Novel Systemic Therapies & Immuno-Oncology

(P 448) DISEASE FREE SURVIVAL (DFS) IN PATIENTS WITH RESECTABLE SOFT TISSUE SARCOMA (STS) FROM EFTISARC-NEO PHASE II TRIAL OF NEOADJUVANT EFTILAGIMOD ALFA (EFTI), PEMBROLIZUMAB AND RADIOTHERAPY (RTH)

Author(s)



Pawel Sobczuk, MD PhD (he/him/his)

Postdoctoral Fellow
Vall d'Hebron Institute of Oncology
Barcelona, Catalonia, Spain

Co-Author(s)

AS

Anna Szumera-Cieckiewicz, MD, PhD

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

PR

Pawel Rogala, MD, PhD

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

AW

Aleksandra Wisniewska, MSc

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

MW

Michal Wagrodzki, MD, PhD

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

AM

Anna Mariuk-jarema, MD

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland



Paulina Jagodzinska-Mucha, MD, PhD

doctor
Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

TS

Tomasz Switaj, MD PhD

Maria Sklodowska-Curie National Research Institute of Oncology, Warsaw, Poland
Warsaw, Mazowieckie, Poland

PT

Paweł Teterycz, MD, PhD

Medical oncologist
Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

AB

Aneta Borkowska, MD PhD

Maria Sklodowska-Curie National Research Institute of Oncology, Warsaw, Poland
Warsaw, Mazowieckie, Poland

KZ

Konrad Zaborowski, MD

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

Marcin Zdzienicki, MD PhD

MZ

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland



Joanna Placzke, MD (she/her/hers)

medical oncologist
Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

PC

Patrycja Castaneda-Wysocka

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland



Anna M. Terlecka, MD (she/her/hers)

Oncology Resident
Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland



Piotr Rutkowski, MD, PhD

Surgical oncologist
Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

KK

Katarzyna Kozak, MD, PhD

Maria Sklodowska-Curie National Research Institute of Oncology
Warsaw, Mazowieckie, Poland

Objective: As previously reported, the EFTISARC-NEO trial has met its primary endpoint, demonstrating improved pathologic response (increased hyalinization and fibrosis) to the combination of neoadjuvant RTH and immunotherapy in patients with STS. Here, we report interim results for the secondary endpoints and clinicopathological correlates.

Methods: Patients (pts) with G2/3, stage III STS of extremities or trunk received efti 30 mg sc Q2W (5x) and pembrolizumab 200

mg iv Q3W (3x) with concurrent RTH (25x2Gy), followed by surgery. Survival outcomes were defined from the date of surgery to any kind of recurrence (DFS), local recurrence (LRFS), or distant metastases (DMFS). Presence of tertiary lymphoid structures (TLS) and CD3+ tumor-infiltrating lymphocytes (TILs) were assessed by immunohistochemistry in the surgical specimen, while expression of LAG-3, PD-L1 and TIGIT was assessed in pre-treatment biopsy. Data cut-off was 30/04/ 2026.

Results: From 07/2023 to 01/2025, 40 pts were enrolled and 38 pts underwent surgery and were evaluated. With a median follow-up of 19.1 months, 8 pts experienced disease recurrence (2 local and 6 distant). 12-month DFS, LRFS, and DMFS rates were 81.1% (95%CI 69.5-94.8), 94.1% (95%CI 86.4-100.0), and 86.2% (95%CI 75.7-98.2), respectively.
No differences in DFS were observed across tumor grade, stage, or subtype.
Exploratory analyses demonstrated presence of TLS in 42.8% (15/35) pts, including immature TLS in 22.8% (8/35). Median number of TILs was 370/mm2 (IQR 215-665). Pts with post-treatment TILs >310/mm2 showed a trend towards better 12-month DFS (95% vs 60%; HR 0.09 (95%CI 0.01-0.72, p 0.023). Hyalinization and fibrosis >52% were also correlated with better DFS (12-month DFS 93.8% vs 71.4%; HR 0.18 (95%CI 0.02-1.43, p=0.066). Presence of TLS. and expression of PD-L1, LAG-3, and TIGIT in the pre-treatment biopsies did not correlate with treatment outcomes.

Conclusion: Efti plus pembrolizumab on top of standard RTH as neoadjuvant therapy showed promising preliminary long-term outcomes warranting registrational relevant trials in pts with STS. High TIL infiltration and fibrosis emerged as potential prognostic factors.

Disclosure(s):

Pawel Sobczuk, MD PhD: No relevant disclosure to display

Joanna Placzke, MD: No financial relationships to disclose

Anna M. Terlecka, MD: No relevant disclosure to display