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Philogen provides update on Fibromun clinical study developments

FIBROSARC is a randomized, controlled Phase III clinical trial evaluating the use of fibromun in combination with doxorubicin, compared with doxorubicin alone as first-line treatment in patients with advanced or metastatic STS. Patients with leiomyosarcoma, liposarcoma, and other rare histologies were enrolled in the study. The primary endpoint was Progression-Free Survival (PFS), while Overall Survival (OS) is a secondary endpoint.

Although FIBROSARC did not meet its primary PFS endpoint in the final analysis, the results indicate promising trends for PFS, ORR, and OS favoring patients treated with fibromun plus doxorubicin, over the doxorubicin monotherapy arm.

At the time of the final analysis of the primary endpoint PFS (131 randomized patients; 92 PFS events):

- mPFS was 7.9 months for the fibromun plus doxorubicin arm versus 4.6 months for doxorubicin alone. Hazard Ratio proportionality was observed at interim analysis, but not at the final analysis
- Objective Response Rate (ORR) was 19.0% with the combination versus 14.3% with doxorubicin alone
- Median OS (mOS) was 28.3 months in the fibromun plus doxorubicin arm versus 19.6 months in the doxorubicin arm. The OS data are immature, with only 54 OS events at the time of this analysis.

The results from FIBROSARC will be presented at upcoming scientific conferences and submitted for publication in a peer-reviewed journal in 2026.

Encouraged by these data and in consideration of the substantial unmet medical need for patients with advanced or metastatic STS, Philogen plans to discuss the results with European and US authorities and to initiate a Philogen-sponsored confirmatory Phase III trial with OS as the primary endpoint. Such a new study is expected to start in 2026.

Prof. Dr. Christoph Schliemann (UK Münster), the Coordinator of the study and the Principal Investigator of the center that had enrolled the largest number of patients, commented: "Fibromun is showing signs of activity in a very difficult-to-treat indication. We remain interested in future applications of this investigational study drug. We are eager to learn about the evolution of overall survival data"

Other details about FIBROSARC study

The sample size for the FIBROSARC trial was calculated based on the assumption of a median PFS (mPFS) of 8.0 months for the treatment arm (fibromun plus doxorubicin) versus 4.4 months for the control arm (doxorubicin; two-sided $\alpha = 0.05$; power: 80%), with a proportional Hazard Ratio.

In February 2024, an independent Data and Safety Monitoring Board (DSMB) had reviewed the interim analysis at 50% of PFS events (i.e., 46 events) and had recommended continuing the study without modification.

Update on other Soft Tissue Sarcoma (STS) programs

FLASH is a randomised controlled Phase II trial evaluating Fibromun in combination with Dacarbazine compared with Dacarbazine alone as last-line treatment in patients with advanced or metastatic soft tissue sarcoma. The study completed patient enrolment and the PFS events for the final study readout are expected by the end of 2025.

FIBROSARC US is a randomised controlled Phase IIb trial evaluating Fibromun in combination with Doxorubicin compared with Doxorubicin alone as first-line treatment in patients with metastatic Leiomyosarcoma. The study has enrolled 81 of the 158 patients foreseen by the protocol. An interim analysis at 50% of the PFS events is expected in Q1 2026 where an independent DSMB will review efficacy and safety data.

About Soft Tissue Sarcoma (STS)

STS comprise a heterogeneous group of more than 100 tumor subtypes arising from mesenchymal or connective tissues. Collectively, they account for approximately 1% of all adult cancers. Doxorubicin monotherapy remains the standard first-line treatment for most subtypes of advanced or metastatic disease.

Fibromun has been granted orphan drug designation for the treatment of STS by both the European Commission and the U.S. Food and Drug Administration.

Glioblastoma programs

Glioblastoma, defined as a high-grade IDH-wildtype glioma, represents the most common malignant primary brain tumor in adults. Its incidence is approximately 3–5 cases per 100’000 people per year, and the median overall survival is approximately 14.6 months from initial diagnosis. The methylation status of the O6-methylguanine-DNA methyltransferase (MGMT) gene promoter is a key prognostic and predictive biomarker for response to standard-of-care therapy. Patients with an unmethylated MGMT promoter typically have a poorer prognosis compared to those with a methylated promoter.

Fibromun has been granted orphan drug designation for the treatment of glioma by both the European Commission and the U.S. Food and Drug Administration.

GLIOSUN is a Phase I/II/IIb trial in newly diagnosed Glioblastoma. Fibromun is administered in combination with chemoradiotherapy based on temozolomide (treatment arm) and is compared to chemoradiotherapy alone (control arm). The Phase I part of the trial with 18 patients has been completed. In the subgroup of patients with unmethylated MGMT promoter, who typically have a

poorer prognosis, the median OS was 17.8 months. The emerging results have been presented at the 20th Meeting of the European Association of Neuro-Oncology (EANO 2025). Data in patients with a methylated MGMT promoter are not yet mature.

GLIOSTAR is a Phase I/II trial in patients with Glioblastoma at first recurrence. Fibromun is administered in combination with lomustine (treatment arm) and is compared to lomustine alone (control arm). The Phase II randomised part of the study has completed enrolment of the 158 patients foreseen by the protocol. The primary endpoint of the Phase II part of the study is OS and the events for final analysis are currently expected for Q1 2026.

GLIOSTELLA is a Phase II trial in patients with glioblastoma at first or later recurrence. Fibromun is given in combination with lomustine at different dose levels of both Fibromun and lomustine. The study completed enrolment of the 90 patients foreseen by the protocol. The primary goal of the study is to address FDA Optimus "Guidance for Industry" on dose optimization. It will also provide safety information and important efficacy insights, including OS data, in this patient population with a high unmet clinical need. Mature data are expected in 2026.

Philogen Contacts

Philogen - Investor Relations
IR@philogen.com - Emanuele Puca | Investor Relations Officer