Pfizer Oncology

LORVIQUA® ▼
LORLATINIB

In patients with or without brain metastases,

MEET ALK+ aNSCLC HEAD ON WITH LORVIQUA

Now available as a first-line option

Touch screen to start

▼ This medicinal product is subject to additional monitoring.

PP-LOR-GLB-0033; Date of Preparation: August 2022

MEET ALK+ aNSCLC
HEAD ON
WITH LORVIQUA

From first-line, in patients with or without brain metastases

Tap below to find out more

PRIMARY ENDPOINT: PFS BY BICR (ITT POPULATION)

INTRACRANIAL EFFICACY IN PATIENTS WITH BRAIN METS AT BASELINE

TIME TO CNS PROGRESSION (ITT POPULATION)

SAFETY PROFILE

Lorlatinib as monotherapy is indicated for the treatment of adult patients with ALK+ advanced NSCLC previously not treated with an ALK inhibitor

LORVIQUA® ▼
LORLATINIB

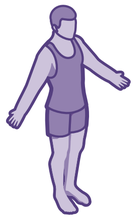
Footnotes & Abbreviations | Study Design | Prescribing Information | References | Safety Information

Pfizer Oncology

www.pfizer.com - PP-LOR-GLB-0033 - Date of Preparation: August 2022

FOOTNOTES & ABBREVIATIONS

ALK=anaplastic lymphoma kinase;
aNSCLC=advanced non-small cell lung cancer;
BICR=blinded independent central review;
CNS=central nervous system;
ITT=intention to treat;
Mets=metastases;
PFS=progression-free survival.



SIGNIFICANTLY IMPROVED PROGRESSION-FREE SURVIVAL WITH LORVIQUA VS CRIZOTINIB (ITT POPULATION, N=296)[1,2]

In a planned interim analysis (data cut-off: 20 March 2020), LORVIQUA met its primary endpoint with superior PFS vs crizotinib (HR: 0.28; 95% CI: 0.19–0.41; P<0.0001)[2]

72% REDUCTION

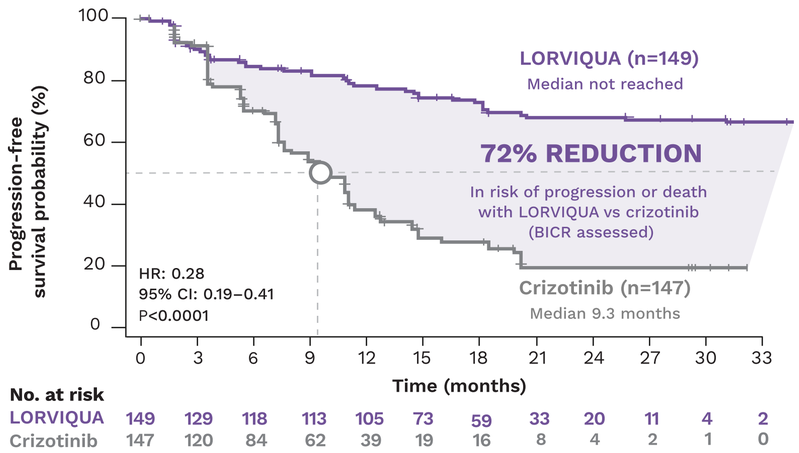
in risk of progression or death with LORVIQUA vs crizotinib (BICR assessed)[1,2]

HR: 0.28; 95% CI: 0.19–0.41; P<0.0001

- 12-month PFS:

  78% with LORVIQUA vs 39% with crizotinib
- Median PFS was not reached for LORVIQUA vs 9.3 months for crizotinib (95% CI: 7.6–11.1)

Progression-free survival by BICR (ITT population, N=296)[1,2]



Intracranial efficacy in patients with brain mets at baseline

FOOTNOTES & ABBREVIATIONS

BICR=blinded independent central review;
CI=confidence interval;
HR=hazard ratio;
ITT=intention to treat;
Mets=metastases;
PFS=progression-free survival.

REFERENCES

1. Pfizer. LORVIQUA (lorlatinib). Summary of Product Characteristics. April 2022.
2. Shaw AT, Bauer TM, de Marinis F, et al; CROWN Trial Investigators. First-line lorlatinib or crizotinib in advanced ALK-positive lung cancer. N Engl J Med. 2020;383(21):2018–2029.

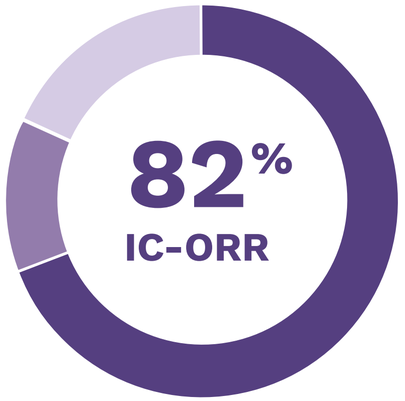
COMPELLING CNS EFFICACY IN PATIENTS WITH MEASURABLE CNS METASTASES AT BASELINE (N=30)[1,2]

Primary Endpoint: PFS by BICR (ITT population)

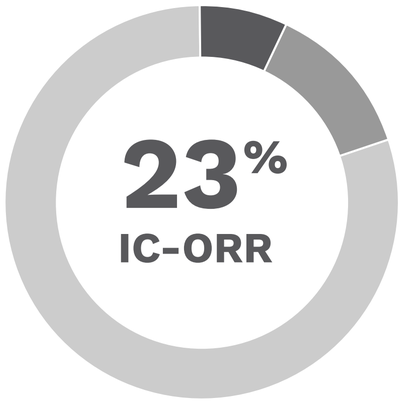
Time to CNS Progression (ITT Population)

Intracranial ORR[a]

LORVIQUA
(n=14/17)



■ Complete response (71%)



Crizotinib
(n=3/13)

■ Complete response (8%)

[a]Intracranial response was assessed by an independent committee using modified RECIST 1.1.[2]
Data cut-off: 20 March 2020.[2]

- **Median IC-DoR:** Not estimable (95% CI: NE–NE) with LORVIQUA vs 10 months (95% CI: 9–11) with crizotinib[1]
- **Intracranial response duration ≥12 months:** 72% with LORVIQUA and 0% with crizotinib[2*]

*In patients with measurable or non-measurable CNS metastases at baseline (n=78).[2]

FOOTNOTES & ABBREVIATIONS

BICR=blinded independent central review;
CI=confidence interval;
CNS=central nervous system;
IC-DoR=intracranial duration of response;
IC-ORR=intracranial objective response rate;
ITT=intention to treat;
NE=not estimable;
ORR=objective response rate;
PFS=progression-free survival;
RECIST=Response Evaluation Criteria in Solid Tumours.

REFERENCES

1. Pfizer. LORVIQUA (lorlatinib). Summary of Product Characteristics. April 2022.
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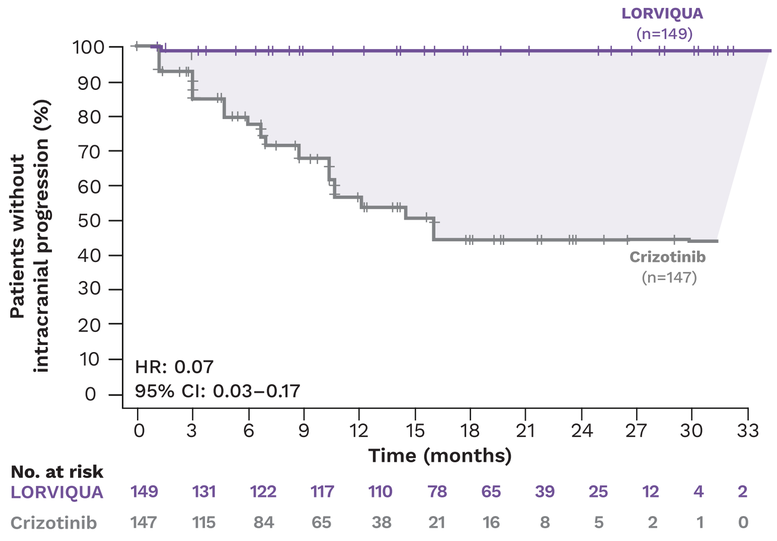
CNS PROGRESSION DELAYED IN NEARLY ALL LORVIQUA-TREATED PATIENTS AT 1 YEAR[1]

- In the ITT population, the percentage of patients **without CNS progression at 12 months was 96% with LORVIQUA and 60% with crizotinib**

  (HR: 0.07; 95% CI: 0.03–0.17)[1]

Time to intracranial progression by BICR (ITT population, N=296)[1]



Intracranial efficacy in patients with brain mets at baseline

Safety profile

FOOTNOTES & ABBREVIATIONS

BICR=blinded independent central review;
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HR=hazard ratio;
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Mets=metastases.

REFERENCES

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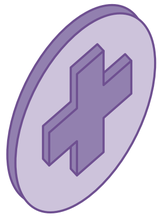

MANAGEABLE SAFETY PROFILE WITH LARGELY MILD-TO-MODERATE ADVERSE REACTIONS[1,2]

- In the interim analysis of the CROWN trial, permanent discontinuations associated with ARs occurred in **7%** of patients treated with LORVIQUA vs 9% of patients treated with crizotinib[2]
- **Established Therapy Management** recommendations are available for many AEs with LORVIQUA[1]
  - Discuss with your local Pfizer representative for more information

ARs (any grade) occurring in ≥20% of patients with LORVIQUA (N=476)[a,1]

Adverse reaction	All grades	Grades 3 and 4
Hyperchloesterolaemia[b]	81.1%	18.3%
Hypertriglyceridaemia[c]	67.2%	19.3%
Oedema[d]	55.7%	2.7%
Peripheral neuropathy[e]	43.7%	2.7%
Weight increased	30.9%	10.1%
Cognitive effects[f]	27.7%	2.9%
Fatigue[g]	27.3%	1.3%
Arthralgia	23.5%	0.8%
Diarrhoea	22.9%	1.5%
Mood effects[h]	21.0%	1.5%

Refer to the LORVIQUA Summary of Product Characteristics for the most up-to-date safety profile.

Time to CNS Progression (ITT Population)

FOOTNOTES & ABBREVIATIONS

AE=adverse event;

AR=adverse reaction;

CNS=central nervous system;

ITT=intention to treat;

SOC=standard of care.

[a] Table represents ARs occurring in 476 adult patients with advanced NSCLC, treated with LORVIQUA 100 mg once daily in the global registration study (N=327) and CROWN (N=149).[1]

[b] Hypercholesterolaemia (including blood cholesterol increased, hypercholesterolaemia).

[c] Hypertriglyceridaemia (including blood triglycerides increased, hypertriglyceridaemia).

[d] Oedema (including generalised oedema, oedema, oedema peripheral, peripheral swelling, swelling).

[e] Peripheral neuropathy (including burning sensation, dysaesthesia, formication, gait disturbance, hypoaesthesia, motor dysfunction, muscular weakness, neuralgia, neuropathy peripheral, neurotoxicity, paraesthesia, peripheral motor neuropathy, peripheral sensory neuropathy, peroneal nerve palsy, sensory disturbance).

[f] Cognitive effects (including events from SOC nervous system disorders: amnesia, cognitive disorder, dementia, disturbance in attention, memory impairment, mental impairment; and also including events from SOC psychiatric disorders: attention deficit/hyperactivity disorder, confusional state, delirium, disorientation, reading disorder). Within these effects, terms from SOC nervous system disorders were more frequently reported than terms from SOC psychiatric disorder.

[g] Fatigue (including asthenia, fatigue).

[h] Mood effects (including affective disorder, affect lability, aggression, agitation, anger, anxiety, bipolar I disorder, depressed mood, depression, depressive symptom, euphoric mood, irritability, mania, mood altered, mood swings, panic attack, personality change, stress).

REFERENCES

1. Pfizer. LORVIQUA (lorlatinib). Summary of Product Characteristics. April 2022.
2. Shaw AT, Bauer TM, de Marinis F, et al; CROWN Trial Investigators. First-line lorlatinib or crizotinib in advanced ALK-positive lung cancer. N Eng J Med. 2020;383(21);2018–2029.

STUDY DESIGN

CROWN was a global, randomised, open-label, multicentre, Phase 3 trial of LORVIQUA vs crizotinib in patients with previously untreated, ALK-positive, locally advanced or metastatic NSCLC (N=296)[1,2]

KEY ENTRY CRITERIA[1,2]

- Histologically or cytologically confirmed locally advanced or metastatic NSCLC
- ALK+ as determined by a CDx immunohistochemical assay
- No previous systemic treatment for metastatic disease
- ≥1 extracranial, measurable target lesion not previously irradiated (according to RECIST 1.1)
- Asymptomatic CNS metastases (treated or untreated) were eligible
- ECOG PS 0, 1, or 2

Randomised 1:1[1]

LORVIQUA
100 mg orally, once daily in 28-day cycles (n=149)[1,2]

Crizotinib
250 mg orally, twice daily in 28-day cycles (n=147)[1,2]

Primary endpoint:[1,2]
PFS by BICR

Key secondary endpoints include:[1,2]
- ORR
- DoR
- PFS, as assessed by investigator
- OS
- IC-TTP
- Safety

In patients with CNS metastases at baseline:
- IC-ORR
- IC-DoR

FOOTNOTES & ABBREVIATIONS

ALK=anaplastic lymphoma kinase;

BICR=blinded independent central review;

CDx=companion diagnostic;

CNS=central nervous system;

DoR=duration of response;

ECOG PS=Eastern Cooperative Oncology Group performance status;

IC-DoR=intracranial duration of response;

IC-ORR=intracranial objective response rate;

IC-TTP=intracranial time to progression;

NSCLC=non-small cell lung cancer;

ORR=objective response rate;

OS=overall survival;

PFS=progression-free survival;

RECIST=Response Evaluation Criteria in Solid Tumours.

REFERENCES

1. Shaw AT, Bauer TM, de Marinis F, et al; CROWN Trial Investigators. First-line lorlatinib or crizotinib in advanced ALK-positive lung cancer. N Eng J Med. 2020;383(21);2018–2029.
2. ClinicalTrials.gov number, NCT03052608. https://clinicaltrials.gov/ct2/show/NCT03052608 (Accessed June 2022).

PRESCRIBING INFORMATION

Before prescribing, please refer to local recommendations and SmPC applicable in your country.

For European residents, please consult the SmPC available at this booth (in English and French languages) or scan the QR code to view on the EMA website: