Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

NOMURA
EQUITY RESEARCH

CUV's statistically significant EPP results

First Look

Breaking news, market events and company announcements

November 3, 2011

Rating Remains	**Buy**
Target price Remains	AUD 3.56
Closing price November 3, 2011	AUD 1.50

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

Zara Lyons - NAL

Clinuvel demonstrates positive treatment effect of afamelanotide in US Phase II study

Analyses from US confirmatory study demonstrated a dramatic improvement in Quality of Life from afamelanotide 16mg in the orphan disease erythropoietic protoporphyria (EPP). The primary objective of evaluating afamelanotide in EPP patients was to determine whether the prophylactic effect has clinical benefit. EPP patients who received afamelanotide (active drug) were able to spend more time in direct sunlight between 10am and 3pm and 10am and 8pm ($p=0.036$, $p=0.025$). Photoprovocation on the back and hand in a subset of patients showed a significant treatment effect up to Day 60 ($p=0.019$ to $p=0.045$, depending on the study day and body site tested). Afamelanotide significantly improved patients' Quality of Life (QoL) as measured by an EPP-specific QoL questionnaire at Day 180 ($p<0.001$) and at Days 60 and 120 ($p=0.001$ and $p=0.003$).

Background

EPP is a rare and severe genetic disorder causing absolute UV and light intolerance in the skin. It occurs as a result of an enzyme deficiency that allows for an abnormal build-up of protoporphyrin, a molecule toxic to the body that transforms into excited states on absorption of light energy, causing photo-oxidative damage to the skin. This is manifested through various symptoms such as tingling, stinging, or burning and may accompany the appearance of a rash or blisters.

With no real treatment options for EPP sufferers beyond limiting light exposure, Clinuvel's afamelanotide therapy may prove efficacious. The disease is rare, affecting around one in 60,000-200,000 people worldwide, according to PubMed, although accurate statistics are hard to find. We estimate there are between 7,000 and 14,000 EPP sufferers across the US and Europe. Afamelanotide appears to be one of the few viable treatment options for EPP.

Clinuvel is currently finalising a Marketing Authorisation Application (MAA) for afamelanotide for submission to the European Medicines Agency (EMA) before the end of 2011. Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein.

What does it mean for CUV?

These statistically significant results should be positive for CUV's Marketing Authorisation Application in the EU. We continue to believe afamelanotide is a potentially valuable treatment for sun and pigment-related disorders. This news is in line with our forecasts; hence we make no change to our valuation.

CUV is already being reimbursed for its product for EPP in select EU countries, and hence the business model has already been substantially de-risked, in our view. Our risk-weighted valuation for the near-term

See Appendix A-1 for analyst certification, important disclosures and the status of non-US analysts.

opportunities in the CUV pipeline is shown below. We use our risk-weighted valuation of the CUV pipeline as our target price.

Fig. 1: CUV – risk weighted valuation of opportunities

Valuation of CUV R&D portfolio	Risk-weighted valuation (A$ps)	Risk-weighting (in line with Clincial trial stage) (%)	Total opportunity (A$ps)
EPP	$1.91	90%	$2.12
Non-segmental Vitiligo	$1.65	21.4%	$7.73
Valuation	**$3.56**		$9.85

Source: Nomura estimates, Tufts data

In addition, CUV are developing a treatment for Non-segmental Vitiligo (NSV). NSV is a de-pigmenting disease that affects c10mn persons in the US and EU. We believe treatment of NSV with CUV's afamelanotide could provide an elegant solution to what is a disfiguring disease with a large unmet clinical need. CUV's afamelanotide is being evaluated as a combination therapy with narrowband UVB (NB-UVB) light therapy in two clinical studies in patients with NSV. We have performed a scenario analysis of the potential NSV opportunity. Starting from potential approval in 2016F, we believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the total CUV NSV opportunity is worth A$7.73/share. At the current clinical stage, this translates to a risk-weighted NPV of A$1.65/share from NSV.

Appendix A-1

Analyst Certification

I, David Stanton, hereby certify (1) that the views expressed in this Research report accurately reflect my personal views about any or all of the subject securities or issuers referred to in this Research report, (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this Research report and (3) no part of my compensation is tied to any specific investment banking transactions performed by Nomura Securities International, Inc., Nomura International plc or any other Nomura Group company.

Issuer Specific Regulatory Disclosures

Mentioned companies

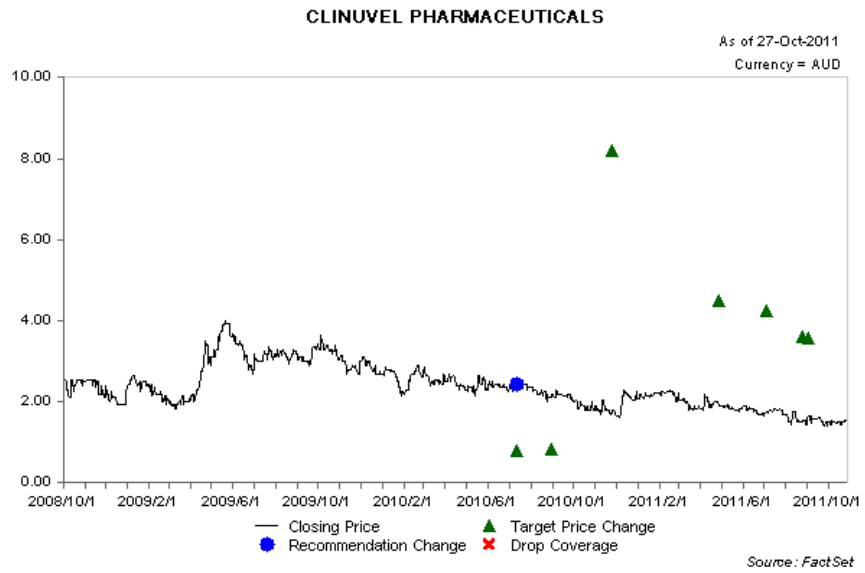
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.50	03-11-2011	Buy	Not rated	

Previous Rating

Issuer name	Previous Rating	Date of change
Clinuvel Pharmaceuticals	Not Rated	12-7-2010

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.50 (03-11-2011)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
02-Sep-2011		3.56	1.65
26-Aug-2011		3.62	1.54
04-Jul-2011		4.26	1.75
27-Apr-2011		4.50	1.95
26-Nov-2010		8.20	1.80
30-Aug-2010		0.82	2.10
12-Jul-2010		0.80	2.45
12-Jul-2010	Buy		2.45

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology Our risk-weighted valuation for EPP, CUV's other near-term opportunity, is A$1.91/share. Starting from potential approval in 2016, We believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the risk-weighted NPV for the NSV opportunity for CUV is A$1.65/share. Given the above analysis, we adopt our risk-weighted valuation of the CUV pipeline (A$3.56) as our TP.

Risks that may impede the achievement of the target price We believe that any delay or failure to progress in clinical trials would present downside risk to our target price. That said, faster-than-expected progression to production of CUV's photoprotective technology could provide an upside boost.

Important Disclosures

Online availability of research and conflict-of-interest disclosures

Nomura Equity Research is available on nomuranow.com, Bloomberg, Capital IQ, Factset, Reuters and ThomsonOne.
Important disclosures may be accessed through the left hand side of the Nomura Disclosure web page http://go.nomuranow.com/research/globalresearchportal or requested from Nomura Securities International, Inc., on 1-877-865-5752. If you have any difficulties with the website, please email grpsupport-eu@nomura.com for technical assistance.

The analysts responsible for preparing this report have received compensation based upon various factors including the firm's total revenues, a portion of which is generated by Investment Banking activities. Unless otherwise noted, the non-US analysts listed at the front of this report are not registered/qualified as research analysts under FINRA/NYSE rules, may not be associated persons of NSI, and may not be subject to FINRA Rule 2711 and NYSE Rule 472 restrictions on communications with covered companies, public appearances, and trading securities held by a research analyst account.

Industry Specialists identified in some Nomura International plc research reports are employees within the Firm who are responsible for the sales and trading effort in the sector for which they have coverage. Industry Specialists do not contribute in any manner to the content of research reports in which their names appear. *Marketing Analysts* identified in some Nomura research reports are research analysts employed by Nomura International plc who are primarily responsible for marketing Nomura's Equity Research product in the sector for which they have coverage. Marketing Analysts may also contribute to research reports in which their names appear and publish research on their sector.

Distribution of ratings (US)

The distribution of all ratings published by Nomura US Equity Research is as follows:
39% have been assigned a Buy rating which, for purposes of mandatory disclosures, are classified as a Buy rating; 8% of companies with this rating are investment banking clients of the Nomura Group*.
54% have been assigned a Neutral rating which, for purposes of mandatory disclosures, is classified as a Hold rating; 3% of companies with this rating are investment banking clients of the Nomura Group*.
7% have been assigned a Reduce rating which, for purposes of mandatory disclosures, are classified as a Sell rating; 0% of companies with this rating are investment banking clients of the Nomura Group*.
As at 30 September 2011. **The Nomura Group as defined in the Disclaimer section at the end of this report.*

Distribution of ratings (Global)

The distribution of all ratings published by Nomura Global Equity Research is as follows:
49% have been assigned a Buy rating which, for purposes of mandatory disclosures, are classified as a Buy rating; 41% of companies with this rating are investment banking clients of the Nomura Group*.
41% have been assigned a Neutral rating which, for purposes of mandatory disclosures, is classified as a Hold rating; 50% of companies with this rating are investment banking clients of the Nomura Group*.
10% have been assigned a Reduce rating which, for purposes of mandatory disclosures, are classified as a Sell rating; 20% of companies with this rating are investment banking clients of the Nomura Group*.
As at 30 September 2011. **The Nomura Group as defined in the Disclaimer section at the end of this report.*

Explanation of Nomura's equity research rating system in Europe, Middle East and Africa, US and Latin America

The rating system is a relative system indicating expected performance against a specific benchmark identified for each individual stock. Analysts may also indicate absolute upside to target price defined as (fair value - current price)/current price, subject to limited management discretion. In most cases, the fair value will equal the analyst's assessment of the current intrinsic fair value of the stock using an appropriate valuation methodology such as discounted cash flow or multiple analysis, etc.

STOCKS

A rating of '**Buy**', indicates that the analyst expects the stock to outperform the Benchmark over the next 12 months. A rating of '**Neutral**', indicates that the analyst expects the stock to perform in line with the Benchmark over the next 12 months. A rating of '**Reduce**', indicates that the analyst expects the stock to underperform the Benchmark over the next 12 months. A rating of '**Suspended**', indicates that the rating, target price and estimates have been suspended temporarily to comply with applicable regulations and/or firm policies in certain circumstances including, but not limited to, when Nomura is acting in an advisory capacity in a merger or strategic transaction involving the company.
Benchmarks are as follows: **United States/Europe**: Please see valuation methodologies for explanations of relevant benchmarks for stocks (accessible through the left hand side of the Nomura Disclosure web page: http://go.nomuranow.com/research/globalresearchportal);**Global Emerging Markets (ex-Asia):** MSCI Emerging Markets ex-Asia, unless otherwise stated in the valuation methodology.

SECTORS

A '**Bullish'** stance, indicates that the analyst expects the sector to outperform the Benchmark during the next 12 months. A '**Neutral'** stance, indicates that the analyst expects the sector to perform in line with the Benchmark during the next 12 months. A '**Bearish'** stance, indicates that the analyst expects the sector to underperform the Benchmark during the next 12 months.
Benchmarks are as follows: **United States**: S&P 500; **Europe**: Dow Jones STOXX 600; **Global Emerging Markets (ex-Asia)**: MSCI Emerging Markets ex-Asia.

Explanation of Nomura's equity research rating system for Asian companies under coverage ex Japan published from 30 October 2008 and in Japan from 6 January 2009

STOCKS

Stock recommendations are based on absolute valuation upside (downside), which is defined as (Target Price - Current Price) / Current Price, subject to limited management discretion. In most cases, the Target Price will equal the analyst's 12-month intrinsic valuation of the stock, based on an appropriate valuation methodology such as discounted cash flow, multiple analysis, etc.
A '**Buy'** recommendation indicates that potential upside is 15% or more. A '**Neutral'** recommendation indicates that potential upside is less than 15% or downside is less than 5%. A '**Reduce'** recommendation indicates that potential downside is 5% or more. A rating of '**Suspended'** indicates that the rating and target price have been suspended temporarily to comply with applicable regulations and/or firm policies in certain circumstances including when Nomura is acting in an advisory capacity in a merger or strategic transaction involving the subject company.
Securities and/or companies that are labelled as '**Not rated'** or shown as '**No rating'** are not in regular research coverage of the Nomura entity identified in the top banner. Investors should not expect continuing or additional information from Nomura relating to such securities and/or companies.

SECTORS

A '**Bullish'** rating means most stocks in the sector have (or the weighted average recommendation of the stocks under coverage is) a positive absolute recommendation. A '**Neutral'** rating means most stocks in the sector have (or the weighted average recommendation of the stocks under coverage is) a neutral absolute recommendation. A '**Bearish'** rating means most stocks in the sector have (or the weighted average recommendation of the stocks under coverage is) a negative absolute recommendation.

Explanation of Nomura's equity research rating system in Japan published prior to 6 January 2009

STOCKS

A rating of '1' or '**Strong buy'**, indicates that the analyst expects the stock to outperform the Benchmark by 15% or more over the next six months. A rating of '2' or '**Buy'**, indicates that the analyst expects the stock to outperform the Benchmark by 5% or more but less than 15% over the next six months. A rating of '3' or '**Neutral'**, indicates that the analyst expects the stock to either outperform or underperform the Benchmark by less than 5% over the next six months. A rating of '4' or '**Reduce'**, indicates that the analyst expects the stock to underperform the Benchmark by 5% or more but less than 15% over the next six months. A rating of '5' or '**Sell'**, indicates that the analyst expects the stock to underperform the Benchmark by 15% or more over the next six months.
Stocks labeled '**Not rated'** or shown as '**No rating'** are not in Nomura's regular research coverage. Nomura might not publish additional research reports concerning this company, and it undertakes no obligation to update the analysis, estimates, projections, conclusions or other information contained herein.

SECTORS

A '**Bullish'** stance, indicates that the analyst expects the sector to outperform the Benchmark during the next six months. A '**Neutral'** stance, indicates that the analyst expects the sector to perform in line with the Benchmark during the next six months. A '**Bearish'** stance, indicates that the analyst expects the sector to underperform the Benchmark during the next six months.
Benchmarks are as follows: **Japan**: TOPIX; **United States**: S&P 500, MSCI World Technology Hardware & Equipment; **Europe**, by sector - *Hardware/Semiconductors*: FTSE W Europe IT Hardware; *Telecoms*: FTSE W Europe Business Services; *Business Services*: FTSE W Europe; *Auto & Components*: FTSE W Europe Auto & Parts; *Communications equipment*: FTSE W Europe IT Hardware; **Ecology Focus**: Bloomberg World Energy Alternate Sources; **Global Emerging Markets**: MSCI Emerging Markets ex-Asia.

Target Price

A Target Price, if discussed, reflect in part the analyst's estimates for the company's earnings. The achievement of any target price may be impeded by general market and macroeconomic trends, and by other risks related to the company or the market, and may not occur if the company's earnings differ from estimates.

Disclaimers

This document contains material that has been prepared by the Nomura entity identified at the top or bottom of page 1 herein, if any, and/or, with the sole or joint contributions of one or more Nomura entities whose employees and their respective affiliations are specified on page 1 herein or identified elsewhere in the document. Affiliates and subsidiaries of Nomura Holdings, Inc. (collectively, the 'Nomura Group'), include: Nomura Securities Co., Ltd. ('NSC') Tokyo, Japan; Nomura International plc ('NIplc'), UK; Nomura Securities International, Inc. ('NSI'), New York, US; Nomura International (Hong Kong) Ltd. ('NIHK'), Hong Kong; Nomura Financial Investment (Korea) Co., Ltd. ('NFIK'), Korea (Information on Nomura analysts registered with the Korea Financial Investment Association ('KOFIA') can be found on the KOFIA Intranet at http://dis.kofia.or.kr); Nomura Singapore Ltd. ('NSL'), Singapore (Registration number 197201440E, regulated by the Monetary Authority of Singapore); Capital Nomura Securities Public Company Limited ('CNS'), Thailand; Nomura Australia Ltd. ('NAL'), Australia (ABN 48 003 032 513), regulated by the Australian Securities and Investment Commission ('ASIC') and holder of an Australian financial services licence number 246412; P.T. Nomura Indonesia ('PTNI'), Indonesia; Nomura Securities Malaysia Sdn. Bhd. ('NSM'), Malaysia; Nomura International (Hong Kong) Ltd., Taipei Branch ('NITB'), Taiwan; Nomura Financial Advisory and Securities (India) Private Limited ('NFASL'), Mumbai, India (Registered Address: Ceejay House, Level 11, Plot F, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai- 400 018, India; Tel: +91 22 4037 4037, Fax: +91 22 4037 4111; SEBI Registration No: BSE INB011299030, NSE INB231299034, INF231299034, INE 231299034, MCX: INE261299034); Banque Nomura France ('BNF'), regulated by the Autorité des marches financiers and the Autorité de Contrôle Prudentiel; NIplc, Dubai Branch ('NIplc, Dubai'); NIplc, Madrid Branch ('NIplc, Madrid') and NIplc, Italian Branch ('NIplc, Italy').

This material is: (i) for your private information, and we are not soliciting any action based upon it; (ii) not to be construed as an offer to sell or a solicitation of an offer to buy any security in any jurisdiction where such offer or solicitation would be illegal; and (iii) based upon information from sources that we consider reliable, but has not been independently verified by Nomura Group.

Nomura Group does not warrant or represent that the document is accurate, complete, reliable, fit for any particular purpose or merchantable and does not accept liability for any act (or decision not to act) resulting from use of this document and related data. To the maximum extent permissible all warranties and other assurances by Nomura group are hereby excluded and Nomura Group shall have no liability for the use, misuse, or distribution of this information.

Opinions or estimates expressed are current opinions as of the original publication date appearing on this material and the information, including the opinions and estimates contained herein, are subject to change without notice. Nomura Group is under no duty to update this document. Any comments or statements made herein are those of the author(s) and may differ from views held by other parties within Nomura Group. Clients should consider whether any advice or recommendation in this report is suitable for their particular circumstances and, if appropriate, seek professional advice, including tax advice. Nomura Group does not provide tax advice.

Nomura Group, and/or its officers, directors and employees, may, to the extent permitted by applicable law and/or regulation, deal as principal, agent, or otherwise, or have long or short positions in, or buy or sell, the securities, commodities or instruments, or options or other derivative instruments based thereon, of issuers or securities mentioned herein. Nomura Group companies may also act as market maker or liquidity provider (as defined within Financial Services Authority ('FSA') rules in the UK) in the financial instruments of the issuer. Where the activity of market maker is carried out in accordance with the definition given to it by specific laws and regulations of the US or other jurisdictions, this will be separately disclosed within the specific issuer disclosures.

This document may contain information obtained from third parties, including ratings from credit ratings agencies such as Standard & Poor's. Reproduction and distribution of third party content in any form is prohibited except with the prior written permission of the related third party. Third party content providers do not guarantee the accuracy, completeness, timeliness or availability of any information, including ratings, and are not responsible for any errors or omissions (negligent or otherwise), regardless of the cause, or for the results obtained from the use of such content. Third party content providers give no express or implied warranties, including, but not limited to, any warranties of merchantability or fitness for a particular purpose or use. Third party content providers shall not be liable for any direct, indirect, incidental, exemplary, compensatory, punitive, special or consequential damages, costs, expenses, legal fees, or losses (including lost income or profits and opportunity costs) in connection with any use of their content, including ratings. Credit ratings are statements of opinions and are not statements of fact or recommendations to purchase hold or sell securities. They do not address the suitability of securities or the suitability of securities for investment purposes, and should not be relied on as investment advice.

Any MSCI sourced information in this document is the exclusive property of Morgan Stanley Capital International Inc. ('MSCI'). Without prior written permission of MSCI, this information and any other MSCI intellectual property may not be reproduced, re-disseminated or used to create any financial products, including any indices. This information is provided on an "as is" basis. The user assumes the entire risk of any use made of this information. MSCI, its affiliates and any third party involved in, or related to, computing or compiling the information hereby expressly disclaim all warranties of originality, accuracy, completeness, merchantability or fitness for a particular purpose with respect to any of this information. Without limiting any of the foregoing, in no event shall MSCI, any of its affiliates or any third party involved in, or related to, computing or compiling the information have any liability for any damages of any kind. MSCI, Morgan Stanley Capital International and the MSCI indexes are services marks of MSCI and its affiliates.

Investors should consider this document as only a single factor in making their investment decision and, as such, the report should not be viewed as identifying or suggesting all risks, direct or indirect, that may be associated with any investment decision. Nomura Group produces a number of different types of research product including, among others, fundamental analysis, quantitative analysis and short term trading ideas; recommendations contained in one type of research product may differ from recommendations contained in other types of research product, whether as a result of differing time horizons, methodologies or otherwise. Nomura Group publishes research product in a number of different ways including the posting of product on Nomura Group portals and/or distribution directly to clients. Different groups of clients may receive different products and services from the research department depending on their individual requirements.

Figures presented herein may refer to past performance or simulations based on past performance which are not reliable indicators of future performance. Where the information contains an indication of future performance, such forecasts may not be a reliable indicator of future performance. Moreover, simulations are based on models and simplifying assumptions which may oversimplify and not reflect the future distribution of returns.

Certain securities are subject to fluctuations in exchange rates that could have an adverse effect on the value or price of, or income derived from, the investment. The securities described herein may not have been registered under the US Securities Act of 1933 (the '1933 Act'), and, in such case, may not be offered or sold in the US or to US persons unless they have been registered under the 1933 Act, or except in compliance with an exemption from the registration requirements of the 1933 Act. Unless governing law permits otherwise, any transaction should be executed via a Nomura entity in your home jurisdiction.

This document has been approved for distribution in the UK and European Economic Area as investment research by NIplc, which is authorized and regulated by the FSA and is a member of the London Stock Exchange. It does not constitute a personal recommendation, as defined by the FSA, or take into account the particular investment objectives, financial situations, or needs of individual investors. It is intended only for investors who are 'eligible counterparties' or 'professional clients' as defined by the FSA, and may not, therefore, be redistributed to retail clients as defined by the FSA. This document has been approved by NIHK, which is regulated by the Hong Kong Securities and Futures Commission, for distribution in Hong Kong by NIHK. This document has been approved for distribution in Australia by NAL, which is authorized and regulated in Australia by the ASIC. This document has also been approved for distribution in Malaysia by NSM. In Singapore, this document has been distributed by NSL. NSL accepts legal responsibility for the content of this document, where it concerns securities, futures and foreign exchange, issued by their foreign affiliates in respect of recipients who are not accredited, expert or institutional investors as defined by the Securities and Futures Act (Chapter 289). Recipients of this document in Singapore should contact NSL in respect of matters arising from, or in connection with, this document. Unless prohibited by the provisions of Regulation S of the 1933 Act, this material is distributed in the US, by NSI, a US-registered broker-dealer, which accepts responsibility for its contents in accordance with the provisions of Rule 15a-6, under the US Securities Exchange Act of 1934.

This document has not been approved for distribution in the Kingdom of Saudi Arabia ('Saudi Arabia') or to clients other than 'professional clients' in the United Arab Emirates ('UAE') by Nomura Saudi Arabia, NIplc or any other member of Nomura Group, as the case may be. Neither this document nor any copy thereof may be taken or transmitted or distributed, directly or indirectly, by any person other than those authorised to do so into Saudi Arabia or in the UAE or to any person located in Saudi Arabia or to clients other than 'professional clients' in the UAE. By accepting to receive this document, you represent that you are not located in Saudi Arabia or that you are a 'professional client' in the UAE and agree to comply with these restrictions. Any failure to comply with these restrictions may constitute a violation of the laws of Saudi Arabia or the UAE.

No part of this material may be (i) copied, photocopied, or duplicated in any form, by any means; or (ii) redistributed without the prior written consent of a member of Nomura Group. Further information on any of the securities mentioned herein may be obtained upon request. If this document has been distributed by electronic transmission, such as e-mail, then such transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this document, which may arise as a result of electronic transmission. If verification is required, please request a hard-copy version.

Nomura Group manages conflicts with respect to the production of research through its compliance policies and procedures (including, but not limited to, Conflicts of Interest, Chinese Wall and Confidentiality policies) as well as through the maintenance of Chinese walls and employee training.

Additional information is available upon request. Disclosure information is available at the Nomura Disclosure web page: http://go.nomuranow.com/research/globalresearchportal/pages/disclosures/disclosures.aspx