

NCCN PREFERRED CATEGORY 1

Ripretinib (QINLOCK®) is THE ONLY category 1 4th-line therapy option for advanced GIST1*

FOR ADVANCED GIST PATIENTS
TREATED WITH ≥3 PRIOR TKIS

BREAK THROUGH RESISTANCE

and provide powerful progression-free survival²

 6.3 months median PFS with QINLOCK® (ripretinib) (n=85) vs
 1.0 month with placebo (n=44)²

HR=0.15 (95% CI, 0.09-0.25); P<0.0001

Choose QINLOCK, the first and only switch-control kinase inhibitor for advanced GIST²

Approved for patients regardless of mutation, including²:

✓ KIT

✓ PDGFRα

✓ WILD TYPE

CI=confidence interval; GIST=gastrointestinal stromal tumor; HR=hazard ratio; KIT=KIT proto-oncogene receptor tyrosine kinase; NCCN*=National Comprehensive Cancer Network*; PDGFRq=platelet derived growth factor receptor α ; PFS=progression-free survival; TKI=tyrosine kinase inhibitor. *Preferred 4th-line therapy (Category 1) for unresectable or metastatic disease.

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 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.

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



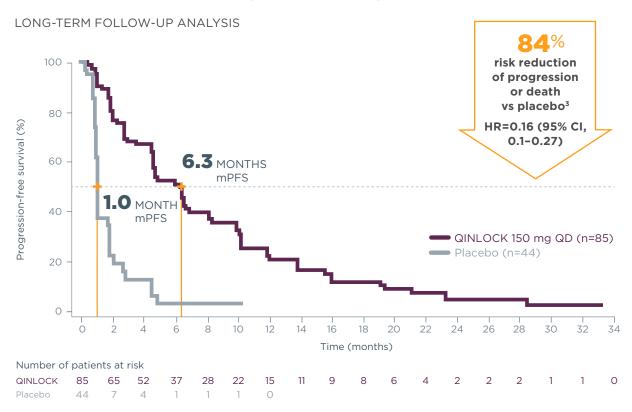
QINLOCK® (ripretinib) DEMONSTRATED POWERFUL PFS RESULTS²

QINLOCK provided superior median PFS vs placebo in the primary analysis²

PRIMARY ENDPOINT: PFS

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

Consistent PFS results at long-term follow-up^{3*}



^{*}The long-term follow-up analysis was conducted approximately 19 months from the data cutoff date in the primary analysis and was not powered to show statistical significance.³

Estimated PFS in INVICTUS at long-term follow-up³

Estimated landmark PFS	QINLOCK (n=85)	Placebo (n=44)
6-months PFS (95% CI)	51.0% (39.4-61.4)	3.2% (0.2-13.8)
12-months PFS (95% CI)	22.2% (13.4-32.4)	NE (NE-NE)
18-months PFS (95% CI)	11.8% (5.6-20.6)	NE (NE-NE)

 ${\sf mPFS=median\ progression-free\ survival;\ NE=not\ estimable;\ QD=once\ a\ day.}$

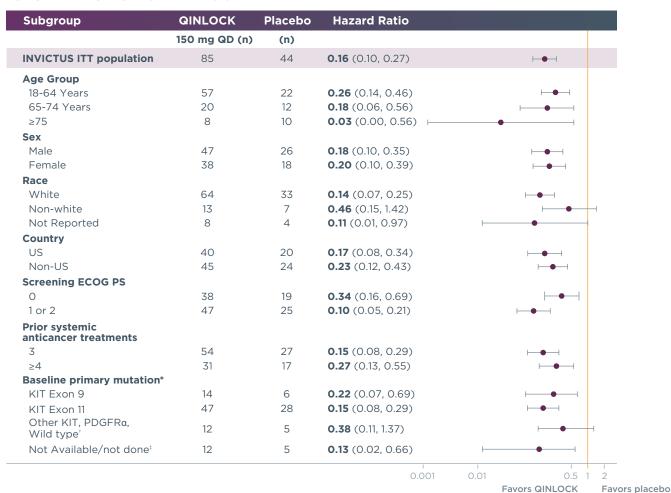
SELECT SAFETY INFORMATION

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 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 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.

QINLOCK® (ripretinib) PROVIDED GENERALLY CONSISTENT PFS ACROSS PRIMARY MUTATIONS AND OTHER SUBGROUPS^{3,4}

PFS results for QINLOCK vs placebo in select patient subgroups at long-term follow-up^{3,4*}

LONG-TERM FOLLOW-UP ANALYSIS



^{*}This analysis was exploratory in nature; it did not control for type 1 error and was not powered to determine treatment effect in any subgroup. Hazard ratio for PFS based on baseline primary mutation status was retrospectively assessed after 9 months of additional follow-up (data cutoff: March 9, 2020) following the primary analysis (data cutoff: May 31, 2019) in tumor samples by tumor biopsy from evaluable patients treated with QINLOCK (n=73) and placebo (n=39).

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. Long-term follow-up analysis (data cutoff: January 15, 2021) includes 19 months of follow-up data after the primary analysis (data cutoff: May 31, 2019).^{2,3,5}

BICR=blinded independent central review; ECOG PS=Eastern Cooperative Oncology Group Performance Status; ITT=intent-to-treat; ORR=objective response rate; OS=overall survival; RECIST=response evaluation criteria in solid tumors.

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.





 $^{^\}dagger$ Includes other KIT exon mutations, PDGFR α mutations, and KIT/PDGFR α wild-type patients.

¹Includes patients who failed sequencing due to low tumor content and patients with no specimen.

QINLOCK® (ripretinib) WAS ASSOCIATED WITH CLINICALLY MEANINGFUL OVERALL SURVIVAL²

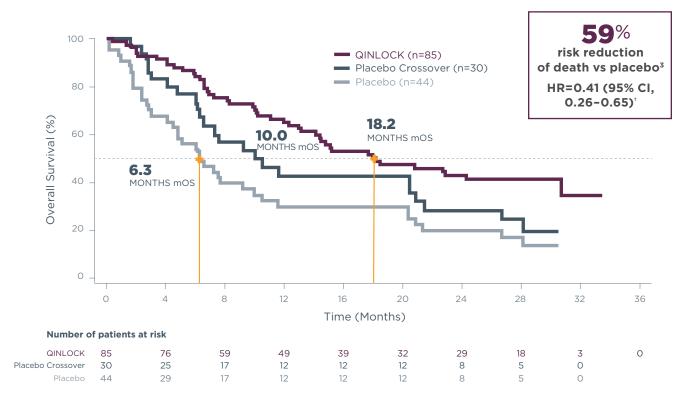
QINLOCK overall survival (OS) vs placebo in the primary analysis^{2,5*}

SECONDARY ENDPOINT: OS

• 15.1 months vs 6.6 months (HR=0.36 [95% CI, 0.21-0.62])^{2,5*}

Median OS of 18.2 months at long-term follow-up^{3†}

LONG-TERM FOLLOW-UP ANALYSIS



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

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 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 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.

^{*}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 in the primary analysis for the secondary endpoints of ORR and OS.^{2,5}

[†]The long-term follow-up analysis was conducted approximately 19 months from the data cutoff date in the primary analysis and was not powered to show statistical significance.³



Estimated OS at long-term follow-up³

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)	50.1% (38.5-60.7)	29.7% (16.8-43.7)
24-months OS (95% CI)	42.8% (31.5-53.7)	19.8% (9.4-33.0)

Patients who started QINLOCK earlier observed an mOS of 18.2 months, while patients who had a delayed start observed an mOS of 10.0 months.[†]

Patients should be started on QINLOCK as soon as indicated.

Clinically meaningful improvement in objective response rate (ORR) by BICR^{2,3,5}

KEY SECONDARY ENDPOINT: ORR PRIMARY ANALYSIS

9.4% QINLOCK **vs. 0.0%** Placebo (*P*=0.0504)^{2.5*}

LONG-TERM FOLLOW-UP ANALYSIS

11.8% QINLOCK vs. 0.0% Placebo^{3†}

• Median duration of response was 14.5 months with QINLOCK vs NE with placebo³

SELECT SAFETY INFORMATION

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.

Photosensitivity: QINLOCK may cause photosensitivity reactions. In 621 patients treated with QINLOCK in clinical trials, photosensitivity reactions occurred in 0.6% of patients. Advise patients to limit direct ultraviolet exposure during treatment with QINLOCK and for at least 1 week after discontinuation of treatment.



^{*}All responses were partial responses.

[†]The long-term follow-up analysis, conducted 19 months after the primary analysis, was not powered to show statistical significance.

SAFETY ESTABLISHED ACROSS A BROAD RANGE OF PATIENTS IN THE INVICTUS TRIAL PRIMARY ANALYSIS^{2,5}

Serious adverse reactions

• Serious adverse reactions occurring in >2% of patients who received QINLOCK® (ripretinib) were abdominal pain (4.7%), anemia (3.5%), nausea (2.4%), and vomiting (2.4%)²

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

Dose modifications due to adverse reactions		
	QINLOCK (n=85) ²	Placebo (n=43)6**
Discontinuation	8%	12%
Dose reduction	7 %	2%
Dose interruption	24%	21%

[•] Safety findings after 19 months of additional follow-up were generally consistent with the primary analysis³

The overall rates of grade 3/4 adverse reactions were similar between QINLOCK and placebo (49.4% vs 44.2%, respectively)⁶

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%

NA=not applicable

SELECT SAFETY INFORMATION

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 1 week after the last dose. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment and for 1 week after the last 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.

^{*}Placebo values represent dose modifications for treatment-emergent adverse events.6

^{†44} patients were randomized to placebo, but 1 did not receive treatment.⁶

 $^{{}^{\}scriptscriptstyle t}\text{In}$ the double-blind treatment period of INVICTUS.

[§]There is no grade 3 or 4 alopecia as per Common Terminology Criteria for Adverse Events v4.03.7

Adverse reactions reported in ≥10% of patients who received QINLOCK® (ripretinib), cont'd2*

	QINLOC	QINLOCK (n=85)		Placebo (n=43)†	
	Grades 1-4	Grades 3-4	Grades 1-4	Grades 3-4	
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	
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.

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

QINLOCK IS DOSED ONCE DAILY, WITH OR WITHOUT FOOD²

The recommended dose of QINLOCK is 150 mg²



BID=twice daily; QD=once daily.

QINLOCK should be taken at the same time each day.

If concomitant use with a moderate CYP3A inducer cannot be avoided: Increase QINLOCK dose to 150 mg twice daily during the coadministration period. If the concomitant moderate CYP3A inducer is discontinued, resume QINLOCK at 150 mg once daily 14 days after the discontinuation.

In the event of a missed dose, advise patients to:

- QINLOCK 150 mg QD: Take a replacement dose only if within 8 hours of the missed dose
- QINLOCK 150 mg BID: Take a replacement dose only if within 4 hours of the missed dose

If more time has passed than outlined above, skip the missed dose and then take the next dose at the regularly scheduled time.



^{†44} patients were randomized to placebo, but 1 did not receive treatment.6

QINLOCK® (ripretinib)—THE FIRST AND ONLY SWITCH-CONTROL KINASE INHIBITOR ENGINEERED TO BLOCK THE DRIVERS OF RESISTANCE IN ADVANCED GIST^{2,8}

QINLOCK provides broad-spectrum inhibition of KIT and PDGFRa kinase signaling in vitro through a dual mechanism of action^{2,8}

Kinase activation requires the interaction of two critical regions^{8,9}:



SWITCH POCKET

As shown in preclinical studies, QINLOCK^{2,8}



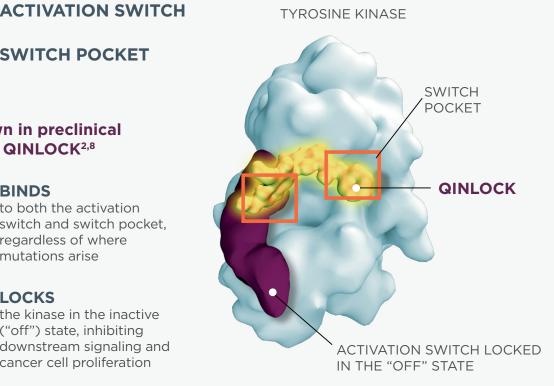
BINDS

to both the activation switch and switch pocket, regardless of where mutations arise



LOCKS

the kinase in the inactive ("off") state, inhibiting downstream signaling and cancer cell proliferation



In vitro studies not designed to assess clinical efficacy.

In preclinical studies, this dual mechanism provided broad-spectrum inhibition of KIT and PDGFRα kinase activity, including²:

- Multiple primary mutations
- Multiple secondary mutations
- Wild type

SELECT SAFETY INFORMATION

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 and moderate CYP3A inducers. If a moderate CYP3A inducer cannot be avoided, increase QINLOCK dosing frequency from the recommended dose of 150 mg once daily to 150 mg twice daily during the co-administration period. If the concomitant moderate CYP3A inducer is discontinued, resume QINLOCK dosage back to 150 mg once daily 14 days after the discontinuation of the moderate CYP3A inducer.

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.

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

QINLOCK® (ripretinib) IS INDICATED FOR ALL PATIENTS IN 4TH-LINE GIST—REGARDLESS OF MUTATION²



Diagnosed with advanced gastrointestinal stromal tumor



Have failed or experienced intolerance to ≥3 prior TKIs, including imatinib



Patients are eligible for treatment with QINLOCK regardless of 2,5:









TIME MATTERS IN ADVANCED GIST. WE CAN HELP WITH YOUR PATIENTS' ACCESS ISSUES

A single point-of-contact to serve practices and patients[†]

- From BIs to PAs and appeals, we provide services and solutions to help get patients started on QINLOCK
- Financial help is available for patients with different types of insurance, or no insurance at all



ripretinio) 50 mg tablets

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
PANTHERx Rare	www.pantherxrare.com	T: 833-711-8824	F: 866-242-6915

[†]Terms and conditions apply. Copay program is subject to an annual benefit maximum. Full terms and conditions provided prior to enrollment. BI=benefits investigation: PA=prior authorization.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines*) for Gastrointestinal Stromal Tumors (GIST) V.1.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed February 5, 2024. 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; 2023. 3. von Mehren M, Heinrich M. George S. et al. Ripretinib as ≥4th-line treatment in patients with advanced gastrointestinal stromal tumour (GIST): Long-term update from the phase 3 INVICTUS study. Poster presented at: 2021 European Society for Medical Oncology Virtual Meeting; September 16-21, 2021. 4. Schöffski P, Bauer S, Heinrich M, et al. Ripretinib demonstrated activity across all KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: Analysis from the phase 3 INVICTUS study. Poster presentation at: 2020 Connective Tissue Oncology Society Virtual Meeting; November 18-21, 2020. 5. Blay JY, Serrano C, Heinrich MC, et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): a double-blind, randomised, placebocontrolled, phase 3 trial. Lancet Oncol. 2020;21(7):923-934. 6. 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 $\ge 4^{th}$ 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. 7. 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_8.5x11.pdf. Accessed 3-10-2020. 8. 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. 9. Hemming ML, Heinrich MC, Bauer S, George S. Translational insights into gastrointestinal stromal tumor and current clinical advances. Ann Oncol. 2018;29(10):2037-2045.

^{*}Patients with ECOG Performance Status 0-2 were included in INVICTUS.5

BREAK THROUGH RESISTANCE



QINLOCK® (ripretinib): THE FIRST AND ONLY SWITCH-CONTROL KINASE INHIBITOR FOR ADVANCED GIST^{2,8}

*Ripretinib (QINLOCK) is NCCN Preferred Category 1.1

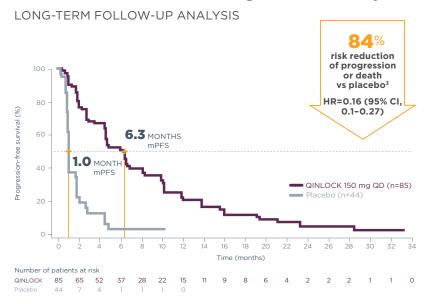
IS THE PREFERRED

4TH-LINE THERAPY OPTION

CATEGORY

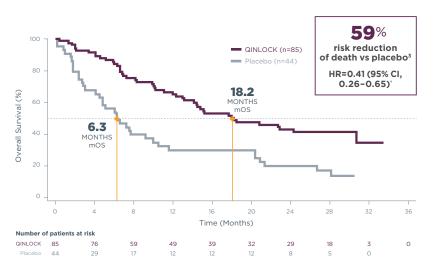
FOR UNRESECTABLE OR METASTATIC GIST

Powerful PFS results in the primary analysis (6.3 months vs 1.0 month; *P*<0.0001); and consistent PFS results at long-term follow-up^{2,3†}



Median OS of 18.2 months at long-term follow-up^{2,3†‡}

LONG-TERM FOLLOW-UP ANALYSIS



Clinically meaningful ORR and OS results^{2,3,5}

- **Primary analysis:** 9.4% with QINLOCK vs 0.0% with placebo (*P*=0.0504)^{2,5}
 - Long-term follow-up analysis: 11.8% with QINLOCK vs 0.0% with placebo^{3†}
- Median OS in primary analysis: 15.1 months with QINLOCK vs 6.6 months with placebo^{2,5‡}
 - Long-term follow-up analysis: 18.2 months with QINLOCK vs 6.3 months with placebo^{3†}

Serious and common adverse reactions

- Serious adverse reactions occurring in >2% of patients who received QINLOCK 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 19 months of additional follow-up³

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 reaction²
- 92% did not discontinue due to an adverse reaction²

Mutational testing is not required to administer QINLOCK²

Visit QINLOCKHCP.com to learn more

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

¹OS was not evaluated for statistical significance as a result of the sequential testing procedure used for the secondary endpoints of ORR and OS.^{2,5}

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

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