

# Threshold Pharmaceuticals

**Pharma & biotech**
**18 November 2014**

## TH-302 Phase II GBM plans confirmed

Additional interim data from the ongoing Phase I/II investigator-led trial of Threshold's TH-302 in glioblastoma (GBM) have been reported at the SNO (society for neuro-oncology) conference. Based on the early signs of efficacy observed, with survival exceeding historic reference data, plans for an investigator-led, two-centre Phase II trial have now been confirmed, supported by an FDA grant. GBM could be an indication eligible for accelerated development, given the unmet medical need.

## Overall survival of 4.6 months in third-line GBM

The [Phase I/II](#) investigator-led trial of TH-302 in combination with Avastin (bevacizumab) as third-line treatment in recurrent GBM patients who progressed following second-line Avastin has now completed recruitment and updated interim data from 23 patients were presented at SNO. Patients in this setting have a very poor prognosis, with progression after around a month, and overall survival (OS) of around three months. In this trial, OS to date is 4.6 months and PFS (progression-free survival) is 2.8 months. There remain one complete and three partial responses, an 18% response rate in the 22 evaluable patients. 10 patients have stable disease (SD), including one patient with SD of nearly 45 months.

## Mild to moderate adverse events

There remain no grade 4 adverse events (AEs) in these 23 patients, which include 13 patients at the highest 670mg/m<sup>2</sup> dose. There have been three Grade 3 AEs; skin ulceration at 340mg/m<sup>2</sup>, oral mucositis and thrombocytopenia both at 670mg/m<sup>2</sup>. The majority of AEs were Grade 1 or 2 mucosal-related, which were not dose-limiting. The maximum tolerated dose has been established as 670mg/m<sup>2</sup>.

## Phase II plans confirmed

The lead investigator from the ongoing Phase I/II study has been awarded an FDA grant to pursue a Phase II study. This planned trial will be in the same patient setting and will recruit up to 33 patients examining 670mg/m<sup>2</sup>. The trial will also include PET imaging to investigate potential predictive markers.

## Valuation: EV of around \$115m

End-September net cash of \$68.5m implies an EV of only c \$115m. TH-302 has been partnered with Merck KGaA in a \$525m deal and has potential across a broad range of tumours, with Phase III trials in both STS and pancreatic cancer ongoing.

### Consensus estimates

Year end	Revenue (\$m)	PBT (\$m)	EPS (\$)	DPS (\$)	P/E (x)	Yield (%)
12/12	5.9	(71.1)	(1.31)	0.0	N/A	N/A
12/13	12.5	(28.2)	(0.49)	0.0	N/A	N/A
12/14e	15.2	(25.0)	(0.46)	0.0	N/A	N/A
12/15e	16.5	(29.4)	(0.55)	0.0	N/A	N/A

Source: Bloomberg

**Price \$2.92**
**Market cap \$183m**

### Share price graph



### Share details

Code	THLD
Listing	NASDAQ
Shares in issue	62.8m

### Business description

Threshold Pharmaceuticals is a US oncology company focused on tumour hypoxia, a low-oxygen condition found in most solid tumours and some blood cancers. TH-302 is in Phase III for STS and pancreatic cancer, in addition to trials in multiple other cancers and is partnered with Merck KGaA.

### Bull

- TH-302 has potential in a number of cancer indications, as both monotherapy in some cancers, and in combination with chemotherapy and antiangiogenics.
- Merck KGaA funds 70% of TH-302 development.
- Solid cash position of \$68.5m (end September).

### Bear

- TH-302 could fail to show a survival benefit in Phase III (STS and pancreatic cancer).
- Oncology is a highly competitive space.
- Single-product risk.

### Analysts

Dr Philippa Gardner	+44 (0)20 3681 2521
Emma Ulker	+44 (0)20 3077 5738
Dr Mick Cooper	+44 (0)20 3077 5734

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

**QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.**

**Threshold Pharmaceuticals is a research client of Edison Investment Research Limited**

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. Edison is authorised and regulated by the Financial Conduct Authority ([www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584](http://www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584)). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. [www.edisongroup.com](http://www.edisongroup.com)

#### DISCLAIMER

Copyright 2014 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Threshold Pharmaceuticals and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") (c) FTSE [2014]. "FTSE(r)" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.