

Soft Tissue Sarcoma™

U P D A T E

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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Soft Tissue Sarcoma™

U P D A T E

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Any procedures, medications or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information and comparison with recommendations of other authorities.

OVERVIEW OF ACTIVITY

Sarcomas constitute a heterogeneous group of rare solid tumors of mesenchymal origin with distinct clinical and pathologic features. More than 50 different subtypes of soft tissue sarcoma (STS) exist in a variety of anatomic locations. Because of this heterogeneity and the historical lack of effective systemic therapeutic options, clinical decision-making for patients with STS has often been made on a case-by-case basis. However, significant research strides made during the past few years have led to the approval of new treatments for the disease in addition to the identification of a number of other novel agents demonstrating great promise. Featuring information on the latest clinical and research developments along with expert perspectives, this CME activity is designed to assist medical oncologists with the formulation of up-to-date clinical management strategies for the care of patients with STS.

LEARNING OBJECTIVES

- Recognize the importance of multidisciplinary collaboration in the diagnosis and management of STS, and use this information to guide therapeutic decision-making.
- Appreciate the recent FDA approvals of trabectedin, eribulin and olaratumab, and discern how these agents can be integrated into the clinical algorithm for patients with STS.
- Appraise available efficacy data with pazopanib for patients with advanced STS, and assess how this agent can be optimally incorporated into current clinical practice.
- Evaluate the role of neoadjuvant and adjuvant chemotherapy in the clinical management of STS.
- Explore emerging data with immune checkpoint inhibitors, and use this information to counsel appropriate individuals regarding potential participation in ongoing trials.

ACCREDITATION STATEMENT

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Penn State College of Medicine and Research To Practice. Penn State College of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

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CME INFORMATION

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Van Tine** — Advisory Committee: Caris Life Sciences, EMD Serono Inc, GlaxoSmithKline, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company, Lilly, Novartis Pharmaceuticals Corporation; Contracted Research: Eisai Inc, Merck, Pfizer Inc; Paid Research: Eisai Inc, Merck; Speakers Bureau: Caris Life Sciences, GlaxoSmithKline, Novartis Pharmaceuticals Corporation. **Dr Pollack** — Advisory Committee: Amgen Inc, Lilly, Nektar; Consulting Agreements: Amgen Inc, Eisai Inc, Lilly; Contracted Research: EMD Serono Inc, Immune Design, Lilly, Merck.

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Interview with Brian A Van Tine, MD, PhD

Tracks 1-20

- | | | | |
|-----------------|--|-----------------|--|
| Track 1 | Incidence and classification of sarcomas | Track 12 | Indications for the use of olaratumab in patients with STS |
| Track 2 | Molecular biology of soft tissue sarcomas (STS) | Track 13 | Case discussion: A 57-year-old man with retroperitoneal leiomyosarcoma and multiple lung nodules receives olaratumab and doxorubicin on a clinical trial |
| Track 3 | Classification of STS | Track 14 | Activity and side-effect profiles of olaratumab and trabectedin |
| Track 4 | Use of the recently FDA-approved platelet-derived growth factor receptor alpha (PDGFR α) monoclonal antibody olaratumab in combination with doxorubicin as front-line therapy for patients with advanced STS | Track 15 | Case discussion: A 57-year-old man with myxoid liposarcoma and lung metastases receives eribulin after disease progression on doxorubicin and trabectedin |
| Track 5 | Mechanism of action and tolerability of trabectedin for liposarcomas and leiomyosarcomas | Track 16 | Investigation of immune checkpoint inhibitors for patients with STS |
| Track 6 | ET743-SAR-3007: Progression-free survival benefit with trabectedin versus dacarbazine for metastatic liposarcoma or leiomyosarcoma after disease progression on conventional chemotherapy | Track 17 | SARC 028: A Phase II study of the anti-PD-1 antibody pembrolizumab in patients with advanced sarcoma |
| Track 7 | Improvement in overall survival with eribulin versus dacarbazine in previously treated advanced liposarcoma or leiomyosarcoma | Track 18 | Case discussion: A 37-year-old man with a 15-cm synovial sarcoma of the left leg achieves a good response to adjuvant doxorubicin and ifosfamide |
| Track 8 | Results of the Phase II REGOSARC trial: Efficacy and safety of regorafenib in nonadipocytic STS | Track 19 | Second opinion: A 54-year-old woman with a 6-cm primary uterine leiomyosarcoma penetrating the uterine wall — Recommendation for adjuvant chemotherapy |
| Track 9 | Clinical experience with pazopanib for STS | Track 20 | Case discussion: A 62-year-old woman with a uterine leiomyosarcoma receives pseudoadjuvant chemotherapy for a single lung metastasis |
| Track 10 | Anaphylactic reactions associated with olaratumab | | |
| Track 11 | Overall survival benefit in the randomized Phase II JGDG trial with the addition of olaratumab to doxorubicin for patients with STS | | |

Interview with Seth M Pollack, MD

Tracks 1-19

- | | | | |
|----------------|--|----------------|--|
| Track 1 | Classification and management of sarcomas | Track 6 | Role of adjuvant chemotherapy for patients with STS |
| Track 2 | Etiology and risk factors for the development of STS | Track 7 | Results of the EORTC 62931 study evaluating the efficacy of adjuvant chemotherapy for resected STS |
| Track 3 | Indications for performing a biopsy in patients with STS | Track 8 | Case discussion: A 60-year-old man with a 10-cm intermediate-grade synovial sarcoma of the inferior vena cava extending to the heart has a short-duration response to adjuvant chemotherapy |
| Track 4 | Implications of grade and stage on prognosis of STS | | |
| Track 5 | Case discussion: A 62-year-old woman with a 7.3-cm high-grade synovial sarcoma and a greater than 40% chance of recurrence receives adjuvant chemotherapy | | |

Interview with Dr Pollack (continued)

- Track 9** **Case discussion:** A 28-year-old man with intermediate-grade myxoid/round cell liposarcoma in the thigh achieves a good response to neoadjuvant chemoradiation therapy
- Track 10** Improvement in overall survival with neoadjuvant chemotherapy for high-risk STS
- Track 11** **Case discussion:** A 55-year-old woman with Li-Fraumeni syndrome and a history of sarcoma is diagnosed with a high-grade, unresectable liposarcoma in the mediastinum
- Track 12** Integration of trabectedin and eribulin into the clinical management of leiomyosarcoma and liposarcoma
- Track 13** **Case discussion:** A 65-year-old woman diagnosed with a myxoid/round cell liposarcoma and a fused CHOP translocation receives trabectedin for recurrent disease
- Track 14** FDA approval of trabectedin for patients with unresectable or metastatic liposarcoma or leiomyosarcoma that has progressed after an anthracycline regimen
- Track 15** Improvement in progression-free survival with pazopanib for STS
- Track 16** Mechanism of action, efficacy and tolerability of olaratumab
- Track 17** Choosing between the addition of olaratumab versus ifosfamide to doxorubicin as front-line therapy for advanced STS
- Track 18** **Case discussion:** A patient in his late fifties with a high-grade leiomyosarcoma that is diagnosed after a car accident is enrolled on a clinical trial of olaratumab and doxorubicin
- Track 19** Activity of immune checkpoint inhibitors for STS

Related Video Program

Visit www.ResearchToPractice.com/STSU117/Video to view video highlights of the interviews with (from left) Drs Van Tine and Pollack by Dr Love and earn additional *AMA PRA Category 1 Credit™*.



Topics covered include:

- ▶ Classification, incidence and management of sarcomas
- ▶ Role of neoadjuvant and adjuvant chemotherapy in the clinical management of soft tissue sarcoma (STS)
- ▶ Recent FDA approval of olaratumab in combination with doxorubicin and integration into the treatment algorithm for advanced STS
- ▶ Integration of the recently FDA approved agents trabectedin and eribulin into the treatment algorithm for metastatic liposarcoma and/or leiomyosarcoma
- ▶ Role of tyrosine kinase inhibitors and immune checkpoint inhibitors in STS

SELECT PUBLICATIONS

- Biermann JS et al. **Bone cancer.** *J Natl Compr Canc Netw* 2013;11(6):688-723.
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- Demetri GD et al. **Efficacy and safety of trabectedin or dacarbazine for metastatic liposarcoma or leiomyosarcoma after failure of conventional chemotherapy: Results of a phase III randomized multicenter clinical trial.** *J Clin Oncol* 2016;34(8):786-93.
- D'Incalci M, Galmarini CM. **A review of trabectedin (ET-743): A unique mechanism of action.** *Mol Cancer Ther* 2010;9(8):2157-63.
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- Harris SJ et al. **Metastatic soft tissue sarcoma, an analysis of systemic therapy and impact on survival.** *Proc ASCO* 2015;**Abstract 10545.**
- Jones RL et al. **Differential sensitivity of liposarcoma subtypes to chemotherapy.** *Eur J Cancer* 2005;41(18):2853-60.
- Judson I et al. **Doxorubicin alone versus intensified doxorubicin plus ifosfamide for first-line treatment of advanced or metastatic soft-tissue sarcoma: A randomised controlled phase 3 trial.** *Lancet Oncol* 2014;15(4):415-23.
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- Penel N et al. **Regorafenib (RE) in liposarcomas (LIPO), leiomyosarcomas (LMS), synovial sarcomas (SYN), and other types of soft-tissue sarcomas (OTS): Results of an international, double-blind, randomized, placebo (PL) controlled phase II trial.** *Proc ASCO* 2016;**Abstract 11003.**
- Pervaiz N et al. **A systematic meta-analysis of randomized controlled trials of adjuvant chemotherapy for localized resectable soft-tissue sarcoma.** *Cancer* 2008;113(3):573-81.
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- Stubbe F et al. **Effective local control of advanced soft tissue sarcoma with neoadjuvant chemoradiotherapy and surgery: A single institutional experience.** *Cancer Radiother* 2016;20(1):6-13.
- Tap WD et al. **Olaratumab and doxorubicin versus doxorubicin alone for treatment of soft-tissue sarcoma: An open-label phase 1b and randomised phase 2 trial.** *Lancet* 2016;388(10043):488-97.
- Tawbi A et al. **Safety and efficacy of PD-1 blockade using pembrolizumab in patients with advanced soft tissue (STS) and bone sarcomas (BS): Results of SARC028 — A multicenter phase II study.** *Proc ASCO* 2016;**Abstract 11006.**
- Van der Graaf WT et al. **Pazopanib for metastatic soft-tissue sarcoma (PALETTE): A randomised, double-blind, placebo-controlled phase 3 trial.** *Lancet* 2012;379(9829):1879-86.
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- Woll PJ et al. **Adjuvant chemotherapy with doxorubicin, ifosfamide, and lenograstim for resected soft-tissue sarcoma (EORTC 62931): A multicentre randomised controlled trial.** *Lancet Oncol* 2012;13(10):1045-54.

QUESTIONS (PLEASE CIRCLE ANSWER):

- The results of the ET743-SAR-3007 trial comparing trabectedin to dacarbazine in patients with previously treated advanced liposarcoma or leiomyosarcoma reported a statistically significant improvement in _____ with trabectedin.
 - Progression-free survival
 - Overall survival
 - Both a and b
- A Phase III trial of eribulin versus dacarbazine in previously treated advanced or metastatic STS demonstrated that the benefit in overall survival with eribulin was greater in patients with which histology?
 - Liposarcoma
 - Leiomyosarcoma
- Which of the following agents are FDA approved for patients with liposarcomas?
 - Eribulin
 - Trabectedin
 - Regorafenib
 - All of the above
 - Both a and b
- The randomized Phase II JGDG trial investigating the addition of olaratumab to doxorubicin versus doxorubicin alone for patients with advanced or metastatic STS demonstrated a statistically significant improvement in _____ with the combination.
 - Overall survival
 - Progression-free survival
 - Both a and b
- Side effects associated with trabectedin include _____.
 - Liver function abnormalities
 - Myelosuppression
 - Rhabdomyolysis
 - All of the above
- The EORTC 62931 study evaluating the efficacy of adjuvant chemotherapy for patients with high-risk STS reported an improvement in overall and disease-free survival with adjuvant chemotherapy.
 - True
 - False
- The Phase II REGOSARC trial assessing the efficacy of regorafenib versus placebo for patients with previously treated advanced STS demonstrated a benefit in progression-free survival in which group of patients?
 - Patients with liposarcoma
 - Patients with nonadipocytic STS
 - Both a and b
- Olaratumab, an agent recently approved for STS, is a(n) _____.
 - Immune checkpoint inhibitor
 - Tyrosine kinase inhibitor
 - Monoclonal antibody to PDGFR α
- Results from the Phase II SARCO28 trial investigating the safety and efficacy of _____ in patients with advanced sarcomas demonstrated promising activity in patients with undifferentiated pleomorphic sarcoma and liposarcoma.
 - Pembrolizumab
 - Nivolumab
 - Nivolumab with ipilimumab
- A recent study by Gronchi and colleagues evaluating the efficacy of neoadjuvant chemotherapy for patients with high-risk STS reported a benefit in overall survival in patients randomly assigned to the epirubicin/ifosfamide arm versus those who received a histologically tailored regimen.
 - True
 - False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Soft Tissue Sarcoma Update — Volume 1, Issue 1

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal
	BEFORE		AFTER	
Results of the Phase II JGDG trial: Survival advantage with the addition of olaratumab to doxorubicin for patients with advanced STS	4	3	2	1
Efficacy and tolerability of trabectedin for patients with liposarcomas and leiomyosarcomas	4	3	2	1
Overall survival benefit with eribulin versus dacarbazine in previously treated advanced or metastatic liposarcomas	4	3	2	1
Early efficacy data with immune checkpoint inhibitors for patients with advanced sarcomas	4	3	2	1
Results of the EORTC 62931 study evaluating the efficacy of adjuvant chemotherapy for resected STS	4	3	2	1

Practice Setting:

- Academic center/medical school
 Community cancer center/hospital
 Group practice
 Solo practice
 Government (eg, VA)
 Other (please specify).....

How many new patients with STS do you see per year? patients

Was the activity evidence based, fair, balanced and free from commercial bias?

- Yes
 No
 If no, please explain:

Please identify how you will change your practice as a result of completing this activity (select all that apply).

- This activity validated my current practice
 Create/revise protocols, policies and/or procedures
 Change the management and/or treatment of my patients
 Other (please explain):

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

.....

The content of this activity matched my current (or potential) scope of practice.

- Yes
 No
 If no, please explain:

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Recognize the importance of multidisciplinary collaboration in the diagnosis and management of STS, and use this information to guide therapeutic decision-making. . . . 4 3 2 1 N/M N/A
- Appreciate the recent FDA approvals of trabectedin, eribulin and olaratumab, and discern how these agents can be integrated into the clinical algorithm for patients with STS. 4 3 2 1 N/M N/A
- Appraise available efficacy data with pazopanib for patients with advanced STS, and assess how this agent can be optimally incorporated into current clinical practice. 4 3 2 1 N/M N/A
- Evaluate the role of neoadjuvant and adjuvant chemotherapy in the clinical management of STS. 4 3 2 1 N/M N/A
- Explore emerging data with immune checkpoint inhibitors, and use this information to counsel appropriate individuals regarding potential participation in ongoing trials. . . . 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

Would you recommend this activity to a colleague?

Yes No

If no, please explain:

Additional comments about this activity:

PART 2 — Please tell us about the faculty and editor for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter				Effectiveness as an educator			
Brian A Van Tine, MD, PhD	4	3	2	1	4	3	2	1
Seth M Pollack, MD	4	3	2	1	4	3	2	1
Editor	Knowledge of subject matter				Effectiveness as an educator			
Neil Love, MD	4	3	2	1	4	3	2	1

Please recommend additional faculty for future activities:

Other comments about the faculty and editor for this activity:

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Signature: Date:

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Soft Tissue Sarcoma™

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