prolonged disease stabilisation in pre-treated patients who were progressing on the background ET at study entry. Further development of SFX-01 in ER+ mBC is warranted.

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341P Final results of the STEM trial: SFX-01 in the treatment and evaluation of ER+ Her2- metastatic breast cancer (mBC)

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Background: SFX-01 is a proprietary synthetic pharmaceutical product based upon a stabilised sulforaphane. In preclinical models SFX-01 inhibits the activity of cancer stem-like cells and reverses resistance to endocrine therapies (ET) tamoxifen (Tam) and fulvestrant (Fulv). The STEM study investigated the potential of SFX-01 to reverse acquired resistance to Tam, Fulv and third generation aromatase inhibitor (AI) therapy.

Methods: STEM is an open label parallel arm exploratory phase II trial. Patients were eligible if they had measurable (RECIST v1.1) estrogen receptor (ER) positive Her2- mBC that had developed acquired resistance to AI (arm A), Tam (arm B) or Fulv (arm C) therapy i.e. mBC was progressing having shown clinical benefit (stable disease (SD) for 6 months or objective response (OR)). SFX-01 300mg bd po was added to the current ET. The co-primary endpoints were clinical benefit rate (CBR) and safety/tolerability. Secondary endpoints included OR rate (ORR) and time to progression (TTP). Patients progression free at 24wks were enrolled into a compassionate use phase to continue SFX-01 and the same ET.

Results: Between January 2017 and July 2018 46 patients were recruited; arm A n = 31, arm B n = 8 and arm C n = 7. 33/46 (71.7%) had visceral involvement. Prior lines of ET were: 1= 17/46 (37.0%), 2= 17/46 (37.0%) and ≥3 = 12 (26%). 8 patients (17.4%) had received prior chemotherapy for mBC. The CBR overall was 12/46 (26.0%) with 2 objective responses (both partial). SFX-01 was well tolerated with grade 1/2 nausea (54.3%) and dyspepsia (32.6%) the most frequent adverse events (AEs). Only 2 grade 3 AEs were possibly drug related. There were no drug related serious AEs. There was no significant association between duration of prior ET and subsequent duration of ET+SFX-01 (Spearman r 0.17; p = 0.26).

Conclusions: SFX-01 300 mg BID was safe and well tolerated in patients with ER+ and HER2- mBC. SFX-01 in combination with ET demonstrated anti-tumour activity and