. Monitor blood pressure as clinically indicated. Based on severity, withhold QINLOCK and then resume at same or reduced dose or permanently discontinue.

Cardiac Dysfunction: In INVICTUS, cardiac failure occurred in 1.2% of the 85 patients who received QINLOCK. In the pooled safety population, cardiac dysfunction (including cardiac failure, acute left ventricular failure, diastolic dysfunction, and ventricular hypertrophy) occurred in 1.7% of 351 patients, including Grade 3 adverse reactions in 1.1% of patients.

In INVICTUS, Grade 3 decreased ejection fraction occurred in 2.6% of the 77 patients who received QINLOCK and who had a baseline and at least one post-baseline echocardiogram. Grade 3 decreased ejection fraction occurred in 3.4% of the 263 patients in the pooled safety population who received QINLOCK and who had a baseline and at least one post-baseline echocardiogram.

In INVICTUS, cardiac dysfunction led to dose discontinuation in 1.2% of the 85 patients who received QINLOCK. The safety of QINLOCK has not been assessed in patients with a baseline ejection fraction below 50%. Assess ejection fraction by echocardiogram or MUGA scan prior to initiating QINLOCK and during treatment, as clinically indicated. Permanently discontinue QINLOCK for Grade 3 or 4 left ventricular systolic dysfunction.

Risk of Impaired Wound Healing: QINLOCK has the potential to adversely affect wound healing. Withhold QINLOCK for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of QINLOCK after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: QINLOCK 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 and for at least 1 week after the final dose. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment and for at least 1 week after the final dose. QINLOCK may impair fertility in males of reproductive potential.

Adverse Reactions: The most common adverse reactions (≥20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase and decreased phosphate.

The safety and effectiveness of QINLOCK in pediatric patients have not been established.

Administer strong CYP3A inhibitors with caution. Monitor patients who are administered strong CYP3A inhibitors more frequently for adverse reactions. Avoid concomitant use with strong CYP3A inducers.

Please see accompanying full Prescribing Information, including Patient Information.

To report SUSPECTED ADVERSE REACTIONS, contact Deciphera Pharmaceuticals, LLC, at 1-888-724-3274 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastrointestinal Stromal Tumors (GISTs) V.1.2021. ©National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Published October 30, 2020. Accessed October 30, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** Qinlock [package insert]. Waltham, MA: Deciphera Pharmaceuticals, Inc; 2020. **3.** Zalcberg J, Heinrich M, George S, et al. Clinical benefit with ripretinib as ≥4th line therapy in patients with advanced gastrointestinal stromal tumors (GIST): Update from the Phase 3 INVICTUS study. Mini oral presentation at: European Society for Medical Oncology Virtual Congress 2020; September 19-21, 2020. **4.** Blay JY, Serrano C, Heinrich MC, et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2020;21(7):923-934. **5.** von Mehren M, Attia S, Bauer S, et al. INVICTUS: A phase 3, interventional, double-blind, placebo-controlled study to assess the safety and efficacy of ripretinib as ≥4th line therapy in patients with advanced gastrointestinal stromal tumors (GIST) who have received treatment with prior anticancer therapies (NCT03353753). Oral presentation at: European Society for Medical Oncology Annual Meeting; October, 2019; Barcelona, Spain. **6.** National Cancer Institute (U.S.). 2010. Common terminology criteria for adverse events: (CTCAE). Available at: https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf. Accessed March 10, 2020. **7.** George S, Heinrich MC, Zalcberg J, et al. Safety profile of ripretinib, including impact of alopecia and palmar-plantar erythrodysesthesia syndrome (PPES) on patient reported outcomes (PROs), in ≥4th-line advanced gastrointestinal stromal tumors (GIST): Analyses from INVICTUS. Poster presentation at: 2020 ASCO Virtual Scientific Program; May 29-31, 2020. **8.** Data on file. Deciphera Pharmaceuticals, Inc; 2020. **9.** Oncologypro.esmo.org. Reactive management of hand-foot skin reaction induced by multikinase treatment. Available at: https://oncologypro.esmo.org/oncology-in-practice/palliative-and-supportive-care/multikinase-inhibitor-related-skin-toxicity/healthcare-professionals/prophylaxis-and-treatment/reactive-management/hand-foot-skin-reaction. Accessed March 10, 2020. **10.** Cancer.net. Hand-Foot Syndrome or Palmar-Plantar Erythrodysesthesia. Available at: https://www.cancer.net/coping-with-cancer/physical-emotional-and-social-effects-cancer/managing-physical-side-effects/hand-foot-syndrome-or-palmar-plantar-erythrodysesthesia. Accessed March 10, 2020. **11.** McLellan B, Ciardiello F, Lacouture ME, et al. Regorafenib-associated hand–foot skin reaction: practical advice on diagnosis, prevention, and management. *Ann Oncol*. 2015;26(10):2017–2026. **12.** Cancer.net. Hair loss or alopecia. https://www.cancer.net/coping-with-cancer/physical-emotional-and-social-effects-cancer/managing-physical-side-effects/hair-loss-or-alopecia. Accessed March 10, 2020. **13.** CancerCare.org: Hair Loss During Treatment: Finding Resources and Support. Available at: https://www.cancercare.org/publications/287-hair_loss_during_treatment_finding_resources_and_support. Accessed March 10, 2020. **14.** Saed S, Ibrahim O, Bergfeld WF. Hair camouflage: A comprehensive review. *Int J Womens Dermatol*. 2017;3(1):S75-S80. **15.** Smith BD, Kaufman MD, Lu WP, et al. Ripretinib (DCC-2618) is a switch control kinase inhibitor of a broad spectrum of oncogenic and drug-resistant KIT and PDGFRA variants. *Cancer Cell*. 2019;35(5):738-751. **16.** Blay JY, Serrano C, Heinrich MC, et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2020;21(7)(suppl):1-5.

deciphera™

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QINLOCK® (ripretinib) QOL RESULTS IN INVICTUS[4]

Clinically relevant differences were observed between QINLOCK and placebo in the following prespecified QOL assessments[4]

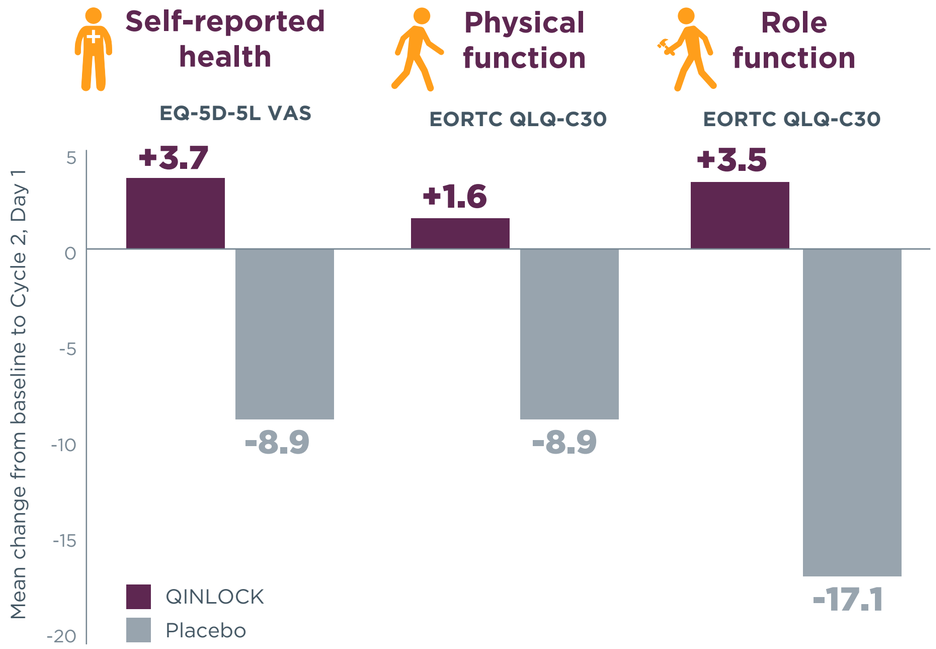
- QOL assessments that were prespecified in the statistical analysis plan compared the change from baseline on Cycle 1, Day 1 to Cycle 2, Day 1 (28 days later) using EQ-5D-5L VAS and the EORTC QLQ-C30 questionnaires
  - Comparisons were only made out to Cycle 2, Day 1 due to the low number of patients in the placebo arm after this point
- The minimally important clinical difference has been defined as a >10% mean score change or a 5-point change

The EQ-5D-5L VAS was calculated from the patient's self-rated health on a vertical visual analogue scale from 0 ("Worst imaginable state of health") to 100 ("Best imaginable state of health"). The analysis included 70 patients in the QINLOCK arm and 32 patients in the placebo arm.[4,16]

The EORTC QLQ-C30 physical function score was calculated from five questions asking patients to respond to items about their strength, endurance, and daily physical functioning on a four-point scale ranging from 1 ("Not at all") to 4 ("Very much"). Responses were converted to a score ranging from 0 to 100, with higher scores indicating better functioning. The analysis included 71 patients in the QINLOCK arm and 32 patients in the placebo arm.[4,16]

The EORTC QLQ-C30 role function score was calculated from two questions asking patients to respond to items about limitations in their daily activities on a four-point scale ranging from 1 ("Not at all") to 4 ("Very much"). Responses were converted to a score ranging from 0 to 100, with higher scores indicating better functioning. The analysis included 70 patients in the QINLOCK arm and 32 patients in the placebo arm.[4,16]

SECONDARY ENDPOINT PRESPECIFIED ANALYSIS[4,16]



Overall health remained stable with QINLOCK compared to a decrease with placebo.

Physical function remained stable with QINLOCK compared to a decrease with placebo.

Role function remained stable with QINLOCK compared to a decrease with placebo.

The QOL endpoint was not evaluated for statistical significance as a result of the sequential testing procedure used for secondary endpoints.

Please see full Safety Information on the preceding page and accompanying full Prescribing Information, including Patient Information.

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APPENDIX

RECOMMENDED DOSAGE MODIFICATIONS FOR QINLOCK® (ripretinib) FOR ADVERSE REACTIONS[2]

Adverse Reaction	Severity*	QINLOCK Dosage Modifications
Palmar-Plantar Erythrodysesthesia Syndrome (PPES) [see QINLOCK Prescribing Information, Warnings and Precautions (section 5.1)]	**Grade 2**	• Withhold QINLOCK until Grade ≤1 or baseline. If recovered within 7 days, resume QINLOCK at same dose; otherwise resume at reduced dose • Consider re-escalating QINLOCK if maintained at Grade ≤1 or baseline for at least 28 days • If PPES recurs, withhold QINLOCK until Grade ≤1 or baseline and then resume QINLOCK at a reduced dose regardless of time to improvement
	Grade 3	• Withhold QINLOCK for at least 7 days or until Grade ≤1 or baseline (maximum 28 days). Resume QINLOCK at a reduced dose • Consider re-escalating QINLOCK if maintained at Grade ≤1 or baseline for at least 28 days
Hypertension [see QINLOCK Prescribing Information, Warnings and Precautions (section 5.3)]	**Grade 3**	• If symptomatic, withhold QINLOCK until symptoms have resolved and blood pressure is controlled • If blood pressure is controlled to Grade ≤1 or baseline, resume QINLOCK at the same dose; otherwise, resume QINLOCK at reduced dose • If Grade 3 hypertension recurs, withhold QINLOCK until symptoms have resolved and blood pressure is controlled. Resume QINLOCK at a reduced dose
	Grade 4	Permanently discontinue QINLOCK
Left Ventricular Systolic Dysfunction [see QINLOCK Prescribing Information, Warnings and Precautions (section 5.4)]	**Grade 3 or 4**	Permanently discontinue QINLOCK
Arthralgia or Myalgia [see QINLOCK Prescribing Information, Adverse Reactions (section 6.1)]	**Grade 2**	• Withhold QINLOCK until Grade ≤1 or baseline. If recovered within 7 days, resume QINLOCK at same dose; otherwise resume QINLOCK at reduced dose • Consider re-escalating QINLOCK if maintained at Grade ≤1 or baseline for at least 28 days • If arthralgia or myalgia recurs, withhold QINLOCK until Grade ≤1 or baseline and then resume QINLOCK at a reduced dose regardless of time to improvement
	Grade 3	• Withhold QINLOCK for at least 7 days or until Grade ≤1 or baseline (maximum of 28 days). Resume QINLOCK at a reduced dose • Consider re-escalating QINLOCK if maintained at Grade ≤1 or baseline for at least 28 days
Other Adverse Reactions [see Adverse Reactions (section 6.1)]	**Grade 3 or 4**	• Withhold QINLOCK until Grade ≤1 or baseline (maximum 28 days), and then resume QINLOCK at a reduced dose; otherwise permanently discontinue • Consider re-escalating QINLOCK if no recurrence of the adverse reaction for at least 28 days • If Grade 3 or 4 recurs, permanently discontinue QINLOCK

The recommended dose reduction for adverse reactions is QINLOCK 100 mg orally once daily. Permanently discontinue QINLOCK in patients who are unable to tolerate 100 mg orally once daily.[2]

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03 (NCI CTCAE v4.03).[6]

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