



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

JideytroTM
(zidesamtinib) | 25 mg
100 mg tablets

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Creating a Protocol, Patient List, and Facility List/Protocol Favorite for JIDEYTROTM

Instructions for the Epic[®] electronic health record (EHR) system

**Please see JIDEYTRO Important Safety Information
on pages 2–5 and [Full Prescribing Information](#).**

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IMPORTANT SAFETY INFORMATION

OVERVIEW & LIMITATIONS

ROS1+ NSCLC

PROTOCOL CONSIDERATIONS

PROTOCOL INSTRUCTIONS

PATIENT LIST CONSIDERATIONS & INSTRUCTIONS

FACILITY LIST & PROTOCOL FAVORITE INSTRUCTIONS

NOTES & DISCLAIMERS

REFERENCES

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

JIDEYTRO™ (zidesamtinib) is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC) who received a prior *ROS1* kinase inhibitor.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS:

Warnings and Precautions reflect the pooled safety population (N=446) who received JIDEYTRO at a dose of 100 mg orally once daily until disease progression or unacceptable toxicity in ARROS-1.

Central Nervous System (CNS) Adverse Reactions (AR):

- Dizziness, ataxia, cognitive and psychiatric disorders occurred in 25% of patients; of these, 2.5% were Grade 3 or 4. One patient (0.2%) with brain metastases experienced a Grade 3 seizure.
- Dizziness, including vertigo, presyncope, and positional dizziness, occurred in 12% of patients; of these, 0.2% were Grade 3. Dosage interruption for dizziness was required in 0.4% and dose reduction in 0.7% of patients.
- Ataxia, including gait disturbance and balance disorder, occurred in 2% of patients; all were Grade 1 or 2.
- Cognitive impairment occurred in 9% of patients; of these, 1.6% were Grade 3 or 4. Cognitive impairment included memory impairment (3.1%), cognitive disorder (1.6%), hallucination (1.1%), delirium (1.1%), aphasia (0.9%), amnesia (0.7%), confusional state (0.7%), anterograde amnesia (0.2%), disturbance in attention (0.4%), and slow speech (0.2%). Dose interruption for cognitive impairment was required in 1.3% of patients.
- Psychiatric disorders occurred in 6% of patients; of these, 0.7% were Grade 3 or 4. Psychiatric disorders included anxiety (3.1%), depression (1.3%), agitation (0.7%), affect lability (0.4%), irritability (0.4%), abnormal behavior (0.2%), depressed mood (0.2%), personality change (0.2%), psychotic disorder (0.2%), and suicidal ideation (0.2%). Dosage interruption for psychiatric disorders was required in 0.9% of patients.
- Advise patients to avoid engaging in hazardous tasks requiring mental alertness and motor coordination, such as operating machinery or driving a motor vehicle if they are experiencing CNS reactions.
- Monitor patients for CNS adverse reactions and suicidal thoughts and behaviors during treatment with JIDEYTRO. Withhold and then resume at the same or reduced dose upon improvement or permanently discontinue JIDEYTRO based on severity.

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IMPORTANT SAFETY INFORMATION

OVERVIEW & LIMITATIONS

ROS1+ NSCLC

PROTOCOL CONSIDERATIONS

PROTOCOL INSTRUCTIONS

PATIENT LIST CONSIDERATIONS & INSTRUCTIONS

FACILITY LIST & PROTOCOL FAVORITE INSTRUCTIONS

NOTES & DISCLAIMERS

REFERENCES

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D):

QTc Interval Prolongation:

- JIDEYTRO can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death. JIDEYTRO has not been studied in patients with a history of QTcF >450 msec on more than one assessment prior to initiation.
- Of the 435 patients who underwent at least one post-baseline electrocardiogram (ECG) assessment, 2% experienced an increase in QTcF of >60 msec compared to baseline after receiving JIDEYTRO and 0.2% increase in QTcF to >500 msec. QTc prolongation led to dose interruption in 0.4% of patients.
- Evaluate ECGs and electrolytes prior to administration of JIDEYTRO and monitor periodically during treatment. Adjust the frequency of monitoring based on risk factors such as known long QT syndromes, clinically significant bradyarrhythmias, severe or uncontrolled heart failure, and concomitant medications associated with QTc interval prolongation.
- Withhold, then resume at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity.

Interstitial Lung Disease (ILD)/Pneumonitis:

- JIDEYTRO can cause severe or life-threatening ILD or pneumonitis.
- ILD/pneumonitis occurred in 1.8% of patients, including Grade 3 or 4 in 0.4%.
- ILD/pneumonitis led to dose interruption in 0.7%, dose reduction in 0.2%, and permanent discontinuation in 0.4% of patients.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold JIDEYTRO in patients with suspected ILD/pneumonitis, then upon recovery resume at the same or reduced dose or permanently discontinue based on severity.

Skeletal Fractures:

- JIDEYTRO can increase the risk of skeletal fractures.
- Five patients (1.1%) experienced skeletal fractures. Grade 3 ankle fractures occurred in two patients (0.4%). Dose interruptions for fractures occurred in 0.4% of patients.
- Promptly evaluate patients with signs or symptoms of fractures.

**Please see Important Safety Information continued
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IMPORTANT SAFETY INFORMATION

OVERVIEW & LIMITATIONS

ROS1+ NSCLC

PROTOCOL CONSIDERATIONS

PROTOCOL INSTRUCTIONS

PATIENT LIST CONSIDERATIONS & INSTRUCTIONS

FACILITY LIST & PROTOCOL FAVORITE INSTRUCTIONS

NOTES & DISCLAIMERS

REFERENCES

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D):

Myalgia with Creatine Phosphokinase (CPK) Elevation:

- JIDEYTRO can cause myalgia with creatine phosphokinase (CPK) elevation.
- Myalgia occurred in 13% of patients. Based on laboratory values, concurrent myalgia with increased CPK occurred in 2.1% of patients.
- Advise patients to report unexplained muscle pain or tenderness. Monitor serum CPK levels prior to administration of JIDEYTRO and every 2 weeks during the first month of treatment and then every 1 to 2 months and as clinically indicated in patients reporting unexplained muscle pain or tenderness. Withhold, then resume JIDEYTRO at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity.

Pancreatic Toxicity:

- JIDEYTRO can cause pancreatic toxicity. In the pooled safety population, among the subgroup of patients who underwent pancreatic lab testing, increased amylase and lipase levels occurred in 22%, and 25% respectively, with Grade 3 increased lipase in 8% of patients. Grade 3 lipase elevation resulted in JIDEYTRO dose reduction in one patient. In the pooled safety population, Grade 3 pancreatitis occurred in one patient (0.2%).
- Evaluate amylase and lipase prior to administration of JIDEYTRO and monitor periodically during treatment. Based on the severity of the adverse reaction, temporarily withhold, reduce the dose, or permanently discontinue JIDEYTRO.

Embryo-Fetal Toxicity:

- Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor kinase (TRK) signaling, findings from animal studies and its mechanism of action, JIDEYTRO can cause fetal harm when administered to a pregnant woman.
- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 6 months after the last dose.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 3 months after the last dose.

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on the following page.**

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(zidesamtinib) | 25 mg
100 mg tablets

 **Nuvalent**
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IMPORTANT SAFETY INFORMATION

OVERVIEW & LIMITATIONS

ROS1+ NSCLC

PROTOCOL CONSIDERATIONS

PROTOCOL INSTRUCTIONS

PATIENT LIST CONSIDERATIONS & INSTRUCTIONS

FACILITY LIST & PROTOCOL FAVORITE INSTRUCTIONS

NOTES & DISCLAIMERS

REFERENCES

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS:

- The most common adverse reactions ($\geq 15\%$) were edema, peripheral neuropathy, constipation, fatigue, and dyspnea.
- The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were increased lipase, increased CPK, increased triglycerides, decreased lymphocytes, and decreased hemoglobin.
- Clinically relevant adverse reactions in $< 10\%$ of patients receiving JIDEYTRO were cognitive disorders, psychiatric disorders, stomatitis, ataxia, ILD/pneumonitis, QTc prolongation, pancreatitis, and ankle fracture.

DRUG INTERACTIONS:

Strong and Moderate CYP3A Inhibitors:

- Avoid concomitant use of JIDEYTRO with a strong or moderate CYP3A inhibitor as this could increase JIDEYTRO exposure, which may increase the risk of JIDEYTRO adverse reactions.

Strong and Moderate CYP3A Inducers:

- Avoid concomitant use of JIDEYTRO with strong or moderate CYP3A inducers as this could decrease JIDEYTRO exposure, which may decrease the effectiveness of JIDEYTRO.

Please see [Full Prescribing Information](#).



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Contents

2

IMPORTANT SAFETY INFORMATION

7

OVERVIEW AND LIMITATIONS

8

LOCALLY ADVANCED OR METASTATIC *ROS1*-POSITIVE
NON-SMALL CELL LUNG CANCER MEDICAL NEEDS

11

PROTOCOL CONSIDERATIONS

› Suggested Protocol Content

21

PROTOCOL INSTRUCTIONS

32

PATIENT LIST CONSIDERATIONS & INSTRUCTIONS

› Reporting Workbench

› SlicerDicer

› Sidekick

42

FAVORITES INSTRUCTIONS

43

NOTES & DISCLAIMERS

44

REFERENCES



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Overview and Limitations

- This document provides healthcare organizations with instructions for creating or updating a protocol, creating a patient list, and adding JIDEYTRO as a facility list and protocol favorite in the Epic EHR system for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC) who received a prior *ROS1* kinase inhibitor.
- The document is informational only. It does not replace professional medical advice, diagnosis, or clinical judgment. Treatment selection is always a decision made by the healthcare provider.
- The processes and instructions outlined in this document may not be complete or accurate for your organization. Additionally, some of the steps are variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider.
- These instructions are specific to JIDEYTRO and the Epic EHR system and are not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.
- The organization is solely responsible for the implementation, testing, monitoring, and ongoing operation of any EHR tools.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

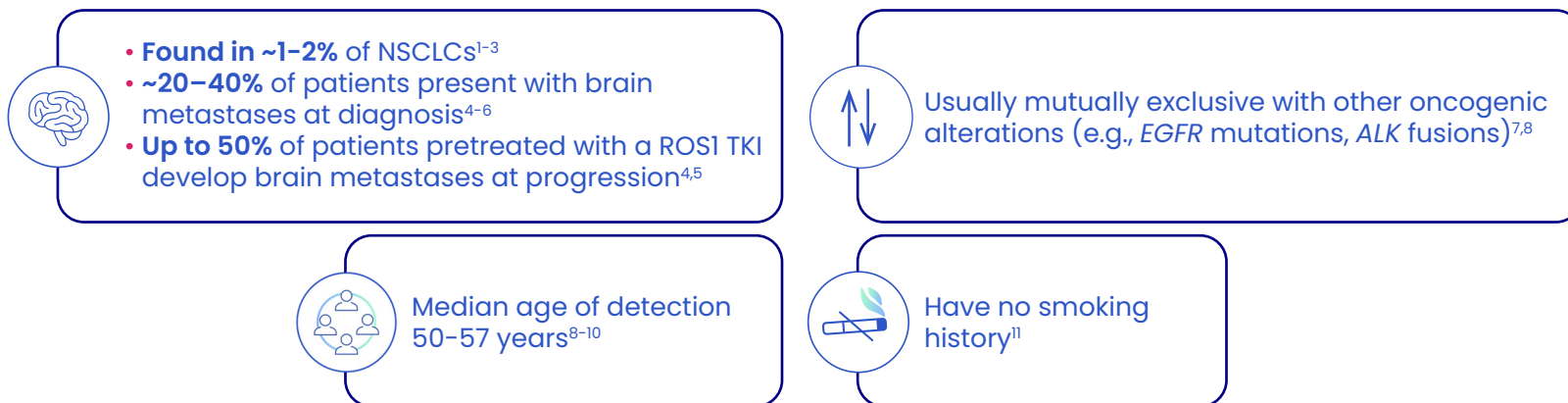
NOTES &
DISCLAIMERS

REFERENCES

Locally Advanced or Metastatic *ROS1*-Positive Non-Small Cell Lung Cancer Medical Needs

Patients With Advanced *ROS1*+ NSCLC Represent a Rare and Clinically Distinct Subset of Advanced NSCLC

Common characteristics for patients with *ROS1* fusions:



Detection of *ROS1* fusions^{2,12}

ALK, anaplastic lymphoma kinase; *EGFR*, epidermal growth factor receptor; FISH, fluorescence in situ hybridization; NSCLC, non-small cell lung cancer; NGS, next-generation sequencing; PCR, polymerase chain reaction; *ROS1*, c-ros oncogene 1; TKI, tyrosine kinase inhibitor.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

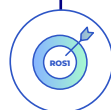
Locally Advanced or Metastatic *ROS1*-Positive Non-Small Cell Lung Cancer Medical Needs

Significant Medical Needs Remain for Patients With *ROS1*+ NSCLC^{13,14}



CNS activity^{5,13,15}

Suboptimal intracranial inhibition may limit activity against brain metastases, a key driver of disease progression



ROS1 selectivity¹⁴

Inadequate target selectivity may lead to off-target or dose-limiting toxicities, treatment intolerance, and increased patient burden



ROS1 mutant activity^{13,14}

ROS1 resistance mutations acquired during treatment with targeted therapies may lead to disease progression

These drivers of disease progression or intolerance may lead to early treatment discontinuation, highlighting the need for a durable treatment option.¹³⁻¹⁵

CNS, central nervous system; NSCLC, non-small cell lung cancer; *ROS1*, c-ros oncogene 1.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Locally Advanced or Metastatic *ROS1*-Positive Non-Small Cell Lung Cancer Medical Needs and JIDEYTRO

JIDEYTRO: A Rationally Designed, *ROS1*-Selective TKI



Indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*+ NSCLC who received a prior *ROS1* kinase inhibitor¹⁶

SCIENTIFIC RATIONALE for JIDEYTRO

ROS1 Activity

- Primary oncogenic driver in ~1–2% of NSCLC¹⁻³

ROS1 Mutant Activity

- ~40% of patients develop secondary *ROS1* G2032R resistance mutations following crizotinib treatment¹⁷

Intracranial Activity

- ~20–40% of patients present with CNS metastases at diagnosis^{4,5}
- ~30–55% of patients develop CNS metastases following 1L crizotinib^{4,17}



1L, first line; CNS, central nervous system; NSCLC, non-small cell lung cancer; *ROS1*, c-ros oncogene 1. TKI, tyrosine kinase inhibitor.

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(zidesamtinib) 25 mg
100 mg tablets

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Considerations

The clinical data elements provided in this section for order sets and protocols are suggestions only. Clinical and operational leadership must determine that the final elements align with the expectations and goals of the organization, as well as all applicable policies, standards, and laws and regulations. Consider reviewing appropriate order sets and protocols for the inclusion of JIDEYTRO. Order sets and protocols may benefit from regular updates to include new treatments, laboratory sets, and other orderable items.

The content in this section provides an overview and quick reference guide for the dosing and administration details for JIDEYTRO as per the Prescribing Information. Step-by-step instructions for applying these medication details in order set and protocol updates are shown in the instructions section for your consideration.

However, treatment selection is always a decision made by the healthcare provider, and protocols may be overridden to reflect this. An EHR newsletter or

other communication may be considered to notify end users of the availability and contents of the updated protocols.

Suggested Protocol Content

JIDEYTRO is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor.

Key clinical details from the JIDEYTRO Prescribing Information are included in this section and may be incorporated as part of creating/updating the protocol based on the suggested steps in the instructions section that follows. JIDEYTRO should be used only as described in the Prescribing Information. The organization may add or edit any details as desired to align with governing EHR policies and standards.

Please consult the most recent version of the JIDEYTRO Prescribing Information for full treatment details.

Please see JIDEYTRO Important Safety Information on pages 2–5 and Full Prescribing Information.

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100 mg tablets

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Considerations (cont'd)

The following content is from the JIDEYTRO Prescribing Information:

Recommended Testing and Evaluation Before Initiating JIDEYTRO

Before initiating JIDEYTRO, evaluate creatine phosphokinase (CPK) level, electrocardiogram (ECG), electrolytes, lipase, and amylase.

Recommended Dosage

The recommended dosage of JIDEYTRO is 100 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity. Swallow JIDEYTRO tablets whole. Do not split, chew, crush, or dissolve the tablet prior to swallowing.

Missed Dose:

If a dose of JIDEYTRO is missed within 12 hours of the regularly scheduled dose, administer the missed dose as soon as possible. If a dose is missed by 12 hours or more, take the next dose at its scheduled time.

Vomiting:

If vomiting occurs at any time after taking JIDEYTRO, take the next dose at its scheduled time.

Dosage Modifications for Adverse Reactions

The recommended dosage reductions of JIDEYTRO for the management of adverse reactions are provided in Table 1.

Table 1: Recommended Dose Reductions for JIDEYTRO Adverse Reactions

Dose Reduction	Recommended Dose and Schedule
First	75 mg once daily
Second	50 mg once daily
Permanently discontinue JIDEYTRO in patients unable to tolerate 50 mg once daily. After dose reduction of JIDEYTRO for adverse reactions, do not re-escalate the dose.	

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Protocol Considerations (cont'd)

The recommended dosage modifications of JIDEYTRO for the management of adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
Central Nervous System Adverse Reactions	Intolerable Grade 2	- Withhold JIDEYTRO until Grade ≤ 1 or baseline. - Resume JIDEYTRO at same or reduced dose, as clinically appropriate.
	Grade 3	- Withhold JIDEYTRO until Grade ≤ 1 or baseline. - Resume JIDEYTRO at reduced dose.
	Grade 4	Permanently discontinue JIDEYTRO.
QTc Interval Prolongation	Grade 2 (QTc interval 481–500 msec)	- Withhold JIDEYTRO until recovery to Grade ≤ 1 or baseline. - Correct electrolytes and/or change concomitant medications. - Resume JIDEYTRO at same dose.
	Grade 3 (QTc interval ≥ 501 msec or QTc) QTc interval increase of >60 msec from baseline)	- Withhold JIDEYTRO until recovery to Grade ≤ 1 or baseline. - Correct electrolytes and/or change concomitant medications. - Resume JIDEYTRO at a reduced dose.

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.

Table continued on next page

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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100 mg tablets

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Protocol Considerations (cont'd)

The recommended dosage modifications of JIDEYTRO for the management of adverse reactions are provided in Table 2.

Table 2 (cont'd): Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
QTc Interval Prolongation	Grade 4 (Torsade de pointes; polymorphic ventricular tachycardia; signs/symptoms of serious arrhythmia)	Permanently discontinue JIDEYTRO.
Interstitial Lung Disease (ILD)/Pneumonitis	Grade 1	- Withhold JIDEYTRO if ILD/pneumonitis occurs or is suspected until recovery to Grade 0. - If resolved within 6 weeks, resume JIDEYTRO at the same dose. - If unresolved after 6 weeks, permanently discontinue JIDEYTRO. Recurrence: - Permanently discontinue JIDEYTRO.
	Grade 2	- Withhold JIDEYTRO if ILD/pneumonitis occurs or is suspected until recovery to Grade 0 or baseline. - If resolved within 6 weeks, resume JIDEYTRO at a reduced dose. - If unresolved after 6 weeks, permanently discontinue JIDEYTRO. Recurrence: - Permanently discontinue JIDEYTRO.

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.

Table continued on next page

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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100 mg tablets

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Protocol Considerations (cont'd)

The recommended dosage modifications of JIDEYTRO for the management of adverse reactions are provided in Table 2.

Table 2 (cont'd): Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
Interstitial Lung Disease (ILD)/Pneumonitis	Grade 3 or 4	Permanently discontinue JIDEYTRO.
Creatine Phosphokinase (CPK) Elevation	CPK elevation >5 times ULN	Withhold JIDEYTRO until recovery to baseline or ≤ 2.5 times ULN, then resume JIDEYTRO at same dose.
	CPK elevation >10 times ULN or Recurrence of CPK elevation of >5 times ULN	Withhold until recovery to baseline or ≤ 2.5 times ULN, then resume JIDEYTRO at a reduced dose.
Increased lipase or amylase	Grade 3	- Withhold JIDEYTRO until Grade ≤ 2 or baseline. - If recovered to baseline or Grade ≤ 2 within 14 days, resume JIDEYTRO at a reduced dose; otherwise permanently discontinue JIDEYTRO.
	Grade 4	Permanently discontinue JIDEYTRO.

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.

Table continued on next page

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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100 mg tablets

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Protocol Considerations (cont'd)

The recommended dosage modifications of JIDEYTRO for the management of adverse reactions are provided in Table 2.

Table 2 (cont'd): Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
Pancreatitis	Grade 3 or 4	• Permanently discontinue JIDEYTRO.
Other Adverse Reactions	Intolerable Grade 2 or Grade 3 or Grade 4	• Withhold JIDEYTRO until Grade $\leq$1 or baseline. • If resolution occurs within 4 weeks, resume JIDEYTRO at the same dose for intolerable Grade 2 or Grade 3 adverse reactions. • If resolution occurs within 4 weeks, resume JIDEYTRO at the next lower dose for Grade 4 adverse reactions. • Permanently discontinue JIDEYTRO if adverse reaction does not resolve within 4 weeks. • Permanently discontinue JIDEYTRO for recurrent Grade 4 events.

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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100 mg tablets

 **Nuvalent**
A GSK company



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Considerations (cont'd)

Contraindications

None.

Central Nervous System Adverse Reactions

JIDEYTRO can cause central nervous system adverse reactions.

In the pooled safety population, a broad spectrum of central nervous system (CNS) adverse reactions, including dizziness, ataxia, cognitive and psychiatric disorders, occurred in 25% of patients who received JIDEYTRO; of these, 2.5% were Grade 3 or 4. One patient (0.2%) with brain metastases experienced a Grade 3 seizure.

Dizziness, including vertigo, presyncope and positional dizziness occurred in 12% of patients who received JIDEYTRO; of these 0.2% were Grade 3. The median time to onset of dizziness was 22 days (range: 1 day to 9 months). Dosage interruption of JIDEYTRO for dizziness was required in 0.4% of patients, and 0.7% of patients required dose reduction.

Ataxia, including gait disturbance and balance disorder, occurred in 2% of patients who received JIDEYTRO and were all Grade 1 or 2. The median time to onset of ataxia was 64 days (range: 6 days to 2.5 years).

Cognitive impairment occurred in 9% of patients who received JIDEYTRO, of these 1.6% were Grade 3 or 4. Cognitive impairment included memory impairment (3.1%), cognitive disorder (1.6%), hallucination (1.1%), delirium (1.1%), aphasia (0.9%), amnesia (0.7%), confusional state (0.7%), anterograde amnesia (0.2%), disturbance in attention (0.4%), slow speech (0.2%). The median time to onset of cognitive impairment was 43 days (range: 4 days to 1.9 years). Dose interruption of JIDEYTRO for cognitive impairment was required in 1.3% of patients.

Psychiatric disorders occurred in 6% of patients who received JIDEYTRO, of these 0.7% were Grade 3 or 4. Psychiatric disorders included anxiety (3.1%), depression (1.3%), agitation (0.7%), affect lability (0.4%), irritability (0.4%), abnormal behavior (0.2%), depressed mood (0.2%), personality change (0.2%), psychotic disorder (0.2%), and suicidal ideation (0.2%). The median time to onset of psychiatric disorders was 57 days (range: 1 day to 10 months). Dosage interruption of JIDEYTRO for psychiatric disorders was required in 0.9% of patients.

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(zidesamtinib) | 25 mg
100 mg tablets

 **Nuvalent**
A GSK company



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Considerations (cont'd)

Central Nervous System Adverse Reactions (cont'd)

Advise patients and caregivers of the risk of CNS adverse reactions with JIDEYTRO. Advise patients to avoid engaging in hazardous tasks requiring mental alertness and motor coordination such as operating machinery or driving a motor vehicle if they are experiencing CNS reactions. Monitor patients for CNS adverse reactions and suicidal thoughts and behaviors during treatment with JIDEYTRO. Withhold and then resume at the same or reduced dose upon improvement or permanently discontinue JIDEYTRO based on severity.

QTc Interval Prolongation

JIDEYTRO can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death. JIDEYTRO has not been studied in patients with a history of QTcF >450 msec on more than one assessment prior to initiation.

In the pooled safety population, of the 435 patients who underwent at least one post baseline electrocardiogram (ECG) assessment, 2% experienced an increase in QTcF of >60 msec compared to baseline after receiving JIDEYTRO and 0.2% increase in QTcF to >500 msec.

The median time from the first dose of JIDEYTRO to the onset of QTc prolongation was 15 days (range: 1 day to approximately 1 month). QTc prolongation led to dose interruption in 0.4% of patients who received JIDEYTRO.

Evaluate ECGs and electrolytes prior to administration of JIDEYTRO and monitor periodically during treatment. Adjust the frequency of monitoring based on risk factors such as known long QT syndromes, clinically significant bradyarrhythmias, severe or uncontrolled heart failure, and concomitant medications associated with QTc interval prolongation. Withhold, then resume at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity.

Interstitial Lung Disease/Pneumonitis

JIDEYTRO can cause severe or life-threatening interstitial lung disease (ILD) or pneumonitis.

In the pooled safety population, interstitial lung disease (ILD)/pneumonitis occurred in 1.8% of patients treated with JIDEYTRO, including Grade 3 or 4 in 0.4%. The median time to first onset of ILD/pneumonitis was 4.5 months (range: 8 days to 11 months).

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100 mg tablets

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Considerations (cont'd)

Interstitial Lung Disease/Pneumonitis (cont'd)

ILD/pneumonitis led to dose interruption of JIDEYTRO in 0.7% of patients. ILD/pneumonitis required dose reduction in 0.2% of patients and permanent discontinuation of JIDEYTRO in 0.4% of patients.

Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold JIDEYTRO in patients with suspected ILD/pneumonitis, then upon recovery resume at the same or reduced dose or permanently discontinue based on severity.

Skeletal Fractures

JIDEYTRO can increase the risk of skeletal fractures.

In the pooled safety population, 5 patients (1.1%) experienced skeletal fractures, and Grade 3 ankle fractures occurred in two patients (0.4%) who received JIDEYTRO. Some fractures occurred in the setting of an accidental fall or other predisposing factors such as osteoporosis, bone metastasis, and age-related degenerative conditions. The median time to fracture was 48 days (range: 32 days to approximately 6 months). JIDEYTRO was interrupted in 0.4% of patients for fractures.

Myalgia with Creatine Phosphokinase Elevation

JIDEYTRO can cause myalgia with creatine phosphokinase (CPK) elevation.

In the pooled safety population, myalgia occurred in 13% of patients who received JIDEYTRO. Based on laboratory values, concurrent myalgia with increased CPK occurred in 2.1% of patients. The median time to onset of myalgia for these patients with CPK elevation was 2 months (range: 8 days to 6 months).

Advise patients to report unexplained muscle pain or tenderness. Monitor serum CPK levels prior to administration of JIDEYTRO and every 2 weeks during the first month of treatment and then every 1 to 2 months and as clinically indicated in patients reporting unexplained muscle pain or tenderness. Withhold, then resume at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity.

Pancreatic Toxicity

JIDEYTRO can cause pancreatic toxicity.

In the pooled safety population, among the subgroup of patients who underwent pancreatic lab testing, increased amylase occurred in 22%

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Considerations (cont'd)

Pancreatic Toxicity (cont'd)

and increased lipase occurred in 25% of patients treated with JIDEYTRO. Grade 3 increased lipase occurred in 8% of these patients. Grade 3 lipase elevation resulted in JIDEYTRO dose reduction in one patient. The median time-to-onset of Grade 3 increased lipase was 143 days (range: 28 to 249 days). In the pooled safety population, Grade 3 pancreatitis occurred in one patient (0.2%) treated with JIDEYTRO.

Evaluate amylase and lipase prior to administration of JIDEYTRO and monitor periodically during treatment. Based on the severity of the adverse reaction, temporarily withhold, reduce the dose, or permanently discontinue JIDEYTRO.

Embryo-Fetal Toxicity

Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor kinase (TRK) signaling, findings from animal studies and its mechanism of action, JIDEYTRO can cause fetal harm when administered to a pregnant woman.

In an animal reproduction study, oral administration of zidesamtinib to pregnant rats during the period

of organogenesis resulted in embryo-fetal mortality, alterations to growth, and structural abnormalities at maternal exposures approximately equivalent to the human exposure at the recommended dose based on area under the curve (AUC).

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 6 months after the last dose.

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 3 months after the last dose.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Instructions

Protocols are commonly used in the management of oncology patients. Protocols (called “treatment plans” in Epic once applied to a patient) consolidate notes, referrals, imaging studies, lab orders and bundles, medications, patient education, coding and billing information, and other orderable items used to manage a medical condition, problem, or age-specific need. Protocols may improve the user experience and help reduce practice variation. They typically created and modified at the enterprise or system level to help reduce practice- or location-specific variation.

Protocols may benefit from clinical updates to incorporate treatment changes or system optimizations. Typically, a practice will conduct a clinical review process to review and approve suggested optimizations. Various stakeholders may participate in reviewing optimization requests prior to implementation. Engage the proper committees and stakeholders for clinical input and review well ahead of the planned implementation date.

Any updates to the content or availability of protocols should be communicated to end users, with training provided as needed. In many cases, end users will have already been trained on how to use these tools as part of the organization’s best practices, thereby potentially reducing the need for additional training.

Protocols may be used to set up JIDEYTRO in the Epic EHR system. Administrative user rights are required to access these tools. An existing protocol may be used as the foundation for a new one. Consider modifying an existing protocol as a starting template while saving the original. Protocols, order sets, and related content will need to be built by a clinical analyst, an IT colleague, or other qualified professional, or as otherwise determined by the organization.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Protocol Instructions (cont'd)

There are 4 main steps to creating or updating a protocol in the Epic EHR system to include JIDEYTRO:

1

Create a new protocol record, ideally by copying an existing protocol for another similar medication or disease state.

2

Create or update the order groups. As part of this step, multiple order groups related to JIDEYTRO may be created/updated. Order groups for JIDEYTRO may be created, as well as any other desired order groups (e.g., schedulable orders, premedications, treatment conditions, monitoring and hold parameters, warnings and precautions, supportive care, healthcare professional [HCP] communications). Review your organization's governing rules and principles regarding protocol builds and adjust the groups as appropriate.

The same order groups may be used in different protocols. Take special care to not inadvertently affect other protocols if making build changes to existing order groups. If working from a copy of an existing protocol, be sure to create copies of existing order groups to avoid inadvertently affecting other protocols.

3

Add links for the Prescribing Information and other resources, such as the Instructions for Use, to the medication record.

4

Add the order groups created in Step 2 to the new protocol, and fill in the protocol details.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Step 1: Create a New Protocol Record

1. In Hyperspace, navigate to the Protocol Builder (**Epic button** > **Admin** > **Beacon Admin** > **Protocol Builder**).
2. Search for an existing protocol that can be used as a template and open it.
Note: *Alternatively, if a similar protocol does not exist, select the Create New button.*
3. After opening the existing protocol, select the Save As button.
4. Give the new protocol an ID and name that conform to your organization's build standards.
For example:
 - i. JIDEYTRO for adult patients with TKI-pretreated, advanced ROS1-positive NSCLC
5. Update the plan description for the new protocol. Consider the suggestion below or select another description to align with internal standards.
 - i. JIDEYTRO for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor.
6. Update the Synonyms for the protocol name. Consider adding regimen acronyms, generic names, disease characteristics, disease location, and other values specific to the protocol. Options include:
 - i. JIDEYTRO
 - ii. Any potential common misspellings of JIDEYTRO or its generic name (zidesamtinib)
 - iii. Non-small cell lung cancer
 - iv. NSCLC
 - v. Metastatic
 - vi. Locally advanced
 - vii. ROS1-positive
7. Update the Clinical Study Reference for JIDEYTRO (consider a link to the Clinical Studies 14 section of the JIDEYTRO Prescribing Information).



Step 2: Create or Update the Order Groups

1. Review the Regimen Category Order Group to confirm that Medications, Premedications, Treatment Conditions, and Supportive Medications (or similar sections that already exist, following your organization's protocol build standards) are values in the category list.
2. In Hyperspace, navigate to the Order Group Builder
(**Epic button > Admin > Beacon Admin > Order Group Builder**).
3. Create the new order groups (see detailed examples on the following pages).

Note: If you started by copying an existing protocol in the Step 1 section on page 23, it will be easier and more efficient to create copies of existing order groups and modify them when necessary. To do this, right-click on the order group within the protocol record, select Open, then select the Save As button. Next, follow the steps starting below for each order group.

IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES



Order Group

1. Create a new order group. Create a name for the new order group, such as “JIDEYTRO 100 MG PO ONCE DAILY,” ensuring that you follow your organization’s standard naming convention.
 - i. Set the default category to Oral Chemotherapy, Chemotherapy Prescriptions, or whichever equivalent order category is used for outpatient oral chemotherapy prescriptions in your organization.
2. Add the details for JIDEYTRO to the order group:
 - i. Right-click in the empty field at the bottom of the window
 - ii. Select Add Orders, and under the Outpatient Medications section in the preference search window, choose JIDEYTRO (zidesamtinib).
 - iii. Complete the outpatient medication details for JIDEYTRO. Details may include the dose, route, frequency, patient or caregiver instructions (Sig), and order comments or pharmacy notes intended for other clinicians.

Suggested clinical details from the Prescribing Information include:

1. JIDEYTRO (zidesamtinib) tablets for oral use are supplied as 25 mg and 100 mg dosage strengths. JIDEYTRO tablets 25 mg are film-coated, oblong, pink tablets, debossed with “25” on one side and “ZDS” on other side of the tablet. JIDEYTRO tablets 100 mg are film-coated, oblong, yellow tablets, debossed with “100” on one side and “ZDS” on other side of the tablet.
2. Store JIDEYTRO at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F).
3. Recommended Testing and Evaluation Before Initiating JIDEYTRO:
 - Before initiating JIDEYTRO, evaluate CPK level, ECG, electrolytes, lipase, and amylase.
4. Recommended Dosage:
 - The recommended dosage of JIDEYTRO is 100 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity. Swallow JIDEYTRO tablets whole. Do not split, chew, crush, or dissolve the tablet prior to swallowing.

Continued on next page

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Order Group (cont'd)

- If a dose of JIDEYTRO is missed within 12 hours of the regularly scheduled dose, administer the missed dose as soon as possible. If a dose is missed by 12 hours or more, take the next dose at its scheduled time.
- If vomiting occurs at any time after taking JIDEYTRO, take the next dose at its scheduled time.

5. Contraindications

None.

6. Warnings and Precautions

Warnings and Precautions include central nervous system adverse reactions, QTc interval prolongation, interstitial lung disease (ILD)/pneumonitis, skeletal fractures, myalgia with creatine phosphokinase elevation, pancreatic toxicity, and embryo-fetal toxicity. For warning and precaution details, see Section 5 of the JIDEYTRO Prescribing Information.

3. Click Accept to save the record and close the builder.

IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES



Order Group: AOG JIDEYTRO 100 MG PO ONCE DAILY

Adding an inpatient version of JIDEYTRO to the protocol is strongly recommended. This will allow providers to order JIDEYTRO through the treatment plan in the event a patient is admitted and treatment should continue. To add the inpatient order:

- 1.** Create a new order group. Create a name for the new order group, such as “AOG JIDEYTRO 100 MG PO ONCE DAILY,” ensuring that you follow your organization’s standard naming convention.
 - i. Set the default category to Chemotherapy, Medications, or whichever equivalent order category is used for chemotherapy treatment in your organization.
- 2.** Choose a selection mode of Single-Select from the dropdown menu.
- 3.** Add the details for JIDEYTRO to the order group:
 - i. Right-click in the empty field at the bottom of the window.
 - ii. Select Add Orders, and under the Inpatient Medications section in the preference search window, choose JIDEYTRO (zidesamtinib).
 - iii. Complete the inpatient medication details for JIDEYTRO. Details may include dose, route, frequency, offset time, admin over, and any special administration instructions or order comments intended for nurses, pharmacists, or HCPs. Suggested clinical details from the Prescribing Information include:
 1. JIDEYTRO (zidesamtinib) tablets for oral use are supplied as 25 mg and 100 mg dosage strengths. JIDEYTRO 25 mg tablets are film-coated, oblong, pink tablets, debossed with “25” on one side and “ZDS” on other side of the tablet. JIDEYTRO tablets, 100 mg are film-coated, oblong, yellow tablets, debossed with “100” on one side and “ZDS” on other side of the tablet.
 2. Store JIDEYTRO at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F).
 3. Recommended Testing and Evaluation Before Initiating JIDEYTRO:
 - Before initiating JIDEYTRO, evaluate CPK level, ECG, electrolytes, lipase, and amylase.

AOG=advanced order group.

Continued on next page

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Order Group: AOG JIDEYTRO 100 MG PO ONCE DAILY (cont'd)

4. Recommended Dosage:

- The recommended dosage of JIDEYTRO is 100 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity. Swallow JIDEYTRO tablets whole. Do not split, chew, crush, or dissolve the tablet prior to swallowing.
- If a dose of JIDEYTRO is missed within 12 hours of the regularly scheduled dose, administer the missed dose as soon as possible. If a dose is missed by 12 hours or more, take the next dose at its scheduled time.
- If vomiting occurs at any time after taking JIDEYTRO, take the next dose at its scheduled time.

5. Contraindications

None.

6. Warnings and Precautions

For warning and precaution details, see Section 5 of the JIDEYTRO Prescribing Information.

4. Ensure that the single-select radio button next to the order's name in the JIDEYTRO Order Composer is unselected.
5. Click Accept to save the record and close the builder.

All Medication Order Groups

1. Dose modification templates can be leveraged when creating order groups to support dosing adjustments. Attach the appropriate Dose modification template to the relevant medication order(s) according to your organizational standards.
 - i. Recommended Dose Reductions for JIDEYTRO Adverse Reactions:
 1. First Dose Reduction: 75 mg once daily
 2. Second Dose Reduction: 50 mg once daily
2. Once all the desired information is added, release and migrate the order groups to the production environment after completing testing.

AOG=advanced order group.



Additional Order Groups

1. Create additional order groups for any other desired orderable medications or procedures and information for the protocol. This may include information about JIDEYTRO treatment conditions, monitoring and hold parameters, warnings and precautions, procedure orders, schedulable orders, HCP communications, labs, and any other pertinent information.
2. Once all the desired information is added, release and migrate the order groups to the production environment after completing testing.

IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Step 3: Add Links for the Prescribing Information and Other Resources

1. Log in to the Medication Master File (ERX) with authorized user credentials.
2. Use the search feature in the Medication Master File to search for and select each strength of JIDEYTRO.
3. Page down to the Inpatient Reference Links screen and add a new row:
 - i. For Display Name, enter "JIDEYTRO Prescribing Information." In the URL field, enter this hyperlink: <https://www.jideytrohcp.com/prescribing-information.pdf>
 - ii. Repeat the above step for other resources for which a link should be included
4. Close the medication record to save the changes.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Step 4: Add the Order Groups Created in Step 2 to the New Protocol

1. Open the protocol record created in the Step 1 section on page 23.
2. In the Configuration tab, modify or add the cycle length as 30 days.
3. Add all the newly created or modified order groups from the Step 2 section on pages 24–29 to the protocol according to the treatment schedule for each cycle.
4. Expand the AOG JIDEYTRO 100 MG PO ONCE DAILY order group header within the protocol builder and change the selection requirement to Recommended. If preferred, organizations may use other build approaches to communicate that optional IP versions of chemotherapy are included in Add Orders (e.g., a provider communication order or an order comment in the outpatient order group).
5. Click Save.
6. Release the protocol and migrate it to the production environment after completing testing.

Note: After the protocol is moved to production, HCPs can navigate to the protocol selection window and click the star icon before the name of the newly created JIDEYTRO plan to add the protocol as a favorite so they can easily access it in the future.

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Patient List Considerations

End-user reporting solutions in Epic are generally available to most end users and allow users to identify patients who meet defined inclusion and exclusion criteria. The primary end-user reporting solutions in Epic are:

- **Reporting Workbench**
- **SlicerDicer**
 - **Sidekick**

Additional reporting solutions are available; however, use of these tools typically requires analyst or reporting privileges and is beyond the scope of most users. The steps below will assist an end user in creating a patient query (also referred to as a “patient list” or “report”) to identify patients with potential care gaps. Consider creating a patient query to identify patients with locally advanced or metastatic *ROS1*-positive NSCLC who have previously received a *ROS1* kinase inhibitor and may be candidates for treatment with JIDEYTRO.

The suggested criteria are listed below. Not every criterion may be routinely documented in the EHR and, depending on the level of integration within the practice or health system, some criteria may be unavailable. For example, biomarker results may not be available in the EHR as structured data. Given variations in documentation and coding practices, the suggested criteria may need to be modified. Any questions should be directed to the appropriate service provider. The health system is solely responsible for the implementation, testing, monitoring, and ongoing operation of any EHR tools.

A manual chart review of the resulting patient list is recommended, as the list is not a substitute or a replacement for the clinical or professional judgment of the healthcare provider. While EHRs may assist providers in identifying patients who may be appropriate for JIDEYTRO therapy, treatment decisions should ultimately be made by the provider in consultation with the patient following review of the patient’s medical records to confirm eligibility.

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Suggested Inclusion Criteria

Consider using the clinical criteria below to help generate a list of patients diagnosed with NSCLC who may have advanced *ROS1*+ disease and be eligible for JIDEYTRO therapy.

Demographics:

- Living status: Alive
- Age: ≥18 years old

Diagnosis: Lung cancer (C34.xx)¹⁸

C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.20	Malignant neoplasm of middle lobe, unspecified bronchus or lung
C34.21	Malignant neoplasm of middle lobe, right bronchus or lung
C34.22	Malignant neoplasm of middle lobe, left bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

Continued on next page

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Suggested Inclusion Criteria (cont'd)

Consider using the clinical criteria below to help generate a list of patients diagnosed with advanced ROS1+ NSCLC who may be eligible for JIDEYTRO therapy.

Staging:

Stage III locally advanced, Stage IIIB/C, Stage IV,
OR Locally advanced or metastatic disease (TNM):

- Tumor status: T4b
- Nodal status: N1-3
- Metastatic status: M1

Biomarker (if available):

- ROS1 positive

Medications:

1. Pharmaceutical class: ROS1 kinase inhibitor

Note: Depending on how information was documented in the EHR, staging information may not always be available as structured data. Consider running the patient query and confirm the patient's staging information with a manual chart evaluation.



Instructions – Reporting Workbench:

1. Access **Reporting Workbench** (click the **Epic logo** > **Reports** > **My Reports**).
2. Navigate to the **Library** tab from the **Reports** menu.
3. Enter “**generic criteria**” or “**find patients**” in the search field and click **Search**.
4. Select the **Find My Patients – Generic Criteria** or **Oncology Generic Criteria** report and click **New Report**.
5. The **Report Settings** window will display and default to the **Criteria** tab.
6. In the **Find Criteria** search field, enter “**living**” and select **Patient: Living Status**.
7. Set the status to **Alive**.
8. In the **Find Criteria** search field, enter “**age**” and select the **Age in Years** criterion.
9. Set the age range to **greater than or equal to 18 years**.
10. In the **Find Criteria** search field, enter “**diagnosis**”.
11. Select the **Diagnosis by Code** criterion.

***Note:** Alternatively, **Diagnosis by Grouper** or **Problems by Grouper** may be leveraged if using an NSCLC or lung cancer diagnosis grouper. Ensure that the diagnoses in the grouper are appropriate for the query. If using a grouper, substitute the grouper for the diagnosis codes below.*

12. Set the **Code Set** to **ICD-10-CM**.
13. Enter the applicable lung cancer diagnosis codes (**C34.xx**).
14. If staging data is available as structured data within the EHR, add criteria to identify patients with:
 - i. Stage III disease
 - ii. Stage IIIB disease
 - iii. Stage IIIC disease
 - iv. Stage IV disease**OR**
 - v. Tumor status: **T4b**
 - vi. Nodal status: **N1–N3**
 - vii. Metastatic status: **M1**

***Note:** Availability of stage and TNM data varies by organization and oncology workflow.*

Continued on next page

Please see **JIDEYTRO Important Safety Information** on pages 2–5 and **Full Prescribing Information**.

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100 mg tablets

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Instructions – Reporting Workbench (cont'd):

15. In the **Find Criteria** search field, enter “**result**”, “**genomic**”, “**molecular**”, or another organization-specific search term to determine whether structured biomarker data are available.
16. If biomarker results are available as structured discrete data, add criteria to identify patients who are **ROS1-positive**.
Note: ROS1 biomarker results may not be available as structured EHR data and may instead reside in pathology reports, molecular testing reports, scanned documents, or external laboratory interfaces.
17. In the **Find Criteria** search field, enter “**Meds**”.
18. Select the **Meds: Current, by pharm. class** criterion or an equivalent medication criterion available at your organization.
19. Select the pharmaceutical class corresponding to **ROS1 kinase inhibitors** (naming conventions may vary depending on the medication compendium used by the organization).
Alternatively, use **Meds: Current, by exact medication** and enter the ROS1 kinase inhibitor medications used by your organization.
20. Using the **Report Logic** field, set the logic operator to:
Patient: Living Status = Alive
AND
Age in Years ≥ 18 years
AND
Lung cancer diagnosis (**C34.xx**)
AND
Stage III locally advanced disease, Stage IIIB disease, Stage IIIC disease, or Stage IV disease
OR
Tumor Status = **T4b**
Nodal Status = **N1–N3**
Metastatic Status = **M1**
AND
ROS1-positive biomarker status (if available)
AND
Current or prior ROS1 kinase inhibitor therapy

Continued on next page



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Instructions – Reporting Workbench (cont'd):

- 21.** Click the **Display** tab to select all display columns to be included in the report (search in the available columns or click + **Add** to manually add a display column). In the **Available Columns** window, consider including the following display columns, as available at your organization:
 - i. Current Medications
 - ii. Diagnosis
 - iii. Cancer Stage
 - iv. TNM Staging
 - v. Biomarker Results
 - vi. Treating Provider
 - vii. Other Desired Patient Information
 - viii. Recent Lab Results (e.g., creatine phosphokinase)
- 22.** Once an **Available Column** has been selected, click the **arrow** to move it to the **Selected Columns** window.
- 23.** In the General tab, enter the desired Report Name and a description such as:
“Adult patients with locally advanced or metastatic ROS1-positive NSCLC who have received a ROS1 kinase inhibitor and may be candidates for JIDEYTRO.”
- 24.** Click **Save and Run** to create the patient list. The report will display all patients matching the selected criteria. Results may be further manipulated if desired or exported to Excel. Complete a manual chart review of the resulting patient list to confirm diagnosis, stage, biomarker status, treatment history, and overall eligibility.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Instructions – SlicerDicer:

1. Access **SlicerDicer** (click the **Epic logo** > **Reports** > **SlicerDicer**).
2. Select the **Patients** or **Patients with Cancer** data model (the numbers in the data model box represent the base population and number of records in the data model).
3. In the right-hand column, select the desired patient base (e.g., **All Patients**).
Note: First-time users of SlicerDicer may see a tutorial prompt during initial use. Complete the tutorial and continue with the steps below.
4. In the **Search for Criteria** field, enter “**status**”.
5. Select the **Patient: Living Status** criterion and set the value to **Alive**.
6. In the **Search for Criteria** field, enter “**age**”.
7. Set the age range to **greater than or equal to 18 years**.
8. In the **Search for Criteria** field, enter “**diagnosis**”. Alternatively, use the + **Browse** button to locate the desired criterion.
9. Select the **Diagnosis** criterion.
10. Set the mode to **ICD/Grouper** and enter the applicable lung cancer diagnosis codes (**C34.xx**).
Note: If your organization has an NSCLC or lung cancer grouper available, the grouper may be used in place of individual diagnosis codes.
11. If stage data are available as structured data in your organization, search for and add criteria to identify:
 - i. Stage III locally advanced disease
 - ii. Stage IIIB disease
 - iii. Stage IIIC disease
 - iv. Stage IV disease**OR**
 - v. Tumor status: **T4b**
 - vi. Nodal status: **N1–N3**
 - vii. Metastatic status: **M1**

Note: Availability of stage and TNM data varies by organization and oncology workflow.

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Instructions – SlicerDicer (cont'd):

12. In the **Search for Criteria** field, enter “**medications**”.

13. Enter and select the desired **pharmaceutical class/subclass and/or medications** corresponding to **ROS1 kinase inhibitors**.

***Note:** Individual medications or medication groupers may be used if pharmaceutical classes or subclasses are not available.*

14. In the **Search for Criteria** field, enter “**result**”, “**genomic**”, “**molecular**”, or another organization-specific search term used to identify biomarker results.

15. If biomarker results are available as structured data, add a criterion to identify patients who are **ROS1-positive**.

***Note:** ROS1 biomarker results may not be available as structured EHR data and may instead reside in pathology reports, molecular testing reports, scanned documents, or external laboratory systems.*

16. If the filters are linked by encounter, unlink them (click the **chain icon** next to the filter criterion so it appears broken) to allow the search to be completed across encounters.

17. Click the **Detail Table** icon in the **Visual Options** section to view the query results.

18. The results can be exported to Reporting Workbench by right-clicking the results bar and selecting **Show Slice in Reporting Workbench**.

19. In Reporting Workbench, select the **Display** tab to configure display columns for the report. Search for desired display information in the **Available Columns** pane.

20. Select all desired display columns and click the **right arrow** to move them to the **Selected Columns** pane.

Continued on next page

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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Instructions – SlicerDicer (cont'd):

21. Consider including the following display columns, as available at your organization:
 - i. Current Medications
 - ii. Diagnosis
 - iii. Cancer Stage
 - iv. Tumor Status
 - v. Nodal Status
 - vi. Metastatic Status
 - vii. Biomarker Results
 - viii. Treating Provider
 - ix. Other Desired Patient Information
22. In the **Display** tab, navigate to the **Detailed Views** section and configure any additional desired information displays. Consider including current and historical medication information if available.
23. In the **General** tab, enter the desired report name and description, such as:
Adult patients with locally advanced or metastatic ROS1-positive NSCLC who have received a ROS1 kinase inhibitor and may be candidates for JIDEYTRO
24. Click **Save** and then **Run** to create the patient list. The list will display all patients meeting the selected criteria. Results can be further reviewed, filtered, exported, or shared according to organizational policies. Complete a manual chart review of the resulting patient list to confirm diagnosis, stage, biomarker status, treatment history, and overall eligibility.



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Sidekick Instructions

Sidekick is Epic's generative AI assistant that can translate plain-language questions into report queries and analyses to streamline data exploration. Depending on your organization's Epic configuration and available structured data, as well as your internal policies regarding use of AI, you can draft a prompt to generate an initial patient list. This list should be reviewed to ensure only appropriate patients are included. If you decide to use a prompt to identify potential patients, consider including the following details in the request:

- lung cancer diagnosis codes
- age
- diagnosis
- ROS1-positive gene status
- current and prior medication (including prior ROS1 kinase inhibitor medication) and dose, route, and frequency
- MRN, diagnosis stage, treating provider



IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

Facility List and Protocol Favorite Instructions

Consider making frequently used medication records and treatment plans favorites to help streamline order entry and improve workflow efficiency. Favorited items are readily accessible within search results, reducing the need to repeatedly search for the same records. The instructions below outline how to add the JIDEYTRO medication record and JIDEYTRO treatment plan to your search for easier access during patient care.

Instructions for saving JIDEYTRO to the search results

1. In a patient's chart, access **Order Entry** mode.
2. In the **Order Search** screen, select the **Facility List** tab in the upper-right corner of the order search window. The **Facility List** tab includes all medications and procedures orders that are orderable at a specific hospital or location and typically includes all Pharmacy and Therapeutics (P&T)-approved orders.
3. In the search field, enter "JIDEYTRO". All matching results will display.
***Note:** Naming conventions may vary by institution. If JIDEYTRO is not found, search using the generic name, formulary name, or other locally configured synonyms used by your organization.*

OR

1. In the **Treatment Plan** search window, search for the JIDEYTRO protocol record.
2. Click on the star next to the name of the treatment plan in the list.



Notes & Disclaimers

IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

- The user (e.g., physician, medical group, integrated delivery network) shall be solely responsible for the implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and setup (customization) for each individual EHR system vary. Nuvalent, Inc. is not responsible the implementation of any instructions provided herein. Each institution is required to update their systems in accordance with organizational requirements. The information provided here in is intended as informational only and may help in considering how and when to upload JIDEYTRO into available EHR systems
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IMPORTANT
SAFETY
INFORMATION

OVERVIEW &
LIMITATIONS

ROS1+ NSCLC

PROTOCOL
CONSIDERATIONS

PROTOCOL
INSTRUCTIONS

PATIENT LIST
CONSIDERATIONS
& INSTRUCTIONS

FACILITY LIST
& PROTOCOL
FAVORITE
INSTRUCTIONS

NOTES &
DISCLAIMERS

REFERENCES

REFERENCES:

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