

# **Year-To-Date and Q3 2016 Results**

Conference call and webcast for investors and analysts, Cambridge, UK

10 November 2016



## **Forward-looking statements**

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This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; effects of patent litigation in respect of IP rights; exchange rate fluctuations; the risk that R&D will not vield new products that achieve commercial success; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful: the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing; the risks associated with manufacturing biologics; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anticompetitive behaviour; the risk that new products do not perform as we expect; failure to achieve strategic priorities or to meet targets or expectations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the risk of misuse of social medial platforms and new technology; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the risks from pressures resulting from generic competition; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; economic, regulatory and political pressures to limit or reduce the cost of our products: the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.



# **Agenda**

Overview	Pascal Soriot
<b>Growth Platforms</b>	Mark Mallon
Finance	Marc Dunoyer
Pipeline	Sean Bohen
Closing and Q&A	Pascal Soriot



### Q3 highlights

### Guidance unchanged; pipeline-driven transformation continues

#### **Business & Financials**

Total Revenue reflects loss of *Crestor* exclusivity and quarterly US *Symbicort* impact/gross-to-net adjustments, lack of *FluMist* and one-off events in Emerging Markets

'New AstraZeneca' grew 6% YTD

- Tagrisso now biggest AZN lung cancer medicine
- Farxiga global SGLT2 leader (42% volume) and largest AZN Diabetes medicine
- Continued strong execution in Emerging Markets
  - #2 in China and fastest growth
  - #3 in Russia

EPS supported by active cost management and one-off tax benefit

- R&D stable despite continued investment in strong pipeline
- SG&A further reduced in line with commitments

A Dow Jones Sustainability leader in Pharmaceuticals/Biotechnology/Life Sciences



## Q3 highlights; continued

### Guidance unchanged; pipeline-driven transformation continues

#### **Pipeline**

### Oncology

- Faslodex: Regulatory submission (JP)
- · Lynparza: Positive Phase III trial
- Tagrisso: Regulatory submission, Priority Review (CN)
- cediranib: Regulatory withdrawal (EU)
- selumetinib: Negative Phase III trial

# Cardiovascular & Metabolic Diseases

- Brilinta: Regulatory approval (JP); Phase III trial in PAD¹ not superior to clopidogrel
- Farxiga + Bydureon: Positive Phase III trial
- ZS-9: Regulatory re-submission (US)

#### Respiratory

Benralizumab: 4th positive Phase III efficacy trial

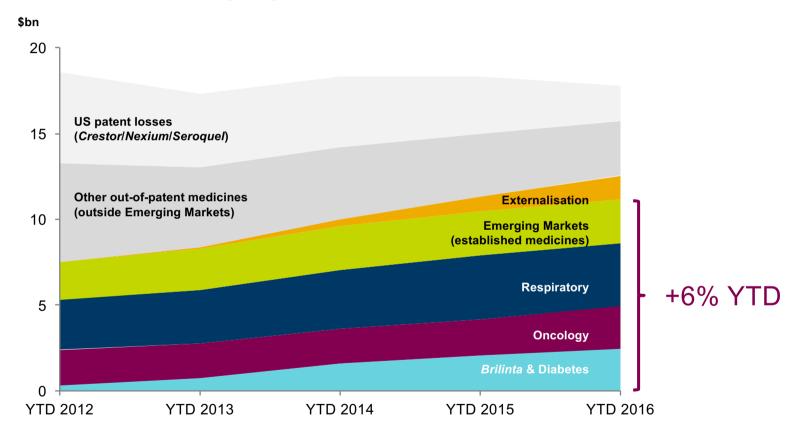
Other

AZD3293 (BACEi): Fast Track (US)



# **Total Revenue: Inflection point approaching**

# New AstraZeneca is emerging from patent losses





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# **Growth Platforms: Robust despite soft Q3**

# Increasing Oncology contribution; Japan stable

		Q3 2016 \$m	% change	% Total Revenue	YTD 2016 \$m	% change	% Total Revenue
	<b>Growth Platforms</b>	3,584	3	63	10,763	6	62
	Emerging Markets	1,395	3	-	4,308	6	-
	Respiratory	1,110	(8)	-	3,543	(2)	-
	Diabetes	606	6	-	1,829	13	-
	Japan	595	0	-	1,593	(2)	-
BRILINT ticagrelor tablets	Brilinta	208	25	-	603	39	-
8	New Oncology <sup>1</sup>	197	n/m	-	448	n/m	-

<sup>1.</sup> New Oncology comprises Lynparza, Iressa (US) and Tagrisso Absolute values at actual exchange rates. Growth rates at CER



# **Growth Platforms: Robust despite soft Q3**

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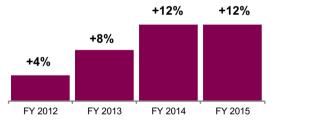


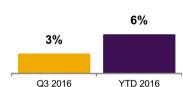
# **Emerging Markets**

### China performing well; softness in other markets

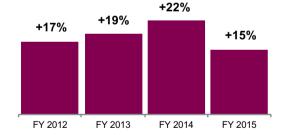
# Long-term target: Mid to high single-digit growth

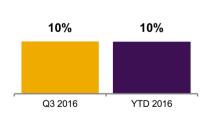
#### **Emerging Markets**





#### China





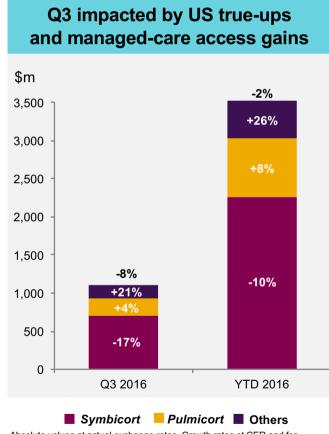
### Good fundamentals; balanced performance

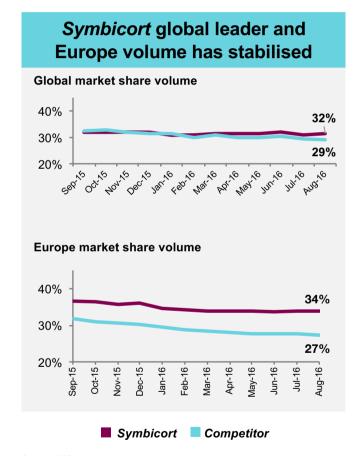
- Balanced presence: China less than half of total. Russia +13%, Brazil +5%
- Established medicines benefiting from patient demographics, better diagnosis and access
- Challenging conditions in some markets
  - Saudi Arabia; Venezuela
- New medicines/pipeline well positioned
  - Tagrisso China regulatory submission complete



## Respiratory

### Symbicort continues as global leader in competitive market





# **US, Europe competitive Emerging Markets growth**

#### **US -11%**

 Volume growth offset by a true-up related to past quarters and managedcare access gains; strategic decision to prepare a platform for future launches incl. Bevespi and benralizumab

#### Europe -7%

- Stable Symbicort competitive environment
- Continued launches of new medicines

#### **Emerging Markets +17%**

- Increase in market uptake continued
  - Pulmicort +20%
  - Symbicort +11%

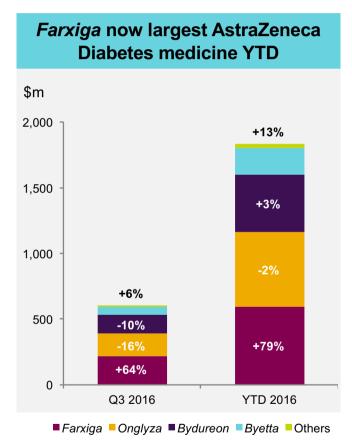
Absolute values at actual exchange rates. Growth rates at CER and for YTD unless otherwise stated

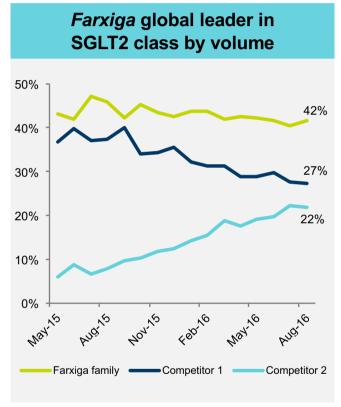
Source: IMS



### **Diabetes**

### Global growth with focus on Farxiga





### **Growth in all regions**

#### US +6%

- Growth market, but intense competition for market share
- Farxiga +78% from improved access and market-share gain

### **Europe +19%**

- Growth in focus medicine Forxiga, and Bydureon
- Forxiga leading the SGLT2 class

### **Emerging Markets +36%**

Strong growth in all medicines;
 Forxiga +120%

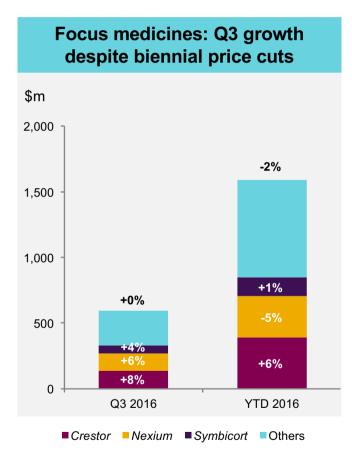
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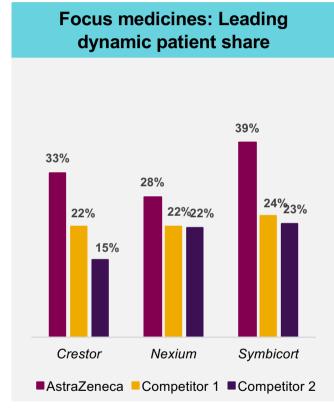
Volume PDOT (Patient Days On Therapy) Source: IMS Health MIDAS, August 2016



## **Japan**

### Performance recovered after the April price cuts





# **New medicines starting to transform Japanese business**

- Tagrisso launched in May;
  2,400 patients treated
- Product Sales accelerated;
   Q3: \$28m; Q2: \$15m
- Brilinta approved in September (limited label from launch)

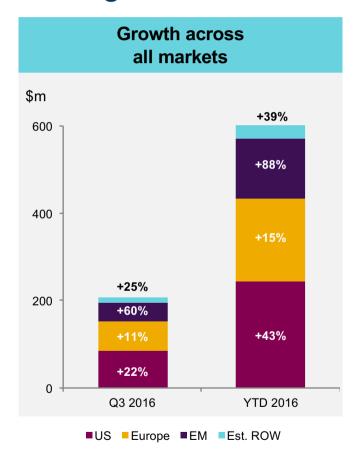
Long-term target: Low single-digit growth

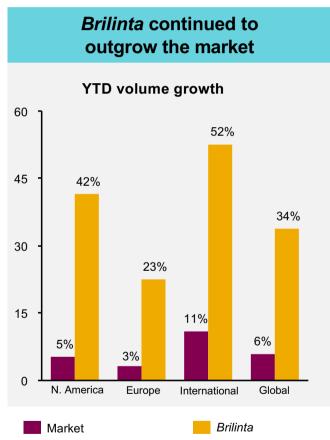




### **Brilinta**

### Solid growth continues





# Strong execution of lifecycle management

#### US

- Lower quarterly growth reflecting inventory increase Q3 2015
- Positive momentum from changes to competitor's label
- 60mg now ~10% of new prescriptions

#### **Europe**

- Broad increase in hospital-discharge share and market-share gains
- 60mg launched in most of Europe

#### **Emerging Markets**

 109% growth in China, with NRDL¹ review underway

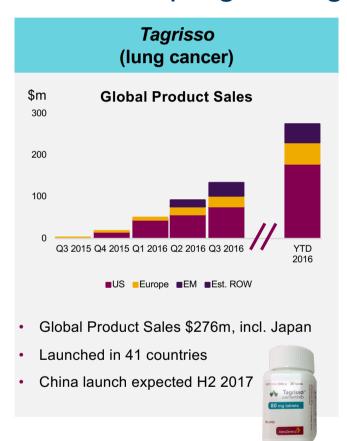
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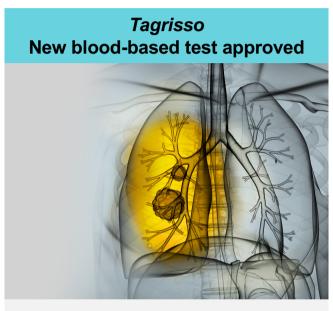
Source: IMS Health MIDAS, data updated to August 2016 Oral anti-platelet medicines, days of therapy



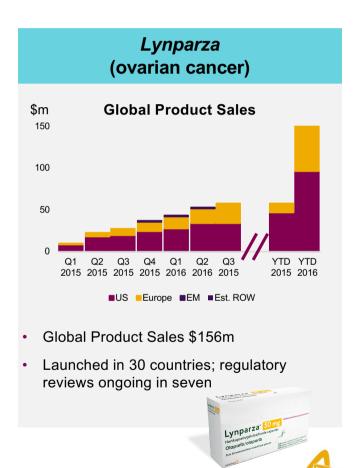
# **New Oncology**

### Launches progressing well





- Current US T790M testing rate >40%; still ~40% chemotherapy use in 2nd-line setting
- US approval of less-invasive ctDNA test in September<sup>1</sup>



1. cobas® EGFR Mutation Test v2 (US-IVD)
Absolute values at actual exchange rates. Growth rates at CER

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# **Reported Profit & Loss**

	YTD 2016 \$m	% change	% Total Revenue	Q3 2016 \$m	% change	% Total Revenue
Total Revenue	17,417	(3)		5,699	(4)	
Product Sales	16,059	(6)	92	5,025	(14)	88
Externalisation Revenue	1,358	56	8	674	617	12
Gross Margin	82%	+63bps	-	82%	-165bps	-
R&D Expense	(4,347)	5	25	(1,402)	4	25
SG&A Expense	(8,027)	(2)	46	(2,403)	(8)	42
Other Operating Income	535	(47)	3	110	(75)	2
Tax Rate	(16)%			(47)%		





### **Core Profit & Loss**

# Other Income weighted towards Q4

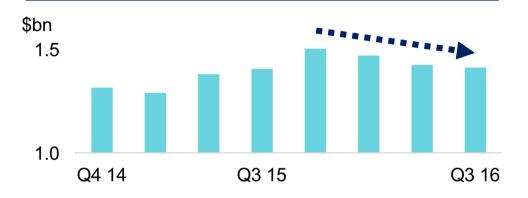
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Product Sales	16,059	(6)	92	5,025	(14)	88
Externalisation Revenue	1,358	56	8	674	617	12
Gross Margin	83%	-90bps	-	84%	-47bps	-
R&D Expense	(4,150)	6	24	(1,337)	0	23
SG&A Expense	(6,119)	(7)	35	(1,892)	(12)	33
Other Operating Income	575	(43)	3	107	(76)	2
Tax Rate	8%			(9)%		



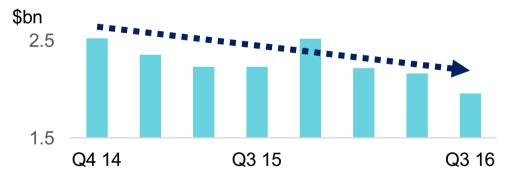


## Continued progress and focus on cost discipline

### Decline in Core R&D costs from Q4 2015 as committed



### Core SG&A cost reduction being steadily delivered



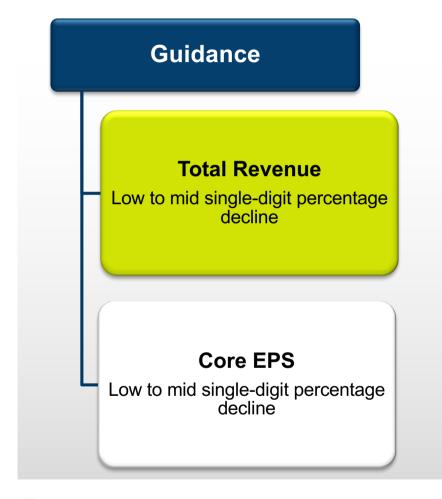
- Stable Core costs in Q3 2016
- Investment focused on a number of potential medicines in pivotal trials

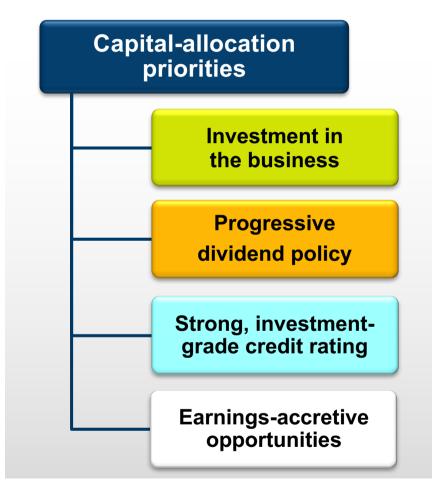
- A 12% reduction on Core costs in Q3 2016
- Particular progress in the US business
- >200 basis-point YTD reduction in the ratio to Total Revenue



Absolute values at CER (2016)

# FY 2016 guidance and capital-allocation guidance







# **Agenda**

Closing and Q&A	Pascal Soriot	
Pipeline	Sean Bohen	
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<b>Growth Platforms</b>	Mark Mallon	
Overview	Pascal Soriot	



# Q3 late-stage pipeline highlights

### Main therapy areas

### **Oncology**

- Faslodex breast cancer (1st line):
   Regulatory submission (JP)
- Lynparza ovarian cancer (2nd line):
   Positive Phase III trial
- Tagrisso lung cancer:
   Regulatory submission, Priority
   Review Designation (CN)
- cediranib ovarian cancer:
   Regulatory submission withdrawal (EU)

# Cardiovascular & Metabolic Diseases

- Brilinta CV disease:
  - -Regulatory approval (JP)
  - -Phase III PAD¹ trial did not show superiority to clopidogrel
- Farxiga + Bydureon type-2 diabetes: Positive Phase III trial
- ZS-9 hyperkalaemia: Regulatory re-submission (US)



### Respiratory

 benralizumab - severe, uncontrolled asthma: 4th positive Phase III efficacy trial (ZONDA)<sup>2</sup>



#### **Other - Neuroscience**

AZD3293 - Alzheimer's disease:
 Fast Track Designation (US)



<sup>1.</sup> PAD = Peripheral Artery Disease

A total of five Phase III trials have reported: BISE, CALIMA, SIROCCO, GREGALE (safety), ZONDA Status since the prior results announcement on 28 July 2016

### **Tagrisso**

## Strong foundation for industry leadership in EGFRm NSCLC

# AURA3 data accepted at World Conference on Lung Cancer (Dec.)

#### **News Release**



TAGRISSO MET PRIMARY ENDPOINT IN PHASE III 2ND-LINE LUNG CANCER TRIAL

Tagrisso demonstrated superior progression-free survival compared to standard platinum-based chemotherapy, with a safety profile consistent with previous trials

First randomised trial to evaluate the clinical benefit of an EGFR T790M medicine, and data are consistent with those supporting Tagrisso approvals

18 July 2016



### Tagrisso forthcoming news flow

#### **Regulatory decisions**

H2 2017 China

#### **Regulatory submissions**

Q4 2016

AURA3 (2nd-line T790M) (US, EU)

#### Key data readouts

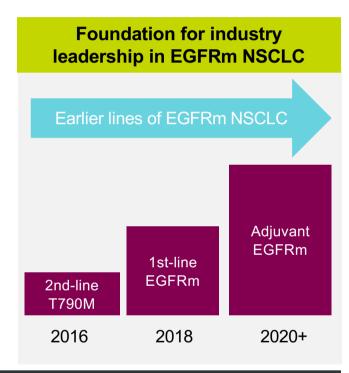
2017

H1: BLOOM (leptomeningeal disease)

H2: FLAURA (1st line)

2020+

ADAURA (adjuvant)



Ambition: Tagrisso as standard of care for EGFRm NSCLC



# ESMO<sup>1</sup> 2016 take-away messages

### Advancement in next-generation Oncology treatments

Immuno-Oncology

Durvalumab: Study 1108 (NSCLC cohort) show impressive monotherapy efficacy Durva + next-gen IO<sup>2</sup>: Combinations with STAT3 / CXCR2 in HNSCC<sup>3</sup>, other solid tumours Next-gen IO: Activated OX40 promotes the survival and proliferation of T-cells



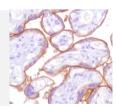
**Faslodex** FALCON t

FALCON trial showed efficacy in HR+ 1st-line metastatic breast cancer Phase II plans to investigate the addition of durvalumab in triple-negative breast cancer



PD-L1 diagnostic assays

Comparative analysis of PD-L1 diagnostic assays in ~500 HNSCC tumour samples



- 1. ESMO = European Society for Medical Oncology
- 2. IO = Immuno-Oncology
- 3. HNSCC = Head & Neck Squamous Cell Carcinoma



# Immuno-Oncology: AstraZeneca's path to market

Key Phase III data coming soon; H1 2017 key to success

	= durvalumab
	= durva + treme
<b>/</b>	= fully recruited

Bladder cancer				<b>DANUBE</b> 1st-line bladder
		MYSTIC 1st line (PFS)		MYSTIC 1st line (OS)
Lung cancer		ARCTIC 3rd line PD-L1 neg.	PACIFIC Stage III unresectable	NEPTUNE 1st line (OS)
Head & Neck cancer	HAWK (Phase II) <sup>1,2</sup> 2nd line PD-L1 pos.	CONDOR (Phase II) <sup>1</sup> 2nd line PD-L1 neg.	KESTREL 1st line	EAGLE 2nd line
	Q4 2016	H1 2017	H2 2017	2018

Potential leadership in IO-IO combinations across multiple cancer types

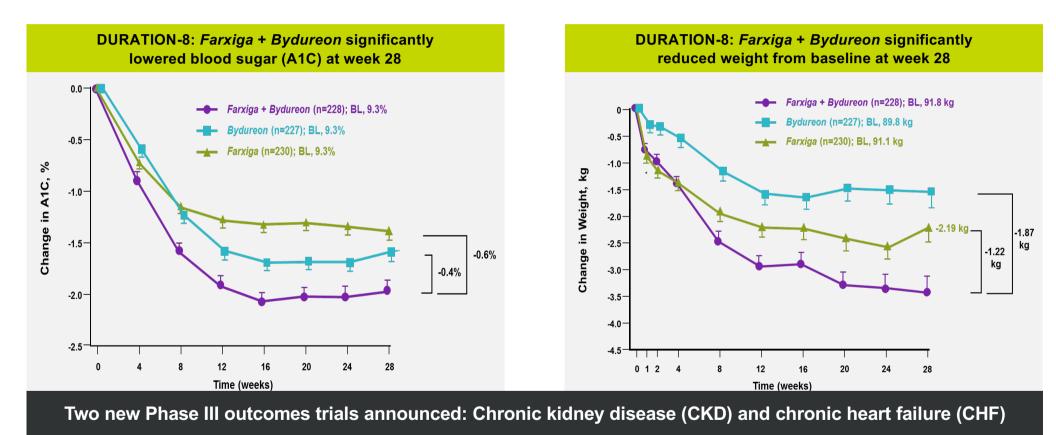


<sup>1.</sup> Potential fast-to-market opportunity ahead of randomised, controlled trials

<sup>2.</sup> Internal data availability

### **Diabetes franchise**

### Farxiga primary focus





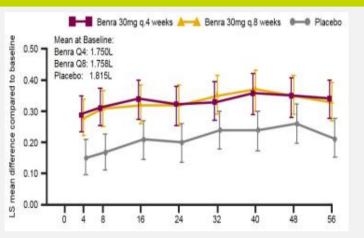
# Respiratory biologics

### Benralizumab has best-in-disease potential

#### **Benralizumab:** Differentiated profile for severe, uncontrolled asthma

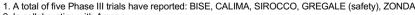
- Reduced annual asthma exacerbation rates (up to 51%)
- Reduced corticosteroid use (ZONDA: 4th positive Phase III efficacy trial)1
- Sustained improvements in lung function
- · Improved daily asthma symptoms and quality of life
- Convenient 8-week dosing in pre-filled syringe
- On track for Q4 2016 US/EU regulatory submissions

### SIROCCO and CALIMA demonstrated sustained lung-function improvement



### Pipeline of first-in-class/disease biologics on track

- Tralokinumab: (anti-IL13; mediator in ~50% of severe, uncontrolled asthma cases): Phase III data readout H2 2017
- Tezepelumab<sup>2</sup>: (anti-TSLP/epithelial cytokine-targeting): Phase II data readout H1 2017



<sup>2.</sup> In collaboration with Amgen



# Pipeline news flow in 2016 & 2017

# Realising potential of new medicines

	Q4 2016	H1 2017	H2 2017
Regulatory decisions	-	Faslodex - breast cancer (1st line) (JP) saxa/dapa - type-2 diabetes (US) ZS-9 - hyperkalaemia (US, EU) brodalumab - psoriasis (US, EU)	Tagrisso - lung cancer (CN)
Regulatory submissions	Tagrisso - lung cancer (US, EU) (AURA3) roxadustat - anaemia (CN) benralizumab - severe, uncontrolled asthma (US, EU)	Faslodex - breast cancer (1st line) (US, EU) Lynparza - ovarian cancer (2nd line) durva + treme - head&neck cancer (CONDOR)¹ (US) acalabrutinib - blood cancer (US)¹ Bydureon - autoinjector (US) benralizumab - severe, uncontrolled asthma (JP)	Lynparza - breast cancer durvalumab - lung cancer (PACIFIC) (US) durva + treme - lung cancer (MYSTIC) - lung cancer (ARCTIC)
Key Phase III/II* data readouts  1. Potential fast-to-market opportunity ahead of 2. AstraZeneca-sponsored trial	randomised, controlled trials	Lynparza - breast cancer durva + treme - lung cancer (MYSTIC) - lung cancer (ARCTIC) - head & neck cancer (CONDOR)*1 acalabrutinib - blood cancer*1	Lynparza - ovarian cancer (1st line) Tagrisso - lung cancer (1st line) durvalumab - lung cancer (PACIFIC) durva + treme - head & neck cancer (KESTREL) moxetumomab - leukaemia roxadustat - anaemia² tralokinumab - severe, uncontrolled asthma

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## Pipeline-driven transformation on track

New AstraZeneca emerging from patent cliff

- Financials on track; unchanged guidance for the year
- 13 new potential medicines in Phase III/under registration
- Oncology progressing ahead of expectations
  - Tagrisso
  - Immuno-Oncology
- Busy news flow over next 12 months





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