3788eP

Health-related quality of life (HRQoL) during neoadjuvant treatment with eftilagimod alfa, pembrolizumab and radiotherapy in patients with soft tissue sarcoma (STS) – results from EFTISARC-NEO trial

Maria Sklodowska-Curie National Research Institute of Oncology

Paweł Teterycz[1,2], Anna Terlecka[1], Paweł Rogala[1], Anna Mariuk-Jarema[1], Paulina Jagodzińska-Mucha[1], Tomasz Świtaj[1], Joanna Placzke[1], Aneta Borkowska[1], Konrad Zaborowski[1], Marcin Zdzienicki[1], Michał Wagrodzki[3], Anna Szumera-Cieckiewicz[3], Patricia Castaneda-Wysocka[4], Piotr Rutkowski[1], Paweł Sobczuk[1], Katarzyna Kozak[1,5]

1. Department of Soft Tissue, Bone/Sarcoma and Melanoma, *Maria Sklodowska-Curie National Research Institute of Oncology , Warsaw, PL* 2. Digital Medicine Center, *Maria Sklodowska-Curie National Research Institute of Oncology , Warsaw, PL* 3. Department of Pathology and Laboratory Diagnostics, *Maria Sklodowska-Curie National Research Institute of Oncology , Warsaw, PL* , *4.* Department of Radiology, *Maria Sklodowska-Curie National Research Institute of Oncology , Warsaw, PL 5. Early Phase Clinical Trials Unit, Maria Sklodowska-Curie National Research Institute of Oncology ,Warsaw, PL*

INTRODUCTION

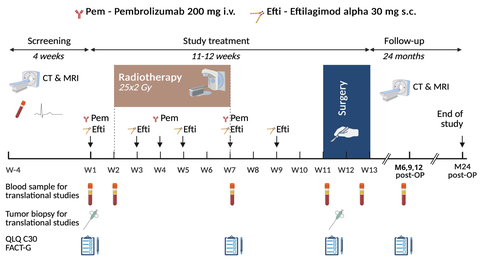
The phase II EFTISARC-NEO trial (NCT06128863; EudraCT 2022-003845-36) (Fig. 1) previously demonstrated increased histologic hyalinization/fibrosis following neoadjuvant eftilagimod alfa, pembrolizumab, and radiotherapy in patients with resectable soft tissue sarcoma (STS). This analysis reports the secondary patient-reported outcomes (PROs) from this cohort.

METHODS

Between July 2023 and January 2025, 40 patients were enrolled. PROs were assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) at baseline, every 6 weeks during treatment, and every 12 weeks post-treatment.

The results were analyzed using mixed models for repeated measures and a minimal important difference of 5 points was selected.

Figure 1. EFTISARC-NEO study plan



RESULTS

Figure 2. Raw mean scores for summary score and each scale of EORTC QLQ-C30

Points represent mean scores with 95% CI bounds. Grey band indicates ±5 point Minimal Important Difference (MID) from baseline. Left-hand side plots show functional scales while right hand side plots – symptoms scales and single item symptom scores.

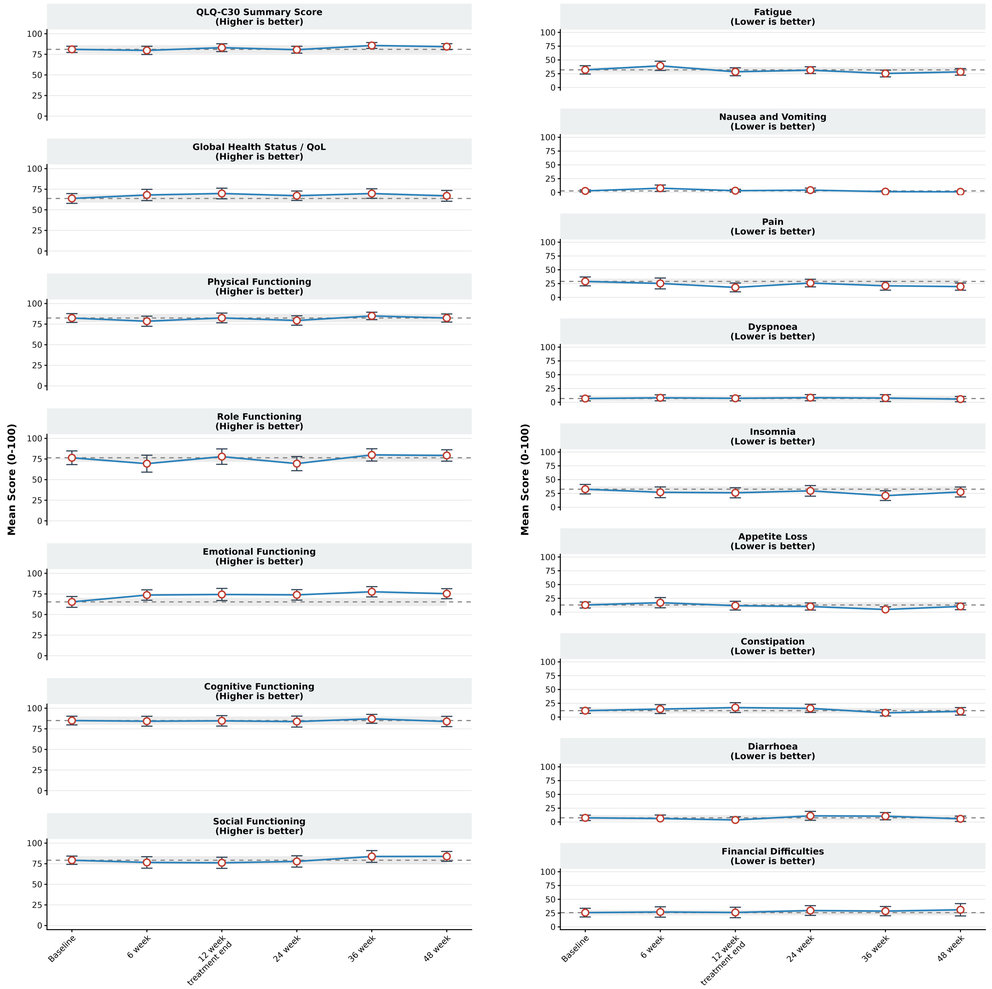
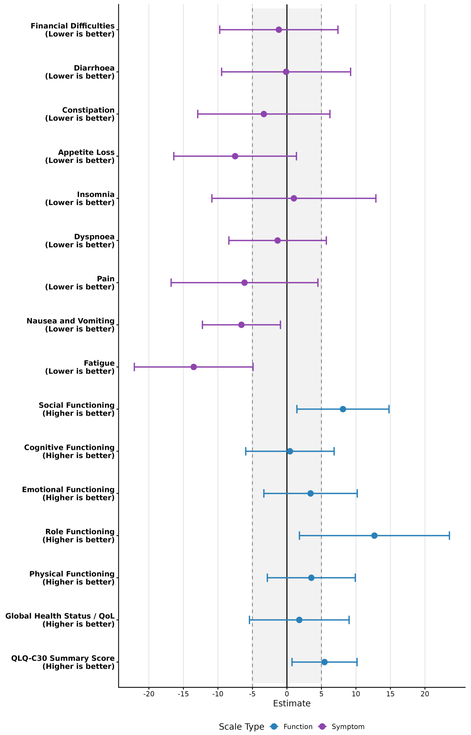


Figure 3. Forest plot

Model-Estimated Change from Baseline to End of Therapy Results from mixed models for repeated measures. Grey band indicates ±5 point Minimal Important Difference.



Patients experienced no significant deterioration in any of the measured scales throughout treatment (Fig. 2). **A significant improvement in the role and social functioning was noted after the end of therapy** (by +12.7 95% CI: 2.31-23.09, p = 0.02 and +8.1 95% CI: 1.63-14.56, p = 0.02 respectively).

Reported **fatigue was significantly lower** since the introduction of the therapy (by up to 14.2 95% CI: 6.16-22.23, p = 0.001, Fig. 3). While the General Health Status remained stable during treatment and observation period, the QLQ-30 summary score improved after completion of treatment (by 6.0 points 95% CI: 1.80-10.19, p = 0.008).

CONCLUSIONS

Neoadjuvant eftilagimod alfa combined with pembrolizumab and radiotherapy is well tolerated in patients with resectable STS, demonstrating **no significant detriment to overall QoL during treatment**. Furthermore, the therapy provides **clinically meaningful postoperative improvements in variety of key health-related quality of life parameters**, further supporting the clinical viability of this multimodal regimen.

DISCLOSURES

Paweł Teterycz: Speaker honoraria – BMS, MSD, Novartis, Pierre Fabre; travel grants – MSD, Novartis, Pierre Fabre; ; Pawel Rogala: Speaker honoraria – BMS, MSD, Novartis, Pierre Fabre, Medison, Sanofi; travel grants – MSD, Pierre Fabre Tomasz Świtaj: Speaker honoraria – BMS, MSD, Novartis, Pierre Fabre, Medison, Sanofi; travel grants – MSD, Pierre Fabre; AT, AB, KZ, SK, MW, PW-C, MZ, AS-C declare no conflicts of interests; Piotr Rutkowski: Speaker honoraria – BMS, Merck, MSD, Novartis, Pierre Fabre, Sanofi; advisory board – Blueprint; Pawel Sobczuk: speaker honoraria – BMS, Swixx Biopharma, Gilead; travel grants – BMS, MSD, Novartis, Pierre Fabre; advisory board – Sandoz; Stocks owner – Celon Pharma; Board member - Polish Society of Clinical Oncology; Katarzyna Kozak: Speaker honoraria – BMS, MSD, Novartis, Pierre Fabre, Sanofi; travel grants – MSD, Pierre Fabre

FUNDING

The study is funded by a grant from the Medical Research Agency – agreement number 2022/ABM/01/00013-00 „Jednoramienne badanie II fazy oceniające skuteczność i bezpieczeństwo pembrolizumabu w połączeniu z agonistą LAG-3 eftilagimodem I radioterapią w leczeniu przedoperacyjnym chorych na mięsaki tkanek miękkich (EFTISARC-NEO)" (PI Katarzyna Kozak). Immutep has provided eftilagimod alfa.

immutep Empowering the Immune System

MEDICAL RESEARCH AGENCY

Corresponding autor: Paweł Teterycz email: pawel.teterycz@nio.gov.pl