GETTING STARTED WITH LARTRUVO

WHO IS LARTRUVO FOR?

LARTRUVO (olaratumab) is a prescription medicine used with a type of chemotherapy called doxorubicin to treat adult patients with soft tissue sarcoma (STS) for whom doxorubicin is appropriate and who cannot be cured with radiation or surgery.

There is an ongoing study to confirm how LARTRUVO works in combination with doxorubicin.

SELECT IMPORTANT SAFETY INFORMATION FOR LARTRUVO

- Infusion reactions related to injecting LARTRUVO have occurred. Most of these reactions happened during or after the first or second LARTRUVO infusion. Signs and symptoms of infusion reactions include flushing, shortness of breath, severe trouble breathing, or fever/chills. In severe cases, severe low blood pressure, anaphylactic shock (a severe, potentially life-threatening allergic reaction), or cardiac arrest (abrupt loss of heart function) may occur. Tell your doctor if you have any of these symptoms. Your healthcare team will monitor you for these side effects. In the case of a severe infusion reaction, your LARTRUVO treatment will have to be immediately and permanently stopped.

Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

Lartruvo™
(OLARATUMAB)
Injection 10 mg/mL

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SELECT IMPORTANT SAFETY INFORMATION FOR LARTRUVO

- LARTRUVO can harm your unborn baby. You should avoid getting pregnant, and use effective birth control while receiving LARTRUVO and for at least 3 months after stopping LARTRUVO.

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INTRODUCTION TO LARTRUVO

Living with soft tissue sarcoma can be difficult, and starting a new treatment brings lots of questions. This brochure helps explain what you can expect from treatment with LARTRUVO.

Your healthcare team may have given you a lot of new information to understand. If you have received this brochure, your doctor thinks LARTRUVO may be able to help you. If you have any questions about your treatment, be sure to talk to your doctor or nurse.

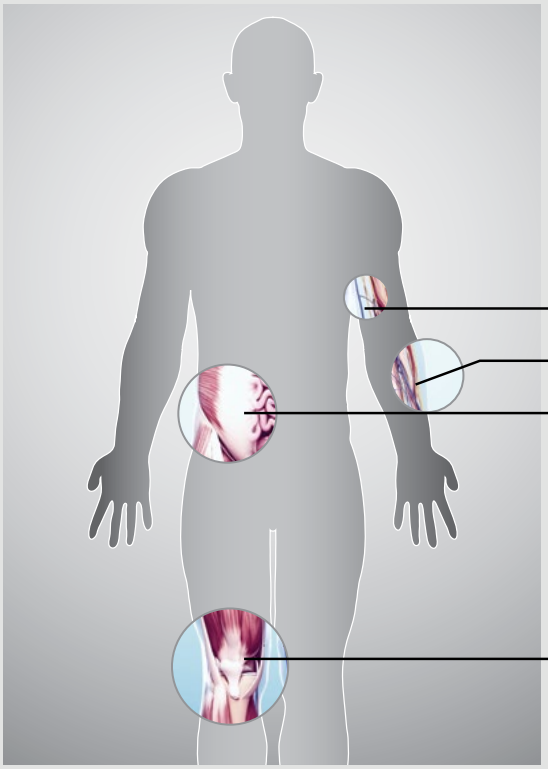
Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

ABOUT STS

WHAT IS STS?

Soft tissue sarcoma, or STS, is a cancer that begins in the soft tissues of the body. This can include the muscles, tendons, fat, blood vessels, or other supporting tissue.

SOFT TISSUE SARCOMA



There are many different kinds of STS, which are often referred to as **subtypes**. Some common subtypes are **leiomyosarcoma (LMS)** and **liposarcoma**, though there are many other types that appear and behave differently.

HOW COMMON IS STS?

Approximately 12,000 people in the U.S. will be diagnosed with STS in 2017.

Even though STS is considered a rare cancer, it is important to know that there are resources available to you. Your healthcare team can provide you with helpful materials to assist you during treatment.

Subtypes: Describes the smaller groups that a type of cancer can be divided into, based on features of the cancer cells.

Leiomyosarcoma (LMS): A subtype of STS that starts in the smooth muscle cells and is most common in the uterus, abdomen, or pelvis.

Liposarcoma: A subtype of STS that develops in the fat cells of the body.

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UNDERSTANDING LARTRUVO

WHAT TYPE OF MEDICINE IS LARTRUVO?

LARTRUVO is a monoclonal antibody, which is different from a traditional chemotherapy. Monoclonal antibodies are proteins made in the laboratory and can be used to treat some cancers. They bind to substances in the body, including both cancer and healthy cells, and can block signals that tell tumors to grow.

LARTRUVO is given with a chemotherapy called **doxorubicin**, which is an essential part of your treatment plan. Your doctor will start treatment with LARTRUVO and doxorubicin, and may adjust the medicines in your treatment plan over time.

With LARTRUVO and doxorubicin, your treatment unites an innovative therapy with an established cancer medicine.

HOW DOES LARTRUVO WORK?

Tumors can send signals throughout the body that tell cells to grow and divide. LARTRUVO works to block certain types of signals and may help slow down cancer growth.

As a monoclonal antibody, LARTRUVO can bind to healthy cells in addition to cancer cells, which may lead to serious side effects.

SELECT IMPORTANT SAFETY INFORMATION

- The most common changes to blood tests were low white blood cell count, low platelet count, high blood sugar, increased blood clotting time, low blood potassium level, and low blood phosphate level.

Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

UNDERSTANDING LARTRUVO (CONT'D)

DOES LARTRUVO WORK IN MY SUBTYPE?

LARTRUVO was studied in many different subtypes. Talk to your healthcare team if you have questions regarding your specific subtype.

WHY IS LARTRUVO RIGHT FOR ME?

LARTRUVO has been shown to be effective for adult patients with STS when used with doxorubicin.

You are taking LARTRUVO because you and your healthcare team believe it is the right choice for you.

Doxorubicin: A common cancer chemotherapy that also goes under the trade name Adriamycin®.

Adriamycin is a registered trademark of Pharmacia & Upjohn S.P.A.

WHO IS LARTRUVO FOR?

LARTRUVO (olaratumab) is a prescription medicine used with a type of chemotherapy called doxorubicin to treat adult patients with soft tissue sarcoma (STS) for whom doxorubicin is appropriate and who cannot be cured with radiation or surgery.

There is an ongoing study to confirm how LARTRUVO works in combination with doxorubicin.

SELECT IMPORTANT SAFETY INFORMATION FOR LARTRUVO

- The most common side effects reported in patients treated with LARTRUVO when given in combination with doxorubicin were nausea; tiredness or weakness; pain in the muscles, joints, and bones; sores and swelling of the mouth and digestive tract; hair loss; vomiting; diarrhea; decreased appetite; stomach pain; weakness, numbness, or pain in the hands and feet; and headache.

Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

HOW LARTRUVO IS GIVEN

HOW WILL I RECEIVE LARTRUVO?

LARTRUVO is given by **intravenous (IV) infusion** in a doctor's office, hospital, or infusion center.

HOW OFTEN IS LARTRUVO GIVEN?

Your treatment will be scheduled in cycles. There are 3 weeks (21 days) in each treatment cycle. You will be given treatment on Days 1 and 8 of each **3-week (21-day) cycle.**

TREATMENT SCHEDULE

2 DAYS OF ACTIVE TREATMENT PER 21-DAY CYCLE

ON THE 1ST DAY OF TREATMENT, YOU WILL RECEIVE BOTH LARTRUVO AND DOXORUBICIN.

ON THE 8TH DAY, YOU WILL RECEIVE LARTRUVO ONLY.

Intravenous (IV) infusion: An infusion of liquid that is delivered through a needle directly into a vein.

3-week (21-day) cycle: This treatment plan is based on a 21-day calendar, or "cycle." After 21 days, the first cycle is complete, and your next treatment cycle begins again on Day 1.

Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

HOW LONG WILL I RECEIVE TREATMENT?

Your healthcare team will decide the appropriate length of treatment.

Your treatment plan may include LARTRUVO and doxorubicin for up to 8 cycles of treatment. After the 8th cycle, your healthcare team may decide to continue treatment with LARTRUVO alone. This will depend on the progress of your disease and how your body responds to therapy.

If your medicine changes, it may also affect the side effects you experience.

If your disease progresses at any point during treatment, your doctor will end treatment with LARTRUVO and discuss with you the appropriate next steps on your treatment path.

SELECT IMPORTANT SAFETY INFORMATION FOR LARTRUVO

- The most common changes to blood tests were low white blood cell count, low platelet count, high blood sugar, increased blood clotting time, low blood potassium level, and low blood phosphate level.

HOW LONG DOES EACH VISIT TAKE?

Each LARTRUVO infusion will last approximately 60 minutes. On the first day of the cycle, your LARTRUVO dose will be given before doxorubicin.

You will receive medications before your LARTRUVO infusion. This will help prepare your body for treatment with LARTRUVO.

FIRST 8 CYCLES OF TREATMENT

Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

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LILLY PATIENTONE MAY HELP WITH THE COSTS OF MEDICATION

Lilly PatientOne: Reimbursement Support

Lilly PatientOne strives to offer reliable and individualized treatment support for eligible patients prescribed a Lilly Oncology product whether they are insured, underinsured, or simply uninsured. For those who qualify, we can help in the following ways:

- Evaluate financial assistance options including co-pay programs and independent patient assistance foundations
- Provide reimbursement assistance (benefits investigation, prior authorization, assessment of other funding options)
- Assist with denied claim appeals

For eligibility requirements, or for more information, call **1-866-4PatOne** (1-866-472-8663) Monday–Friday, 9 AM–7 PM ET or visit **www.LillyPatientOne.com**.

SELECT IMPORTANT SAFETY INFORMATION FOR LARTRUVO

- Infusion reactions related to injecting LARTRUVO have occurred. Most of these reactions happened during or after the first or second LARTRUVO infusion. Signs and symptoms of infusion reactions include flushing, shortness of breath, severe trouble breathing, or fever/chills. In severe cases, severe low blood pressure, anaphylactic shock (a severe, potentially life-threatening allergic reaction), or cardiac arrest (abrupt loss of heart function) may occur. Tell your doctor if you have any of these symptoms. Your healthcare team will monitor you for these side effects. In the case of a severe infusion reaction, your LARTRUVO treatment will have to be immediately and permanently stopped.

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COMMON SIDE EFFECTS OF LARTRUVO

If you experience serious side effects at any point during treatment, your doctor may end, delay, or modify your treatment plan.

This is not a full list of side effects. For additional safety information, please see the accompanying full Prescribing Information.

THE MOST COMMON SIDE EFFECTS OF LARTRUVO INCLUDE:

- Nausea
- Tiredness or weakness
- Pain in the muscles, joints, and bones
- Sores and swelling of the mouth and digestive tract
- Hair loss
- Vomiting
- Diarrhea
- Decreased appetite
- Stomach pain
- Weakness, numbness, or pain in the hands and feet
- Headache

Talk to your healthcare team if you notice any side effects, including any signs of fever.

You are encouraged to report negative side effects of prescription drugs to the FDA. **Visit www.fda.gov/safety/medwatch or call 1-800-FDA-1088.**

HAVE A QUESTION?

If you have any questions about your treatment, give us a call at **The Lilly Answer Center: 1-800-LILLYRX** (1-800-545-5979).

By calling this number, you'll have access to a healthcare professional who can provide additional information. The toll-free number is a service provided by Eli Lilly and Company and is not intended to replace the advice of your healthcare team.

If you have a medical emergency, immediately call 911 (or your local emergency services number).

If you are seeking medical advice, direct those questions to your healthcare team. Your own healthcare team is the best source of information regarding your health.

Please see Important Safety Information and full Prescribing Information for additional information about LARTRUVO.

IMPORTANT SAFETY INFORMATION FOR LARTRUVO

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IMPORTANT SAFETY INFORMATION FOR LARTRUVO

What is the most important information I should know about LARTRUVO?

- Infusion reactions related to injecting LARTRUVO have occurred. Most of these reactions happened during or after the first or second LARTRUVO infusion. Signs and symptoms of infusion reactions include flushing, shortness of breath, severe trouble breathing, or fever/chills. In severe cases, severe low blood pressure, anaphylactic shock (a severe, potentially life-threatening allergic reaction), or cardiac arrest (abrupt loss of heart function) may occur. Tell your doctor if you have any of these symptoms. Your healthcare team will monitor you for these side effects. In the case of a severe infusion reaction, your LARTRUVO treatment will have to be immediately and permanently stopped.
- LARTRUVO can harm your unborn baby. You should avoid getting pregnant, and use effective birth control while receiving LARTRUVO and for at least 3 months after stopping LARTRUVO.

What are the most common side effects of LARTRUVO?

- The most common side effects reported in patients treated with LARTRUVO when given in combination with doxorubicin were nausea; tiredness or weakness; pain in the muscles, joints, and bones; sores and swelling of the mouth and digestive tract; hair loss; vomiting; diarrhea; decreased appetite; stomach pain; weakness, numbness, or pain in the hands and feet; and headache.
- The most common changes to blood tests were low white blood cell count, low platelet count, high blood sugar, increased blood clotting time, low blood potassium level, and low blood phosphate level.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/safety/medwatch or call 1-800-FDA-1088.

What should I tell my doctor before receiving treatment with LARTRUVO?

Before you receive LARTRUVO, tell your doctor if you:

- Are pregnant or may be pregnant. If you become pregnant during treatment, discuss this with your doctor.
- Are breastfeeding: your doctor will tell you not to breastfeed during LARTRUVO treatment and for at least 3 months after stopping LARTRUVO.

Tell your doctor about all the medications you are taking, including prescription and over-the-counter medications.

LARTRUVO is available by prescription only.

Please see full Prescribing Information for additional information about LARTRUVO.

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HELPFUL RESOURCES

Feel free to explore these advocacy organizations and educational materials for additional information and resources.

National Cancer Institute—Adult Soft Tissue Sarcoma
www.cancer.gov/types/soft-tissue-sarcoma/patient/adult-soft-tissue-treatment-pdq

American Cancer Society
www.cancer.org/cancer/soft-tissue-sarcoma

Sarcoma Alliance
www.sarcomaalliance.org

Sarcoma Foundation of America
www.curesarcoma.org

Cancer Treatment Centers of America
www.cancercenter.com/soft-tissue-sarcoma

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Trial 1 demonstrated a significant improvement in overall survival. The efficacy results are summarized in Table 3 and Figure 1.

Table 3: Efficacy Results in Trial 1

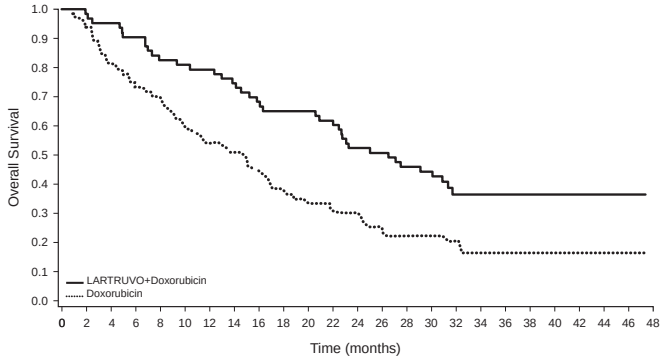
	LARTRUVO + Doxorubicin N=66	Doxorubicin N=67
Overall Survival		
Number of deaths (%)	39 (59%)	52 (78%)
Median, months (95% CI)	26.5 (20.9, 31.7)	14.7 (9.2, 17.1)
Hazard Ratio (95% CI)[a]	0.52 (0.34, 0.79)	
p-value	p<0.05	
Progression-Free Survival[b]		
Number of events (%)	37 (56%)	34 (51%)
Median, months (95% CI)	8.2 (5.5, 9.8)	4.4 (3.1, 7.4)
Hazard Ratio (95% CI)[a]	0.74 (0.46, 1.19)	
Objective Response Rate (CR + PR)[b]		
(95% CI)	18.2% (9.8, 29.6)	7.5% (2.5, 16.6)
CR, n (%)	3 (4.5%)	1 (1.5%)
PR, n (%)	9 (13.6%)	4 (6%)

Abbreviations: CI = confidence interval, CR = complete response, PR = partial response

[a] Unstratified Cox model.

[b] Based on independent review.

Figure 1: Kaplan-Meier Curves of Overall Survival



Number at Risk

LARTRUVO+Doxorubicin	66	62	60	57	52	51	50	47	43	41	41	39	33	32	29	26	16	16	15	8	3	3	1	1	0
Doxorubicin	67	61	51	46	43	37	34	32	28	23	21	19	19	15	13	13	10	7	6	6	5	3	2	1	0

16 HOW SUPPLIED/STORAGE AND HANDLING

LARTRUVO is supplied in single-dose vials as a sterile, preservative-free, clear to slightly opalescent and colorless to slightly yellow solution.

NDC 0002-7190-01
190 mg/19 mL (10 mg/mL) single-dose vial, individually packaged in a carton
NDC 0002-8926-01
500 mg/50 mL (10 mg/mL) single-dose vial, individually packaged in a carton

Store vials in a refrigerator at 2°C to 8°C (36°F to 46°F) until time of use. Keep the vial in the outer carton to protect from light. DO NOT FREEZE OR SHAKE the vial.

17 PATIENT COUNSELING INFORMATION

Infusion-Related Reactions

Advise patients to report signs and symptoms of infusion reactions [see Dosage and Administration (2.2) and Warnings and Precautions (5.1)].

Embryo-Fetal Toxicity

Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential of the potential risk to the fetus, to use effective contraception during treatment with LARTRUVO and for 3 months after the last dose, and to inform their healthcare provider of a known or suspected pregnancy [see Use in Specific Populations (8.1, 8.3)].

Lactation

Advise patients not to breastfeed during treatment with LARTRUVO and for 3 months after the last dose [see Use in Specific Populations (8.2)].

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