

**AGM Presentation** 

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#### Highlights of the year

- Clinical proof of concept clearly demonstrated in final top line data released from STEM (SFX-01 in the Treatment and Evaluation of Metastatic Breast Cancer) Phase IIa clinical study
- Dosing and three month visits completed in ongoing SAS (SFX-01 After Subarachnoid Haemorrhage) Phase IIb clinical study. Results expected in early Q4 of this calendar year
- SFX-01 featured in a Nature Reviews Drug Discovery as a prominent Nrf2/KEAP1 activator
- Susan Clement-Davies, ex-Torreya and Citigroup, appointed as Non-Executive Director
- First European notice of grant for SFX-01 composition of matter patent
- Financial performance in line with expectations
- Heavily oversubscribed fundraising in May 2019 raised £5.0m before expenses



#### Recent placing and use of funds

- Placing announced on 17 April 2019
- Gross proceeds of £5m
- Use of proceeds
  - to strengthen the balance sheet for future partnering;
  - developing product formulation for use in STEM II and other investigator-led clinical studies; and
  - conducting further toxicology studies that will remove current restrictions on the duration of clinical trial treatment phases.



#### Next steps and news flow

- New development programmes associated with product formulation and expanded toxicology
- Near-term news flow with regard to investigator-led clinical trials in new disease areas
- STEM II clinical trial protocol in development and evaluation of access to non-dilutive capital
- The SAS Phase IIb study in haemorrhagic stroke projected to read out in early Q4 (calendar year)
- Out-licensing discussions underway with the potential for substantial value enhancement for shareholders



### **Supplementary material for Q&A**



**STEM**: <u>SFX-01 treatment and evaluation</u> in patients with <u>metastatic breast cancer</u>



## Breast cancer is the most common cancer and the second most frequent cause of cancer death in women

- ER+ breast cancer is the most prevalent breast cancer sub-type (70%)
- Metastatic breast cancer (MBC) means that the cancer has spread to other parts of the body
- MBC is incurable with 5-year survival rates of 22%<sup>1</sup>
- First-line endocrine therapy provides 9-15 months of progression free survival<sup>2</sup>
- Combination with CDK4/6 inhibitors extends to c.25 months<sup>2</sup>
- Limited options thereafter and novel, well tolerated therapies are urgently needed

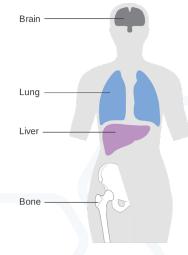


Image: Cancer Research UK



#### STEM, the first Phase II trial on SFX-01

- Objectives to evaluate the:
  - > anti-tumour activity of SFX-01 after failure of at least one and up to three prior endocrine therapies
  - safety and tolerability in combination with the three commonly used endocrine approaches and with long-term exposure
- Open-label, Phase II, European multicentre study in 46 patients led by Chief Investigator Dr Sacha Howell at Manchester's Christie NHS Foundation Trust
- Patients taking either a third generation aromatase inhibitor (AI) or tamoxifen or fulvestrant and have documented evidence of progressive disease
- These patients have very advanced disease, with only palliative chemotherapy as a final option. They are kept on their failing endocrine therapy and SFX-01 is added to the regime
- Patients had 6-weekly scans until progression, up to a maximum of 24 weeks
- At the end of the trial, patients who continued to receive benefit entered the compassionate use phase



#### SFX-01 successfully met both primary endpoints

- Primary Endpoint 1: Clinical Benefit Rate (CBR, where CBR = Complete Response + Partial Response + Stable Disease) at 24 weeks using RECIST v1.1
  - SFX-01 can both stabilise and shrink endocrine resistant metastatic breast cancer.
- Primary Endpoint 2: Treatment-Emergent Adverse Events (Safety and Tolerability) to determine the safety and tolerability of SFX-01 in combination with AI or tamoxifen or fulvestrant
  - > SFX-01 is well tolerated with no safety concerns



# An impressive clinical benefit rate in patients that have become resistant to all endocrine therapies, and have advanced and progressive disease

- Clinical Benefit Rate across all patients was c. 24%
- Disease stabilisation seen in patients from all participating countries
- Objective response seen in 2 patients (4%)
- 13 patients entered the compassionate use programme after 24 weeks



### Market opportunity for SFX-01 is initially second-line therapy post-CDK4/6i failure

	Everolimus + Exemestane	Fulvestrant	SFX-01 + Fulvestrant
Safety profile	Poor	Good	Good (Target)
Efficacy (Progression-Free Survival)	7.8 months	3 to 6 months	> or = 7.8 months (Target)
Sales	Everolimus \$1.5bn <sup>1</sup>	Fulvestrant \$940m²	SFX-01 >\$1bn³

- Substantial market opportunity CDK4/6i sales projected to reach c.\$9bn by 2021e<sup>4</sup>
- Partner SFX-01 as second-line therapy to CDK4/6i potential upfront of \$50m+5



<sup>&</sup>lt;sup>1</sup> Novartis Full Year Results 2017 – covers Afinitor sales across multiple cancers, not just ER+ MBC; <sup>2</sup> AstraZeneca Full Year Results 2017;

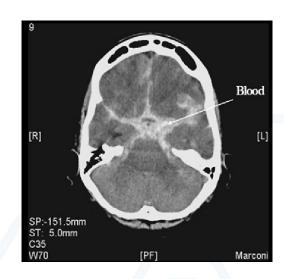
<sup>&</sup>lt;sup>3</sup> finnCap analyst report, April 2019 (US and EU only); <sup>4</sup> Biopharm Insight Consensus Broker Forecast; <sup>5</sup> IMS Pharma Deals: Review of 2016

### **SAS**: <u>S</u>FX-01 <u>A</u>fter <u>S</u>ubarachnoid Haemorrhage



## Subarachnoid haemorrhage (SAH) accounts for approximately 5% of all strokes

- Defined by bleeding in the outer layers of the brain due to a ruptured brain aneurysm
- 40% of patients die within 30 days and for the survivors c.50% will have long-term cognitive impairment
- A Delayed Cerebral Ischaemia (DCI) occurs days after the SAH and, at that point, becomes the most important cause of mortality and poor neurological outcome
- Current standard of care, nimodipine, was first approved in 1989 and new pharmacological treatments are needed to prevent and treat DCI





#### SAS read-out projected for early Q4 of this calendar year

- **SAS**: <u>SFX-01 After Subarachnoid Haemorrhage a Phase IIb, double-blind, placebo-controlled trial on 90 patients (45 in test and placebo arm respectively)</u>
- Administered alongside the calcium channel antagonist, nimodipine
- Primary Endpoints: improved blood flow (ultrasound) associated with the DCI, levels of drug in plasma and cerebral spinal fluid & safety
- Secondary endpoints: cognitive measures at 3 and 6 months
- Chief Investigator: Mr Diederik Bulters, Consultant Neurosurgeon, Wessex Neurological Centre in Southampton
- Orphan designation granted by FDA



## Commercial opportunity: Potentially, the first drug approval in SAH since 1989

- Estimated peak sales of c. \$500m¹ (c.f. \$1.7bn projection for EG1962²) as SAH orphan drug
- Partner and/or co-develop post-Phase IIb (2019) to fund pivotal Phase III
  - Up-front payment potential post-Phase IIb of >\$70m³ and post-Phase III of >\$150m³
  - Royalty rates estimated in high teens
- Broader deal for stroke increases value and bio-dollars
- Partners companies interested in SAH/stroke or targeting Nrf2 pathway. Likely to be large biotech or specialty pharma

