

Evgen Pharma plc
("Evgen" or "the Company" or "the Group")

Confirmation of SFX-01 radiosensitisation effect *in-vivo* in Rhabdomyosarcoma

Alderley Park, UK - 27 June 2023 Evgen Pharma plc (AIM: EVG), a clinical stage drug development company developing sulforaphane-based medicines, provides an update on the research partnership with Sapienza University of Rome, which has confirmed the radiosensitising effects of lead asset SFX-01 *in-vivo* in Rhabdomyosarcoma (RMS), the most frequent soft tissue sarcoma in childhood.

A radiosensitising agent is a drug that makes tumor cells more sensitive to radiation therapy, enhancing its effectiveness. The work was carried out by Prof. Francesco Marampon of the Department of Radiotherapy and Dr Simona Camero of Prof. Francesca Megiorni's research group at the Department of Experimental Medicine at the Sapienza University of Rome.

Data* presented at the ESMO Sarcoma and Rare Cancers Congress in March this year showed that SFX-01 was effective at reducing RMS tumour cell growth *in-vitro*, both as a single agent and in combination with radiotherapy where it was found to be synergistic.

These positive effects have now also been confirmed *in-vivo* in a mouse xenograft model of RMS. The group investigated the effects of SFX-01 given orally on the growth of patient derived RMS tumour cells, *in-vivo*.

SFX-01 was shown to be effective at reducing the growth of tumour masses given as a single agent dosed once daily orally. It was also given in combination with a radiotherapy regime where it was shown to act synergistically, resulting in a more positive outcome than would be expected by simply adding the two agents together.

The data from both sets of studies will now be brought together for submission to a peer reviewed publication.

Dr Helen Kuhlman, Evgen CBO, commented:

"The collaboration with Prof. Marampon's group continues to generate very encouraging data on SFX-01 as a radiosensitising agent - demonstrating the possibilities for SFX-01 wherever radiotherapy is used as standard of care. Our clinical work has shown that SFX-01 is safe and well tolerated, so its potential to enhance the effects of radiotherapy without causing additional therapeutic burden on patients is highly exciting."

Prof. Francesco Marampon, of Università Sapienza di Roma, Lead Investigator, added:

"The systemic therapy of rhabdomyosarcomas has not changed in recent decades and the frequent finding of locoregional recurrences suggests the need for radiosensitising therapies that increase local control. Unfortunately, with sarcomas, particularly with rhabdomyosarcoma, exciting data are rarely obtained in vivo and, precisely for this reason, I am very excited to observe this result!"

Rhabdomyosarcoma (RMS) is a rare type of cancer that forms in soft tissue and can develop in muscle, fat, blood vessels, or in any of the other tissues that support, surround and protect the organs of the body. RMS can occur at any age, but most often affects children. The prognosis and treatment options depend on the type of rhabdomyosarcoma, where it starts, tumour size and whether the cancer has spread. Treatment is usually with a combination of surgery, chemotherapy and radiation therapy. Currently, the long-term outcomes in patients with metastatic rhabdomyosarcoma remain poor.

SFX-01 is a patented composition of synthetic sulforaphane and alpha-cyclodextrin. Evgen has already completed three trials of SFX-01 in patients, demonstrating good safety data, including a [positive open label trial in metastatic breast cancer](#) using the prototype capsule formulation.

Evgen's core technology is Sulforadex®, a method for synthesising and stabilising sulforaphane and novel proprietary analogues based on sulforaphane. Sulforaphanes have shown potential benefits in neurodevelopmental disorders, oncology and inflammatory conditions. SFX-01, Evgen's lead asset, is the only stabilised sulforaphane suitable for clinical research and eventual approval as a medicine.

[*105P SFX-01 in the treatment of rhabdomyosarcoma: Preclinical results in cellular models - ESMO Open](#)

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Notes to Editors

About Evgen Pharma plc

Evgen Pharma is a clinical stage drug development company developing sulforaphane based medicines for the treatment of multiple diseases. The Company's core technology is Sulforadex®, a method for synthesising and stabilising the highly biologically active compound sulforaphane and novel proprietary analogues based on sulforaphane.

The Company's lead asset, SFX-01, is a patented composition of synthetic sulforaphane and alpha-cyclodextrin and has undergone clinical trials for oestrogen-positive (ER+) metastatic breast cancer and recently a Phase 1b study of the Company's new enteric coated tablet formulation. The FDA has granted Orphan Drug status to SFX-01 in malignant glioma. SFX-01 will be investigated initially in this indication as an investigator sponsored study in the Netherlands.

The Company also has a wide number of collaborations with leading academic centres in the UK, Europe and the US as part of the continuing strategy to build the scientific data for the compound. With respect to areas outside of oncology and inflammation, Evgen signed an out-licensing deal with JuvLife, the dietary products and functional foods division of Juvenescence Ltd, for the development of a naturally-sourced sulforaphane nutritional health supplement, stabilised using Evgen's Sulforadex® technology. More recently Evgen completed an out-licensing transaction with Stalicia SA, a Swiss specialist company in neurodevelopmental disorders, commencing with autism spectrum disorder. The deal, if successful, will generate milestone payments of \$160.5m and a double-digit royalty on sales.

The Company has its headquarters and registered office at Alderley Park, Cheshire. It is listed on AIM in London and trades under the ticker symbol EVG.

For further information, please visit: www.evgen.com

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