

Context Therapeutics

Clinical update

Initial data from the SMILE study encouraging

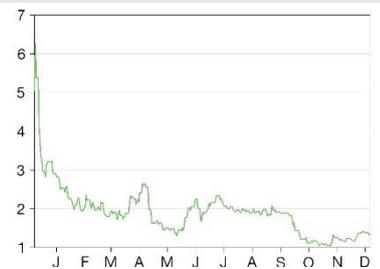
Pharma and biotech

8 December 2022

Price **\$1.38**
Market cap **\$22m**

Net cash (\$m) at 30 September 2022 39.4
 Shares in issue 15.97m
 Free float 67%
 Code CNTX
 Primary exchange Nasdaq
 Secondary exchange N/A

Share price performance



Context Therapeutics has announced encouraging four-month progression-free survival (PFS) data from the Phase II SMILE trial, which is investigating the company's first-in-class, oral progesterone receptor antagonist ONA-XR (onapristone extended release) in HR+/HER2-metastatic breast cancer (mBC). The preliminary findings, presented recently at the San Antonio Breast Cancer Symposium (SABCS), demonstrate that patients treated with ONA-XR in combination with fulvestrant had a four-month PFS of 44% (n=9) and the combination was well-tolerated. Considering the fulvestrant monotherapy following progression of CDK4/6 inhibitors has been shown to offer a median PFS of **approximately two** months in the same population, we view the reported results as encouraging, although it is too early to draw definitive conclusions from the preliminary data. Nevertheless, we view this as another positive development following the recent **readout for endometrial cancer**.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/20	0.0	(3.2)	(9.28)	0.0	N/A	N/A
12/21	0.0	(10.6)	(3.74)	0.0	N/A	N/A
12/22e	0.0	(18.1)	(1.13)	0.0	N/A	N/A
12/23e	0.0	(27.4)	(1.72)	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding exceptional items.

As a reminder, the SMILE trial is a Phase II, open-label, single-arm, multi-center, investigator-sponsored trial evaluating ONA-XR in combination with Faslodex (fulvestrant) in second-line or third-line ER+/HER2- mBC patients who have progressed on first-line standard of care (aromatase inhibitor + CDK4/6 inhibitor). The study is sponsored by the Wisconsin Oncology Network and will enroll up to 39 patients across four trial sites in the United States (the first patient was dosed in October 2021). The primary endpoint will be overall response rate (ORR) and secondary endpoints will include duration of tumor response, PFS, disease control rate, time to response and incidence of adverse events. Following previous encouraging preliminary Phase II data in endometrial cancer (ONA-XR + anastrozole), which demonstrated a four-month PFS of 77.7%, we see this recent data in breast cancer as a further positive support for the company's development pipeline.

In addition to Wisconsin Oncology Network presenting the SMILE data at SABCS, Context also provided an initial report on the trial design of the ELONA Phase Ib/II clinical trial, which is evaluating ONA-XR in combination with elacestrant (Menarini's oral selective estrogen degrader) in second- and third-line HR+/HER2-mBC patients. Data from the Phase Ib portion of the trial is expected in Q4 2023.

Business description

Context Therapeutics is a clinical-stage women's oncology company. Lead candidate ONA-XR is a 'full' progesterone receptor antagonist currently being evaluated in three Phase II and one Phase Ib/II clinical trial in hormone-driven breast, endometrial and ovarian cancer. The other asset is a bi-specific monoclonal antibody, CLDN6xCD3, with the selected candidate CTIM-76 undergoing IND-enabling studies (IND submission is planned for Q124).

Analysts

Soo Romanoff +44 (0)20 3077 5700
 Dr Harry Shrives +44 (0)20 3077 5700
 Jyoti Prakash +44 (0)20 3077 5700

healthcare@edisongroup.com

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia