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Evgen Pharma PLC
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Evgen Pharma plc

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

Preliminary pharmacokinetic results from Phase 1b study of new SFX-01 tablet formulation

Delivery of active ingredient beyond the stomach confirmed in a time course consistent with enteric coated tablet release. Clear dose relationship demonstrated and SFX-01 well tolerated across all doses with no serious adverse events.

Alderley Park, UK - 22 March 2023: Evgen Pharma plc (AIM: EVG), a clinical stage drug development company developing sulforaphane-based medicines, announces top line pharmacokinetic data of its placebo-controlled, dose-escalating, randomised Phase I/Ib clinical trial.

The study aimed to provide further insight into the pharmacokinetic and pharmacodynamic characteristics of the new enteric coated (EC) tablet formulation of the Company's lead asset SFX-01, as well as investigating how sulforaphane released from the tablet engages with molecular targets of interest. The new form of active ingredient in this SFX -01 tablet has additional patent protection.

Highlights

- Sulforaphane was released by the new enteric coated tablet beyond the acid environment of the stomach based on the time course seen, as predicted
- Levels of sulforaphane and its active metabolites in blood increased predictably with increasing dose
- Total levels of sulforaphane and active metabolites in blood are in the range previously seen to be effective in pre-clinical experiments and clinical studies in a range of target diseases including breast cancer and glioblastoma
- No serious adverse events observed
- Pharmacodynamic analysis now underway, via highly sophisticated experiments on a longer time scale, focused on how the drug modulates disease-relevant molecular targets and will be reported in due course
- The study is on schedule for full reporting in the second quarter of 2023.

The new enteric-coated tablet formulation of SFX-01 will replace the previous prototype capsule formulation. It releases sulforaphane to a targeted part of the intestine, with the goals of predicable release and minimisation of gastro-intestinal side effects. The new formulation will be suitable for large scale trials and commercial supply.

A pharmacokinetic study looks at how the drug is absorbed and circulates in the body, while a pharmacodynamic study investigates how the drug engages with molecular targets relevant to disease. The completed healthy volunteer study examined both in a double-blinded, placebo-controlled modular design involving three cohorts of volunteers, each receiving different doses of SFX-01 or matching placebo.

Dr Huw Jones, Evgen CEO, commented:

"These top line results confirm release of the active ingredient from SFX-01 to the bloodstream in a time course that shows our new enteric coated tablet works as predicted. We have also seen a marked increase in blood levels with increasing dose with no serious adverse events. The full analysis of the data continues, focusing on SXF-01's effects on particular molecular targets and we will provide further updates as key data from this insightful study emerge."

Further details will be discussed in a presentation and Q&A by Company CEO Dr Huw Jones and CMO Dr Glen Clack on Thursday 23 March at 14:00 GMT on the Investor Meet Company platform.

The presentation is open to all existing and potential shareholders. Questions can be submitted pre-event via your Investor Meet Company dashboard up until 9am the day before the meeting or at any time during the live presentation.

Investors can sign up to Investor Meet Company for free and add to meet EVGEN PHARMA PLC via this link.

Investors who already follow Evgen on the Investor Meet Company platform will automatically be invited.

-Ends-

Enquiries:

Evgen Pharma PLC Dr Huw Jones, CEO Richard Moulson, CFO	**+44 1625 466591**
FinnCap (Nominated Advisor and Broker) Geoff Nash / Teddy Whiley (Corporate Finance) Alice Lane/ Nigel Birks (ECM)	**+44 20 7220 0500**
Instinctif Partners Melanie Toyne-Sewell / Rozi Morris/ Adam Loudon	**+44 207 457 2020** **Evgen@Instinctif.com**

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 naturally occurring 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. In September 2021 the FDA granted Orphan Drug status to SFX-01 in malignant glioma.

The Company also has a wide number of collaborations with leading academic centres in the UK, Europe and AsiaPac as part of the continuing strategy to build safety and efficacy data sets around the compound. With respect to non-core areas, 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. Evgen also has a licensing deal with STALICLA SA in neurodevelopmental disorders and schizophrenia.

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

About SFX-01

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.

SFX-01 is a patented composition of synthetic sulforaphane and alpha-cyclodextrin. The Company has already completed three trials in patients, including a positive open label trial in metastatic breast cancer using the prototype capsule formulation.

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