

# H1 2016 Results

28 July 2016



### **Forward-looking statements**

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement:

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>	Luke Miels
Finance	Marc Dunoyer
Pipeline	Sean Bohen
Closing	Pascal Soriot



## **Q2** highlights

### On track for the year; Oncology progressing very rapidly

### Financials: On track with full-year guidance

Total Revenue reflects patent expiries and phasing of Externalisation Revenue R&D investment stabilising and SG&A declining in line with commitments EPS impacted by *FluMist* inventory write-down

### **Pipeline: Continued progression**

#### Oncology

- Tagrisso: Positive Phase III
- · Faslodex: Positive Phase III
- IO: Very rapid IO-IO combination recruitment; Phase III MYSTIC and ARCTIC fully recruited
- Lynparza: Fast Track Designation (US)

# Respiratory & Autoimmunity

- Benralizumab: Two positive Phase III
- Brodalumab: FDA Advisory Committee positive recommendation

# Cardiovascular & Metabolic Diseases

- Qtern (saxa/dapa): Approval (EU); resubmission acceptance (US)
- ZS-9: Complete Response Letter (US)
- · Brilinta: Phase III THEMIS fully recruited



# Building a pure-play innovator in three therapy areas

Focusing and slimming down portfolio to optimise resource allocation

1. Accessing Therapy Area (TA) capability / upside

- **BACE** inhibitor
- **Brodalumab**
- Tralokinumab (AD1)
- Durvalumab (haematology)



Recurring revenue



- 2. Increasing commercial reach
- Movantik/Moventig
- ✓ Plendil
- ✓ Anaesthetics

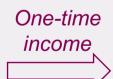
**Dividend** commitment

**R&D** investment

in main TAs

3. Streamlining portfolio / divestment

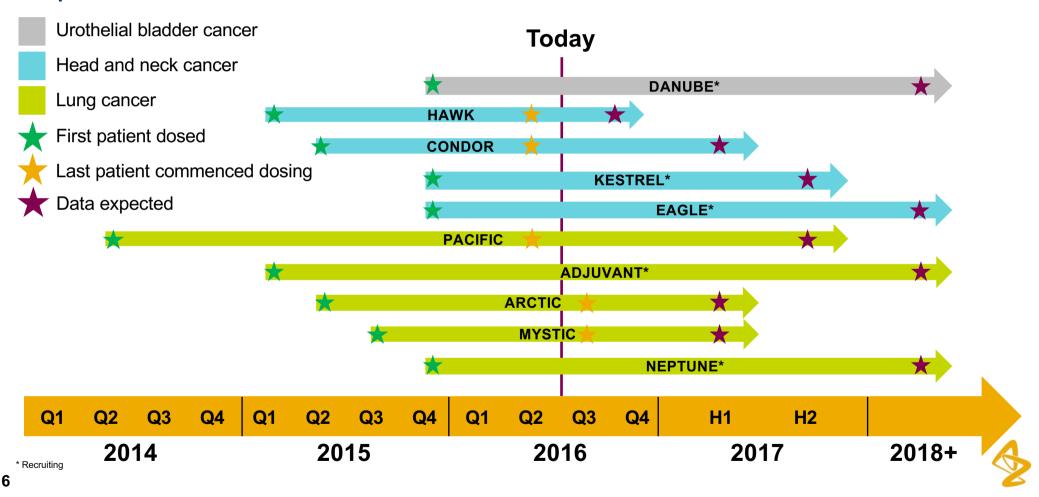
- Myalept
- ✓ Imdur





## **Strong momentum in Immuno-Oncology**

### Unprecedented recruitment into IO clinical trials



### **Growth Platforms**



#### **Luke Miels**

EVP, Global Product & Portfolio Strategy, Global Medical Affairs and Corporate Affairs



# **Growth Platforms: Continuing progress**

### Now account for more than 60% of Total Revenue

		Q2 2016 \$m	% change	% Total Revenue	H1 2016 \$m	% change	% Total Revenue
	<b>Growth Platforms</b>	3,744	8	67	7,179	7	61
Egents quarter parameter.	Emerging Markets	1,448	9	-	2,913	7	-
	Respiratory	1,226	1	-	2,433	1	-
	Diabetes	645	13	-	1,223	18	-
	Japan	569	1	-	998	(3)	-
BRILINT ticagrelor tablets	A. Brilinta	214	51	-	395	48	-
\$	New Oncology	152	n/m	-	251	n/m	-



# **Growth Platforms: Continuing progress**

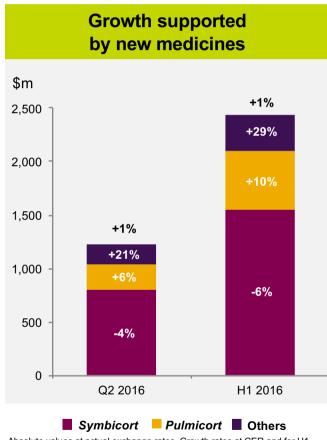
### Now account for more than 60% of Total Revenue

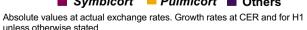
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Diabetes	645	13	-	1,223	18	-
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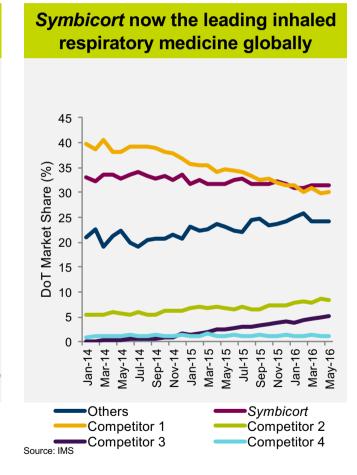


### Respiratory

### Emerging Markets offsetting performance in established regions







### **US.** Europe competitive **Emerging Markets strength**

#### **US -2%**

- Overall solid volume growth offset by managed-care implementation
- New medicine *Daliresp* doing well

#### Europe -11%

- Overall lower market growth; unchanged price pressure
- New bronchodilators Duaklir, Eklira grew nicely

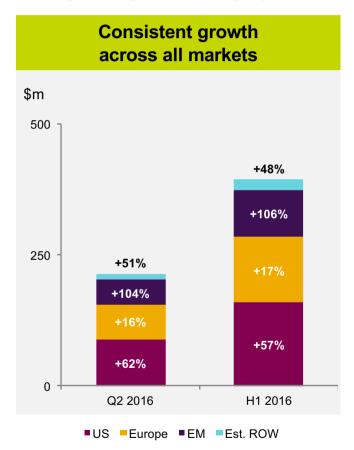
#### **Emerging Markets +23%**

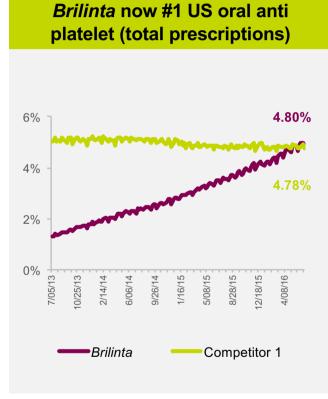
- Increase in penetration continued
  - Pulmicort +23%
  - Symbicort +25%



### **Brilinta**

### Ongoing strong growth





# Global execution of lifecycle management

#### US

 New ACC/AHA guidelines (preferred over clopidogrel in ACS) supported stronger growth

#### **Europe**

 Encouraging performance supported by indication leadership across markets and the post-MI approval

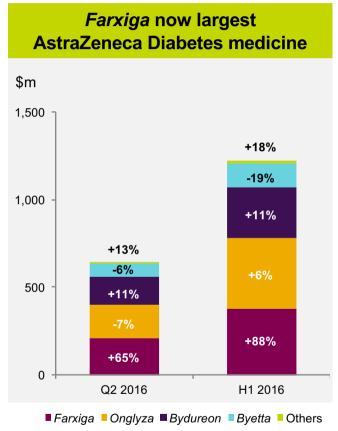
#### **Emerging Markets**

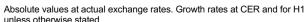
 China largest market and strongest growth (+181%) driven by improved and innovative market access

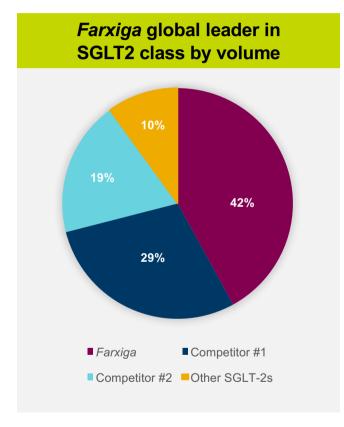


### **Diabetes**

### Global franchise growth







### **Encouraging growth in all regions**

#### US +9%

- Growing market with competition for market share
- Farxiga +82% from improved access

#### **Europe +27%**

- Growth across all classes; benefit from increased market presence
- Forxiga leading the SGLT2 class

#### **Emerging Markets +44%**

Strong growth in oral medicines;
 Forxiga +135%, Onglyza +16%

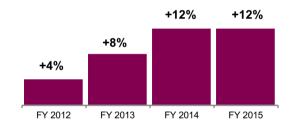


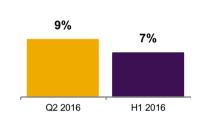
## **Emerging Markets**

### Growth on track

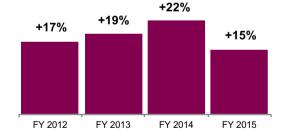
### **Meeting the long-term target**

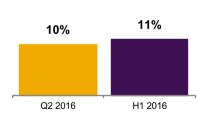
#### **Emerging Markets**





#### China





### **Broad-based performance**

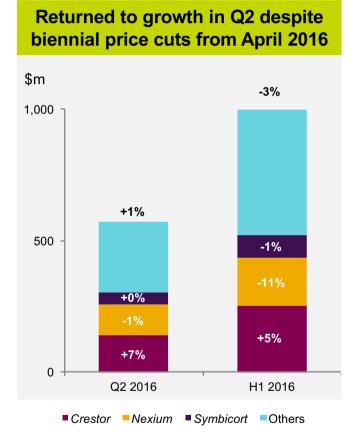
- Established portfolio benefiting from better diagnosis, access and patient demographics/trends
- Balanced presence: Less than half of Product Sales in China. Brazil +13%, Russia +12%
- Challenging conditions in some Latin-American and Middle-Eastern markets
- New medicines and pipeline well-positioned for emerging patient needs
  - Tagrisso China regulatory submission H2 2016

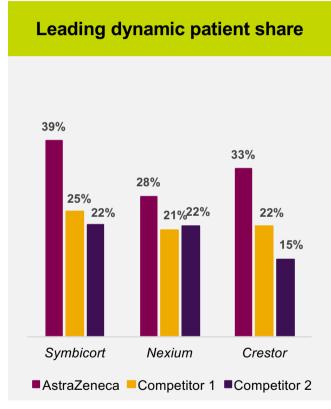
Long-term target: Mid-to-high single-digit growth



## **Japan**

### Performance recovering from April price cuts





# **Established medicines being supported by New Oncology**

- Improving market rank despite competitive challenges; now #6 company, up from #8 in 2015
- Tagrisso launched 25 May; initial uptake encouraging (Q2 Product Sales \$15m)

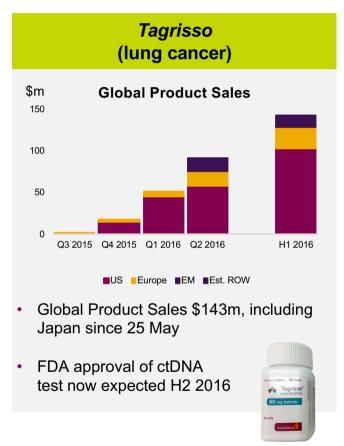
**Long-term target**: Low single-digit growth

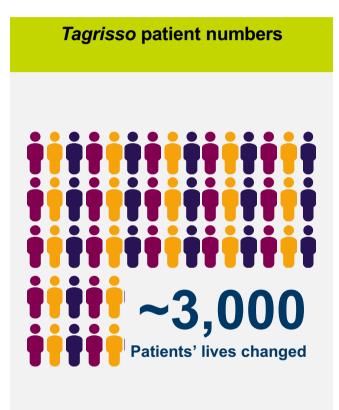


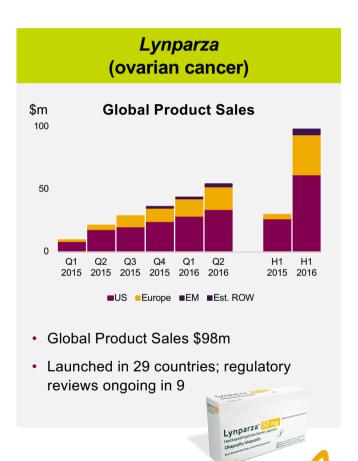


### **New Oncology**

### Launches progressing well







Absolute values at actual exchange rates. Growth rates at CER and for H1 unless otherwise stated

### **Finance**



### **Marc Dunoyer**

Chief Financial Officer



# **Reported Profit & Loss**

\$0.51

(45)

**Reported EPS** 

17

	H1 2016 \$m	% change	% Total Revenue	Q2 2016 \$m	% change	% Total Revenue
Total Revenue	11,718	(3)		5,603	(10)	
Product Sales	11,034	(2)	94	5,469	(5)	98
Externalisation Revenue	684	(12)	6	134	(72)	2
Cost Of Sales Gross Profit	(2,066) 9,652	(11) (1)	18 82	(1,062) 4,541	(2) (12)	19 81
R&D Expense	(2,945)	6	25	(1,465)	1	26
SG&A Expense	(5,624)	-	48	(3,052)	5	54
Tax Rate	14%			(3)%		



\$0.00

(99)

### **Core Profit & Loss**

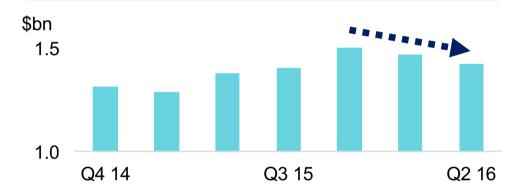
# Phasing of Externalisation Revenue; cost discipline progressing

	H1 2016 \$m	% change	% Total Revenue	Q2 2016 \$m	% change	% Total Revenue
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Product Sales	11,034	(2)	94	5,469	(5)	98
Externalisation Revenue	684	(12)	6	134	(72)	2
Cost Of Sales	(1,980)	5	17	(1,014)	3	18
<b>Gross Profit</b>	9,738	(4)	82	4,589	(13)	82
R&D Expense	(2,813)	9	24	(1,384)	3	25
SG&A Expense	(4,227)	(5)	36	(2,100)	(3)	37
Tax Rate	17%			17%		
Core FPS	\$1.78	(20)		\$0.83	(31)	

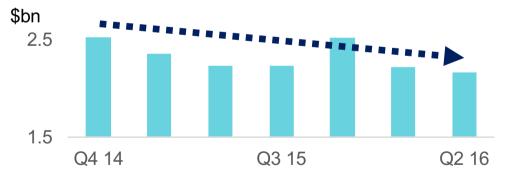


## Continued progress and focus on cost discipline

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



Core SG&A cost reduction being steadily delivered



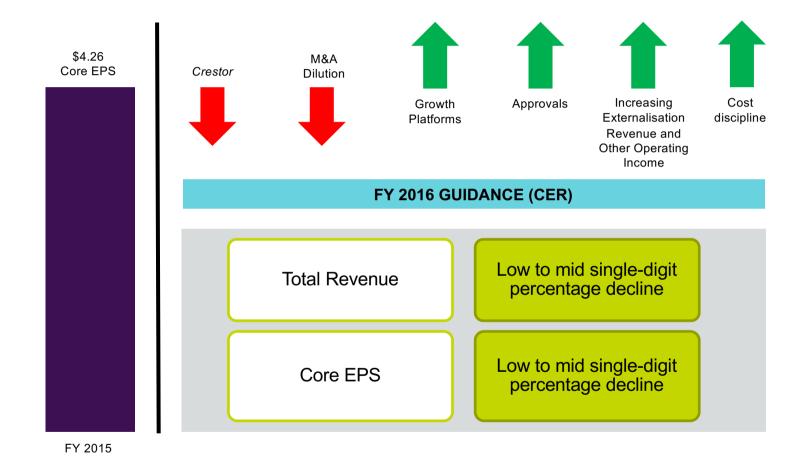
- Consistent sequential declines in Core R&D costs
- Investment reflected the number of potential medicines in pivotal trials

- Efficiency savings in sales and marketing operations
- Further reductions in IT costs



Absolute values at CER (2016)

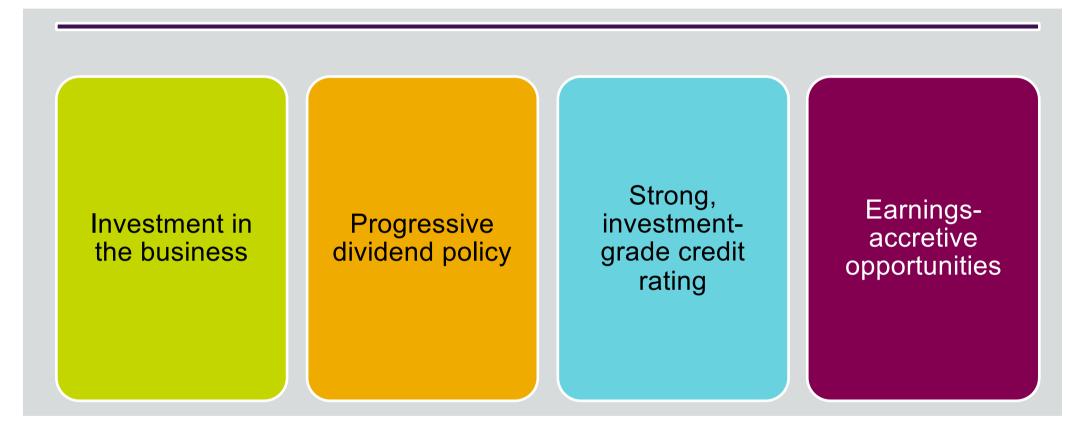
# A year of challenges and opportunities







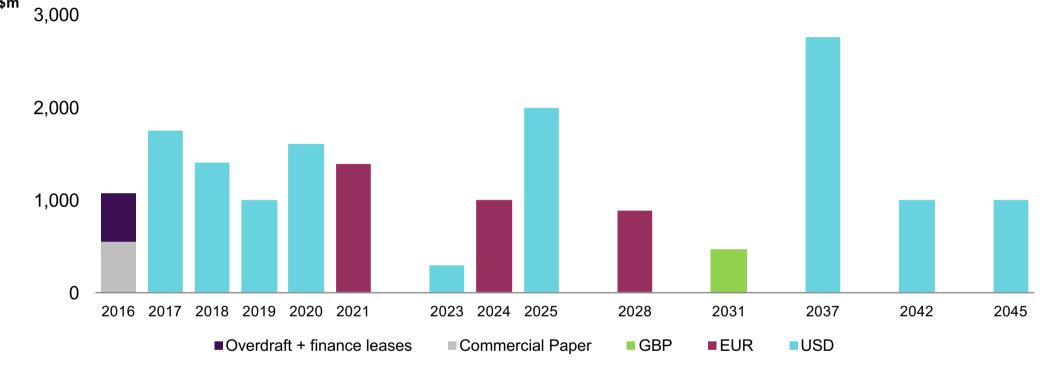
# **Capital-allocation priorities**





## **Debt profile and credit ratings**





Moody's: A3 Stable outlook

– Standard & Poor's: A- Stable outlook

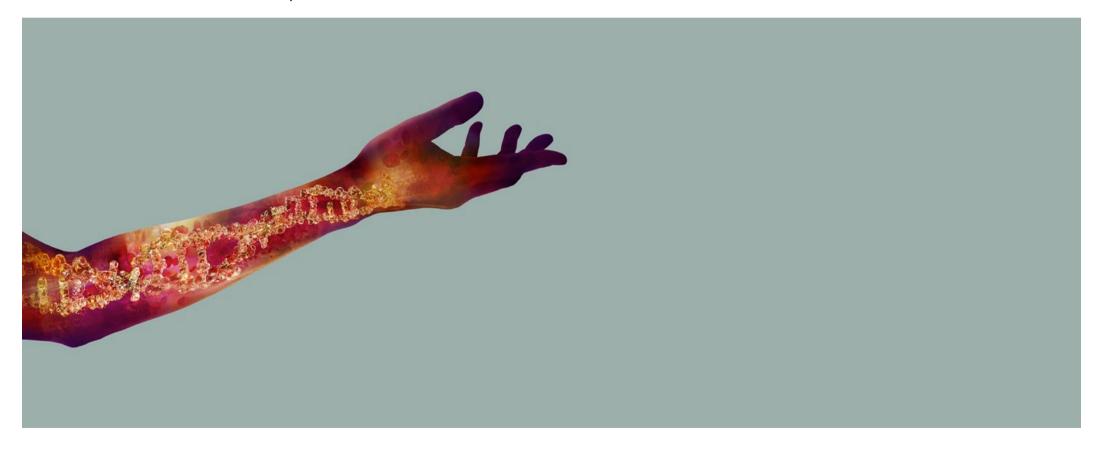


# **Pipeline**



### Sean Bohen

EVP, Global Medicines Development & Chief Medical Officer



### **Q2** late-stage pipeline headlines

### Main therapy areas

### **Respiratory & Autoimmunity**

- benralizumab severe asthma:
   Two positive Phase III trials
- brodalumab psoriasis: FDA Advisory Committee unanimously recommends approval



# Cardiovascular & Metabolic Diseases

- Brilinta CV disease: Phase III THEMIS trial fully recruited
- Qtern & saxa/dapa type-2 diabetes: Approval (EU); resubmission acceptance (US)
- ZS-9 hyperkalaemia: Complete Response Letter (US)



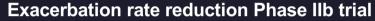
### **Oncology**

- Faslodex breast cancer: Positive Phase III trial (1st-line mBC HR+)
- Lynparza
  - gastric cancer: Phase III endpoints not met
  - 2nd-line ovarian cancer: Fast Track Designation (US)
- Tagrisso lung cancer: Positive Phase III trial (2nd-line confirmatory trial)
- selumetinib differentiated thyroid cancer: Orphan Drug Designation (US)
- durva + treme lung cancer: Phase III MYSTIC, ARCTIC trials fully recruited

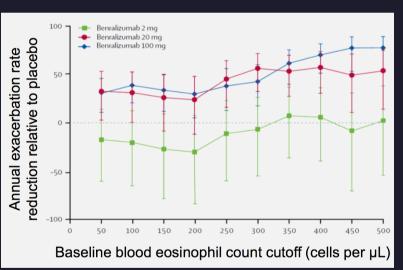


### **Benralizumab**

Potential best-in-disease eosinophil-depleting antibody for severe asthma



- Reduction in eosinophils and asthma exacerbation
- Improvement in overall lung function
- Simple, convenient dosing and administration



Phase III trial results expected at the European Respiratory Society meeting



## **ASCO 2016 take-away messages**

### Well-positioned with deep and broad pipeline

Immuno-Oncology

Durvalumab: Strong data in 2nd line; PDL1-positive bladder cancer
Durva + treme: IO-IO combo supported by competitor data; key newsflow from H1 2017



Lynparza and DNA Damage Response (DDR)

Lynparza: Study 19 with compelling early survival data in ovarian cancer; lifecycle on track AZD1775 (Wee1) and subsequent DDR medicines advancing fast in the clinic



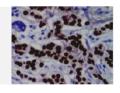
Tagrisso (lung cancer)

BLOOM trial showed efficacy in CNS disease, a key differentiator Early 1st-line data encouraging; lifecycle development with 1st-line data in 2017



**Haematology** 

Acalabrutinib: Impressive efficacy in front-line CLL with a differentiated safety profile Celgene collaboration on track and first clinical trials have initiated





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# Immuno-Oncology: AstraZeneca's path to market

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

= durvalumab
= durva + treme
= fully recruited

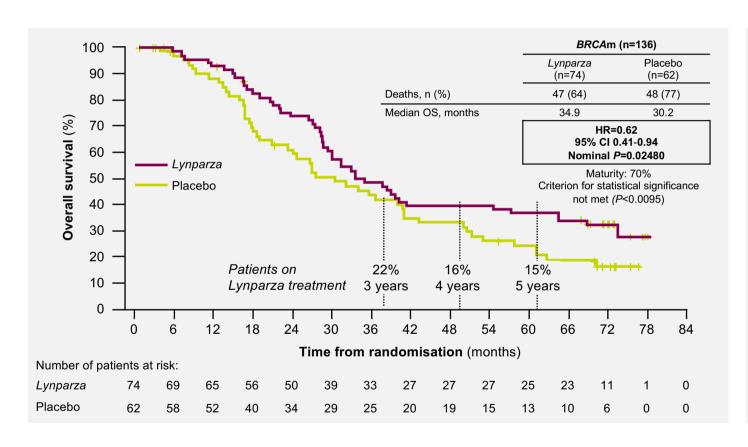
Bladder cancer				<b>DANUBE</b> 1st-line bladder
		MYSTIC 1st line (PFS)		MYSTIC 1st line (OS)
Lung cancer		ARCTIC 3rd line PD-L1 neg.	PACIFIC Stage III unresectable	NEPTUNE 1st line (OS)
Head & Neck cancer	HAWK (Phase II)¹ 2nd line PD-L1 pos.	CONDOR (Phase II) <sup>1</sup> 2nd line PD-L1 neg.	KESTREL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

Potential leadership in IO-IO combinations across multiple cancer types

<sup>1</sup> 

## Lynparza: Ovarian cancer

### Early long-term survival in BRCA-mutated patients



- First PARP inhibitor to show long-term overall survival data
- Long-term responders indicate Immuno-Oncology-like benefit with 15% of patients on treatment for five years
- sBRCA-mutated patients show similar benefit to gBRCA
- Future patient selection to be based on HRRm test, including BRCAwt/HRRm patients (~8% of all ovarian cancer patients)



Source: ASCO 2016, abstract 5501

### DDR: Beyond Lynparza

Establish Lynparza

leadership as monotherapy

Advancing chemotherapy-free options, extending survival

Launch AZD1775 (Wee1) monotherapy and combination

Expand *Lynparza* beyond BRCA

Launch *Lynparza* combinations

Deliver next-generation DDR medicines (AZD0156, AZD2811, AZD6738 and others)

Scientific leadership in DDR

2016 - 2018 2019 - 2021 2022 - 2025



# Pipeline newsflow in 2016 & 2017

# Realising potential of new medicines

	H2 2016	H1 2017	H2 2017
Regulatory decisions	cediranib - ovarian cancer (EU) brodalumab - psoriasis (US)	brodalumab - psoriasis (EU) saxa/dapa - type-2 diabetes (US) ZS-9 - hyperkalaemia (EU)	-
Regulatory submissions	benralizumab - severe asthma (US, EU) ZS-9 - hyperkalaemia (US) roxadustat - anaemia (CN) Tagrisso - lung cancer (CN) acalabrutinib - blood cancer (US) <sup>1</sup>	Brilinta - PAD <sup>2</sup> Lynparza - breast, ovarian (2nd line) cancers selumetinib - lung cancer durvalumab - head & neck cancer (HAWK) <sup>1</sup> (US) durva + treme - head&neck cancer(CONDOR) <sup>1</sup> (US)	Lynparza - ovarian cancer (1st line) durvalumab - lung cancer (PACIFIC) (US) durva + treme - lung cancer (MYSTIC, ARCTIC)
Key Phase III/II* data readouts  1. Potential fast-to-market opportunity ahead of 2. PAD = Cardiovascular outcomes in Periphera 3. AstraZeneca-sponsored trial		durva + treme - head & neck cancer (CONDOR)*1 - lung cancer (MYSTIC, ARCTIC)	tralokinumab - severe asthma roxadustat - anaemia³ Lynparza - ovarian cancer (1st line) Tagrisso - lung cancer (1st line) durvalumab - lung cancer(PACIFIC) durva + treme - head & neck cancer (KESTREL) moxetumumab - leukaemia

# Closing



### **Pascal Soriot**

**Chief Executive Officer** 



## Pipeline-driven transformation on track

- Financials on track reconfirming guidance for the year
- 14 new potential medicines in Phase III/under registration
- Oncology pipeline progressing very rapidly, in particular IO-IO combination programmes
- Strong newsflow over next 18 months





# H1 2016 Results

28 July 2016

