

# Q1 2018 Results

Conference call and webcast for investors and analysts

18 May 2018



## Forward-looking statements

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and Chief Medical Officer



# **Agenda**



Overview



**Oncology** 



**CVRM**, Respiratory, EMs



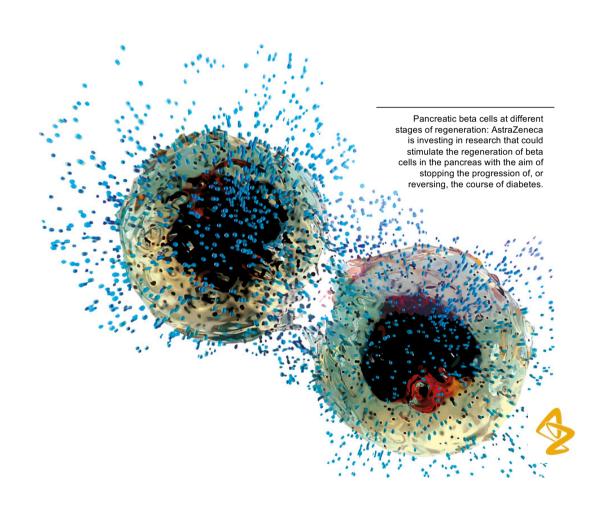
**Finance** 



Pipeline and news flow



**Closing and Q&A** 



# Encouraging launches underpin 2018 return to growth The pipeline-driven transformation of AstraZeneca continues

#### **Business & financials**

#### Product Sales declined 2%, as anticipated

- Strong performance by newer medicines (+66%) and China
- Impact of EU/JP loss of Crestor exclusivity and divestments (~2%)

Total Revenue declined 9% due to lower Initial Externalisation Revenue

#### Newer medicines show strength: >\$0.4bn additional sales vs. Q1 2017¹ and 66% growth

- Oncology: +33%; strong performances from Lynparza, Tagrisso and Imfinzi
- New CVRM<sup>2</sup>: +8%; Brilinta (+24%); Farxiga (+39%)
- Respiratory: -6%; Symbicort competition and Pulmicort supply delay in China; Fasenra off to a strong start
- Emerging Markets: +8%
  - China: +22%; record \$1bn quarter

#### Core EPS \$0.48. 2018 guidance reiterated

#### More-focused, pharma-sized biopharmaceutical company: Seroquel divested in some international markets

Absolute values at actual exchange rates; change at CER and for Q1 2018, unless otherwise stated. Guidance at CER.



<sup>1.</sup> Lynparza, Tagrisso, Imfinzi, Calquence, Brilinta, Farxiga, Bevespi and Fasenra. Absolute growth at Constant Exchange Rates (CER) versus Q1 2017.

<sup>2.</sup> Cardiovascular, Renal and Metabolic diseases.

# The pipeline continues to deliver

## Q1 highlights from late-stage pipeline

#### Pipeline news

Oncology	<ul><li>Lynparza</li><li>Tagrisso</li></ul>	ovarian cancer 2L; tablets breast cancer lung cancer 1L	Approval (EU) Regulatory submission acceptance (EU) Approval (US) CHMP positive opinion (EU) Priority review status (JP)
	• Imfinzi • Imfinzi + treme	unresectable Stage III NSCLC¹ lung cancer 3L (ARCTIC)	Approval (US) Did not meet primary endpoints in PDL1- low/neg. patients
	<ul><li>moxetumomab pasudotox</li><li>selumetinib</li></ul>	hairy cell leukaemia 3L neurofibromatosis type 1	Regulatory submission acceptance (US) Priority Review (US) Orphan Drug Designation (US)
Cardiovascular, Renal and Metabolic	<ul><li>Forxiga</li><li>Lokelma (ZS-9)</li></ul>	type-1 diabetes hyperkalaemia	Regulatory submission acceptance (EU) Approval (EU)
Respiratory	• Fasenra	COPD <sup>2</sup> (GALATHEA)	Did not meet primary endpoint

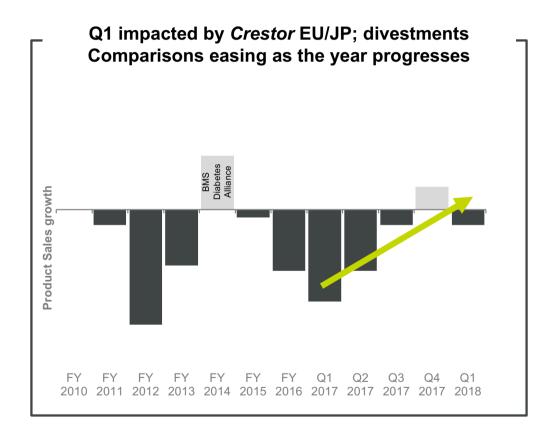
<sup>1.</sup> Non-small cell lung cancer.

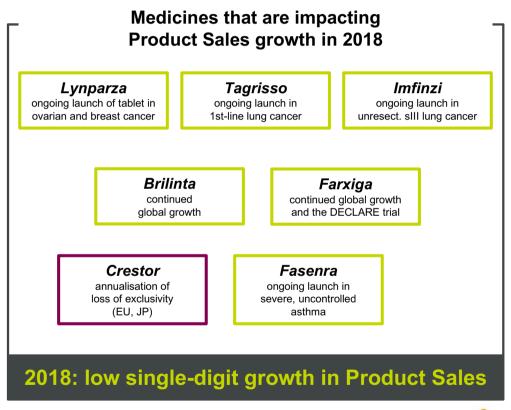


<sup>2.</sup> Chronic obstructive pulmonary disease. Status since the latest results announcement on 2 February 2018.

# 2018: return to growth on track

#### Momentum to improve during the year







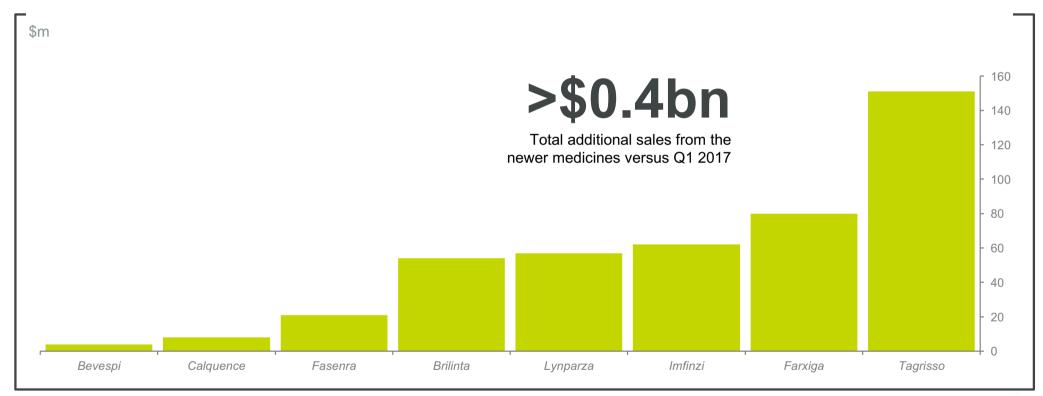
# Product Sales: Oncology and China were the key drivers Overall performance impacted by *Crestor* EU / JP and divestments

	Q1 2018 \$m	% change	% Product Sales
Product Sales	4,985	(2)	100
Oncology	1,230	33	25
New CVRM	900	8	18
Respiratory	1,181	(6)	24
Other	1,674	(19)	34
Emerging Markets	1,765	8	35
-of which China	1,025	22	21



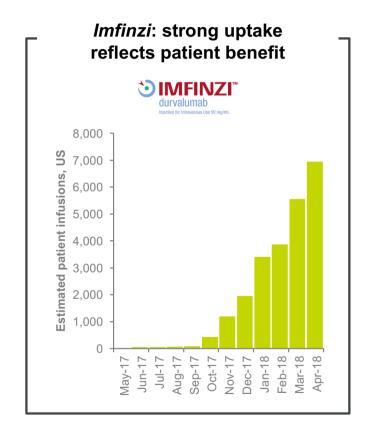
# Product Sales: newer medicines show strength

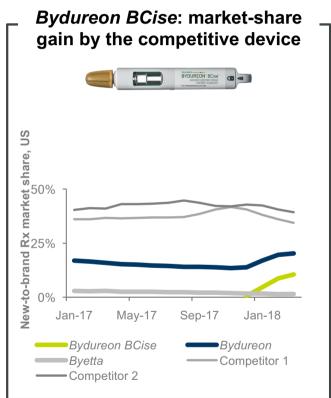
>\$0.4bn in additional sales; growth of 66% in Q1 2018





## Product launches: positive leading indicators







Source: external market research.

Source: IQVIA.

Source: IQVIA.



# **Agenda**



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**Oncology** 



**CVRM**, Respiratory, EMs



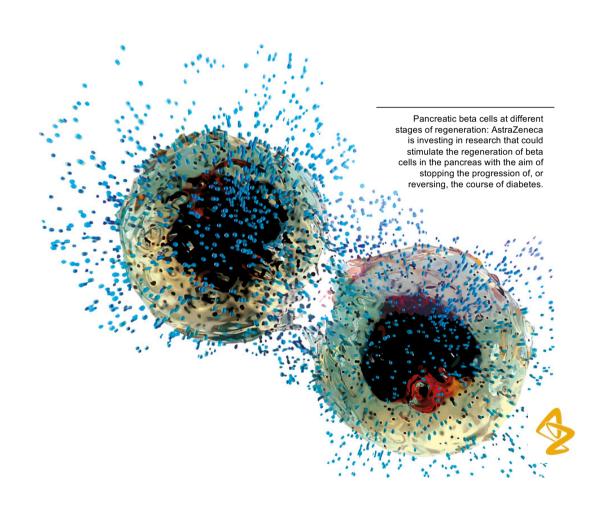
**Finance** 



Pipeline and news flow

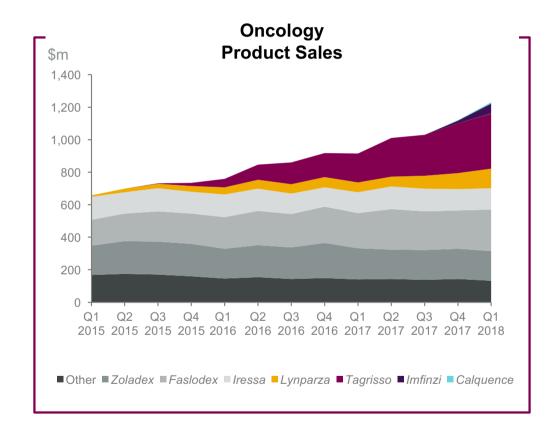


**Closing and Q&A** 



## Oncology

### New medicines drove strong performance



#### Strong performances from the new medicines Lynparza, Tagrisso, Imfinzi and Calquence

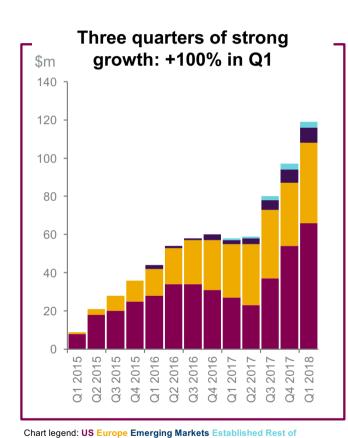
- Oncology +33% and 25% of total Product Sales
- New medicines contributed \$0.3bn in additional sales vs. Q1 2017
  - Lynparza: growth accelerated
  - Tagrisso: continued growth in the 2nd line
  - Imfinzi: inflection point realised
  - Calquence: encouraging uptake
- Other Oncology medicines still growing (+1%)



### Lynparza

## Expanding benefits to more patients





# Approved in >50 countries worldwide

- US +144%
   Growth accelerated due to tablet formulation, the broad label in ovarian cancer and the launch in breast cancer
- Europe +44%
   Steady progress in 2nd-line ovarian cancer, with encouraging reimbursement
- Emerging Markets/Est. RoW Increasing contribution to sales (\$11m). Japan launched in April

# Busy, ongoing launch activity

- Launching in the US for breast cancer
- Launching in the EU for broad ovarian cancer label and tablets
- Launching in Japan for the first time
- · Co-promotion well implemented





World.

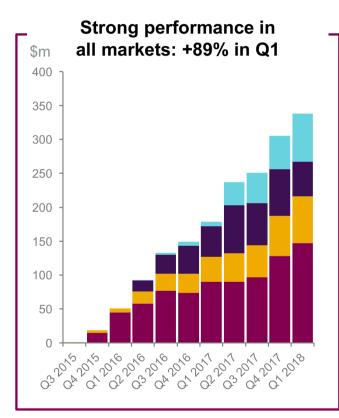
Absolute values at actual exchange rates; change at CER.



### Lung cancer: Tagrisso



### Strong 2nd-line business; ready for 1st-line approvals



# Approved in >75 countries worldwide

- US +63%
   Higher testing rates and general momentum underpinned growth
- Europe +74%
  Continued momentum from
  France, Germany and Italy
- Japan +21%
   Sequential growth negative due to mandatory expiry of free ctDNA testing
- Emerging Markets
   Very strong performance in China

# 1st-line approvals will expand patient benefit

- Unprecedented 1st-line progression-free survival data
- Brazil first approval as a 1st-line treatment; US followed on 18 April
- EU regulatory decision expected this quarter and JP decision expected H2 2018
- New lifecycle opportunities (Phase III LAURA trial, Stage III)

Chart legend: US Europe Established Rest of World Emerging Markets.

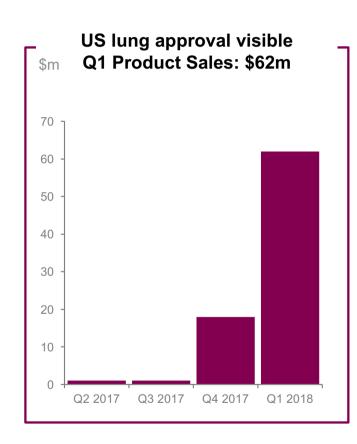
Absolute values at actual exchange rates; change at CER.



### Lung cancer: Imfinzi



### Encouraging start in unresectable Stage III NSCLC



# Encouraging launch in the US

- Approved 19 February
   Label reflects PACIFIC trial data
- Product Sales \$62m
   Majority of sales in new lungcancer indication with some use in bladder cancer
- Early experience positive
   Encouraging initial feedback from physicians and patients
- Continued physician education key to success

# Unresectable Stage III lung cancer status

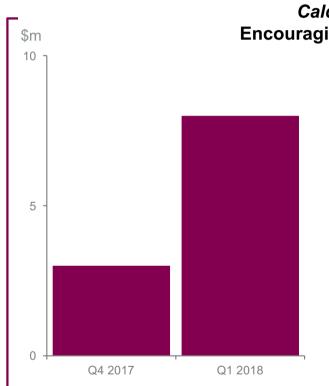
- EU
   Regulatory decision expected H2
   2018
- JP
   Regulatory decision expected H2

   2018
- Rest of World
   Canada approval early May.
   Regulatory review underway in Australia, Brazil and Switzerland with decisions expected later in 2018



### Haematology: Calquence and moxetumomab

### Emerging franchise; initially in smaller indications



# Calquence Encouraging US launch



- Approved 31 October 2017
   2nd-line mantle cell lymphoma, a fast-to-market opportunity
- Product Sales \$8m
- Encouraging early uptake
   Achieved ~1/4 of new-patient starts in approved indication
- Lifecycle plans underway in larger indications
   First data in chronic lymphocytic leukaemia expected from 2019

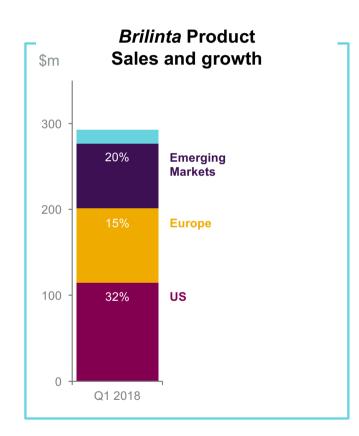
#### Moxetumomab pasudotox Priority review granted

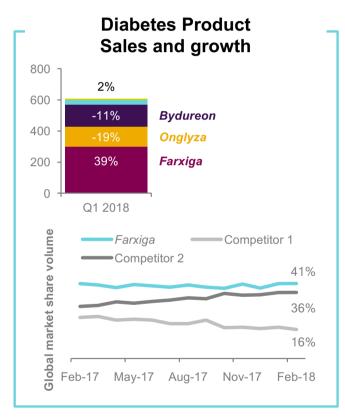
- First AstraZeneca/MedImmune antibody-drug conjugate
- Under US priority regulatory review, with a Q3 2018 PDUFA/action date
- Intended indication is 3rd-line hairy cell leukaemia (HCL)
- Small indication with ~1,000 new US patients per year



#### **New CVRM**

### Brilinta and Farxiga delivered strong results





# Continued success of newer medicines

#### Brilinta +24%

Continued double-digit growth across all regions

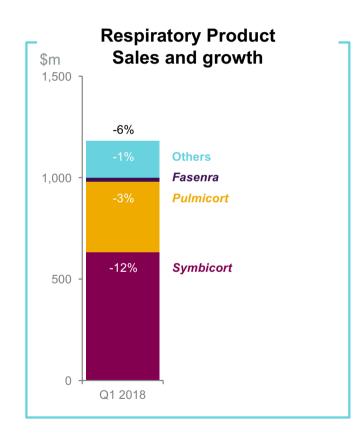
#### Farxiga +39%

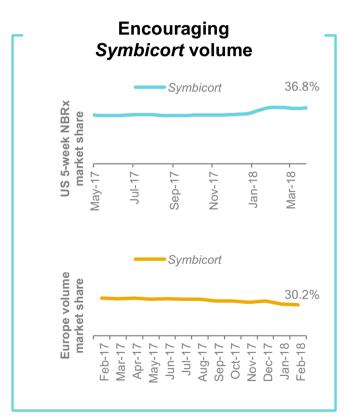
- US (+32%) saw increased market share, but in a slowing market
- Ex-US (58% of total; increasing)
   Strong growth continued, e.g.
   Europe (+30%), Emerging Markets (+62%)



## Respiratory

### Competitive market; strong Fasenra launch





#### US competitive; new medicines, Emerging Markets encouraging

#### **US -23%**

- Symbicort (-28%); volume growth in price-competitive environment; some phasing of govt. purchases
- Fasenra launch very encouraging (\$19m)

#### Europe -3%

- Rel. stable Symbicort volume
- Duaklir (+32%)
- Fasenra sales in Germany

#### **Emerging Markets +5%**

· Pulmicort supply delay in China



### Respiratory: Fasenra

### Encouraging US weekly new-to-brand prescriptions



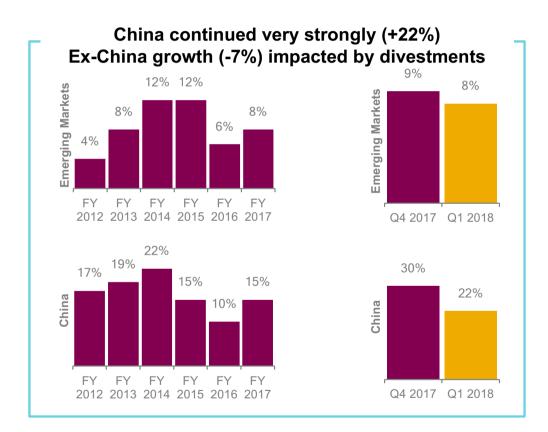
\$21m

# Launched

Fasenra is now launched in the US, Japan and the EU (incl. Germany, Austria, Denmark, The Netherlands and Sweden)

## **Emerging Markets**

### China continued strongly



# All three main therapy areas performed well

- Mid to high single-digit growth continued
  - Growth ex-China reduced by divestments and general economic conditions in Russia
- Oncology +36%: Tagrisso (\$71m) matched Iressa (+8%) in \$ sales. Hormone-receptor medicines continued growth with Faslodex leading
- New CVRM +30%: Brilinta (+20%); Forxiga (+62%)
- Respiratory +5%: Pulmicort (+2%, \$270m) due to supply delay in China. Symbicort (+10%, \$128m)



# **Agenda**



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Oncology



**CVRM**, Respiratory, EMs



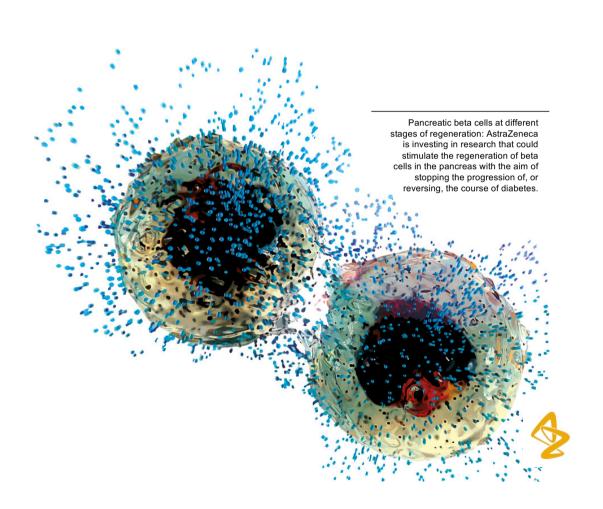
**Finance** 



Pipeline and news flow



**Closing and Q&A** 



# **Reported Profit & Loss**

	Q1 2018 \$m	% change	% Total Revenue
Total Revenue	5,178	(9)	100
- Product Sales	4,985	(2)	96
- Externalisation Revenue	193	(67)	4
Gross Margin	77.3%	(4) pp <sup>1</sup>	-
Operating Expenses	3,817	(5)	74
- R&D Expenses	1,279	(16)	25
- SG&A Expenses	2,457	2	47
Other Operating Inc. & Exp.	469	97	9
Tax Rate	16%	-	-
EPS	\$0.27	(29)	-

<sup>1.</sup> Percentage points.



Absolute values at actual exchange rates; change at CER.

Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales.

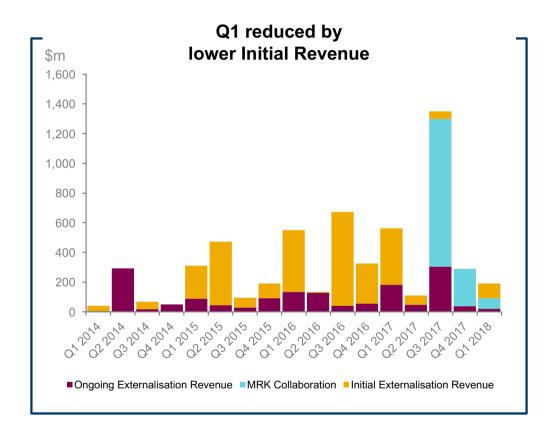
### **Core Profit & Loss**

	Q1 2018 \$m	% change	% Total Revenue
Total Revenue	5,178	(9)	100
- Product Sales	4,985	(2)	96
- Externalisation Revenue	193	(67)	4
Gross Margin	78.8%	(4) pp	-
Operating Expenses	3,349	(1)	65
- R&D Expenses	1,240	(12)	24
- SG&A Expenses	2,028	6	39
Other Operating Inc. & Exp.	124	(64)	2
Tax Rate	18%	-	-
EPS	\$0.48	(51)	-



#### **Externalisation Revenue**

#### Q1 lower due to Initial Revenue

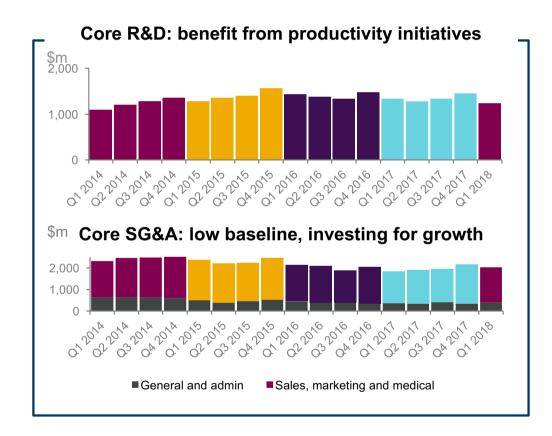


#### Main highlights

- Initial Externalisation Revenue \$102m from partnering legacy medicines
- Ongoing Externalisation Revenue \$91m, mainly from Merck collaboration (*Lynparza* US breast cancer approval, \$70m)
  - Regular milestones; approval (~1/3) and salesrelated (~2/3); mono and combo therapy
  - Remaining \$500m option payments in 2018-2019



# Total Core operating expenses declined by 1%



# Total Core operating expenses declined by 1%

- Core R&D declined by 12%
  - Maintained activity level; benefit from productivity improvements and Merck collaboration
  - FY 2018: continue to anticipate in the range of a low single-digit percentage decline to stable
- Core SG&A increased by 6%
  - Low baseline in Q1 2017; ongoing investment in launches and growth, including in China
  - FY 2018: continue to expect increase by a low to mid single-digit percentage



## 2018 guidance reiterated; unchanged capital allocation

# **Product Sales**

A low single-digit percentage increase

**Core EPS** 

\$3.30 to \$3.50

# Capital allocation

priorities

Investment in the business

Progressive dividend policy

Strong, investmentgrade credit rating

Immediately earnings-accretive, value-enhancing opportunities



# **Agenda**



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Oncology



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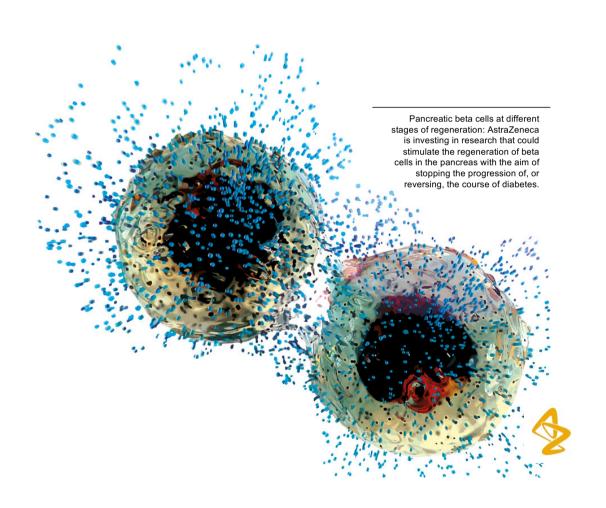
**Finance** 



Pipeline and news flow



**Closing and Q&A** 



# Oncology: good progress in lifecycle management Data from Spring congresses highlight steady progress

# Data from Spring congresses highlight steady progress

# Regulatory and other Development progress

#### Approvals

- Lynparza ovarian cancer (broad 2L label; tablets) (EU)
- Tagrisso lung cancer (1L) (US)
- Imfinzi lung cancer (Stage III) (US)

#### Submission acceptances

- Lynparza breast cancer (EU)
- moxetumomab pasudotox HCL (3L) (US, Priority Review)

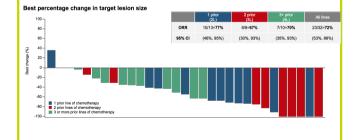
#### Major Phase III data readouts

- Imfinzi + tremelimumab - lung cancer
 (3L) (ARCTIC trial) - did not meet primary
 endpoints in PDL1-low/neg. patients

# SGO<sup>1</sup> Annual Meeting on Women's Cancer

- MEDIOLA trial: Lynparza + Imfinzi well tolerated in ovarian cancer
- ORR<sup>2</sup> 72% in full cohort, but 77% in patients with one prior therapy

Ovarian cancer, full cohort, response



# AACR<sup>3</sup> Annual Meeting ELCC<sup>4</sup>

- Lynparza breast cancer OS data; AZD0156 (ATM inhibitor), AZD6738 (ATR inhibitor) combo
- IO: Imfinzi + tremelimumab lung cancer (Study 006); bladder cancer (Study 010)
- Tagrisso lung cancer (FLAURA trial) post-progression data

<sup>1.</sup> SGO: Society of Gynecologic Oncology.

<sup>2.</sup> Objective response rate.

<sup>3.</sup> AACR: American Association for Cancer Research.4. ELCC: European Lung Cancer Congress.

SS.

## Oncology: ASCO<sup>1</sup> 2018 highlights

## Key data accepted at the annual meeting

# ASCO 2018 >90 abstracts 14 orals 7 'Best of ASCO'

# DNA Damage Response

- Lynparza + abiratertone prostate cancer - Phase II Study 8 trial
- Lynparza + vistusertib (AZD2014, mTORC1/2 inhibitor) - ovarian cancer and TNBC<sup>2</sup>
- capivasertib (AZD5363, AKT inhibitor) TNBC Phase II
- AZD2811 (aurora kinase B inhibitor) - advanced solid tumours
   Phase I

#### Immuno-Oncology

- Imfinzi monotherapy
  - unresectable Stage III NSCLC -Phase III PACIFIC trial (safety)
  - NSCLC 3L Phase II ATLANTIC trial (updated results)
- Imfinzi mono and combinations
  - -/+ treme GI<sup>3</sup> cancers Phase I Study 1108/021 trials
  - -/+ treme SCLC<sup>4</sup> Phase I Study 1108/010 trials
  - + treme NSCLC Phase I Study 006 trial
  - + CTx mesothelioma Phase II DREAM trial

# Haematology & Other

- Calquence Waldenstrom Macroglobulinemia (WM) - Phase I/II
- Moxetumomab pasudotox relapsed/refractory HCL - Phase II '1053' trial

#### <u>Other</u>

 selumetinib - neurofibromatosis type 1 (NF-1) - Phase II SPRINT trial



<sup>1.</sup> American Society of Clinical Oncology.

<sup>2.</sup> Triple-negative breast cancer.

<sup>3.</sup> Gastrointestinal.

<sup>4.</sup> Small-cell lung cancer.

#### **CVRM**

### Lokelma first approval; Diabetes focus on Farxiga

# Regulatory and other Development progress

- Approvals
  - Lokelma (ZS-9) hyperkalaemia (EU)
  - Bydureon + insulin (DURATION-7) (US)
- Submission acceptances
  - Forxiga type-1 diabetes (EU)

# Farxiga's CVD-REAL 2 study at ACC<sup>1</sup> Consistent with CVD-REAL 1 in 2017

 >400,000 patients treated with SGLT2 inhibitors; ~75% with Farxiga

#### Hospitalisation for heart failure

Database	N	# of events		HR (95% CI)
Korea	336,644	5149		0.87 (0.82, 0.92)
Japan	67,780	565	<b>⊢⊞-</b> 1	0.75 (0.63, 0.89)
Singapore	2726	67		0.62 (0.38, 1.02)
Israel	19,472	128	<b>⊢=</b> →	0.53 (0.37, 0.75)
Canada	16,064	88		0.36 (0.24, 0.56)
Total	442,686	5997	-	0.64 (0.50, 0.82)
			Favor SGLT2i ←	→ Favor oGLD
ITT, unadjusted analysis		Hazard Ratio:	0.25 0.50 1.00	2.00

- Treatment with SGLT2 inhibitors associated with a <u>lower risk</u><sup>2</sup> of
  - 49% for all-cause death
  - **36%** for hospitalisation for heart failure
  - **19%** for myocardial infarction
  - 32% for stroke

compared to other type-2 diabetes medicines



# Late-stage pipeline news flow in 2018 and 2019

## Unlocking and realising the potential of new medicines

	Q2 2018	H2 2018	2019
Regulatory decision	<b>Tagrisso</b> - lung cancer (EU) <b>Lokelma</b> - hyperkalaemia (US)	Lynparza - breast cancer (JP) Tagrisso - lung cancer (JP) Imfinzi - lung cancer (PACIFIC) (EU, JP) moxetumomab pasudotox - HCL 3L (US) Bydureon autoinjector - type-2 diabetes (EU) Bevespi - COPD (EU)	<b>Lynparza</b> - breast cancer (EU)
Regulatory submission	Duaklir - COPD (US)	Bevespi - COPD (JP) Lynparza - ovarian cancer 1L Imfinzi +/- treme - lung cancer (MYSTIC) - head & neck cancer 2L (EAGLE) selumetinib - thyroid cancer PT010 - COPD Fasenra - COPD	Lynparza - pancreatic cancer Imfinzi + treme - lung cancer 1L (NEPTUNE) Imfinzi +/- treme - lung cancer (POSEIDON) - small-cell lung cancer (CASPIAN) - bladder cancer 1L (DANUBE) - head & neck cancer 1L (KESTREL) Calquence - chronic lymphocytic leukaemia Brilinta - CAD²/type-2 diabetes CVOT Farxiga - type-2 diabetes CVOT (DECLARE) roxadustat - anaemia (US) anifrolumab - lupus
Key Phase III data readouts	Lynparza - ovarian cancer 1L	Imfinzi +/- treme	Lynparza - pancreatic cancer
	Fasenra - COPD (TERRANOVA)	<ul> <li>lung cancer (MYSTIC) (final OS)</li> <li>head &amp; neck cancer 2L (EAGLE)</li> <li>head &amp; neck cancer 1L (KESTREL)</li> <li>selumetinib - thyroid cancer</li> </ul>	Imfinzi - lung cancer (PACIFIC) (final OS) Imfinzi + treme - lung cancer 1L (NEPTUNE) Imfinzi +/- treme - lung cancer (POSEIDON) - small-cell lung cancer (CASPIAN)
		Farxiga - type-2 diabetes CVOT¹ (DECLARE) roxadustat - anaemia	- bladder cancer 1L (DANUBE)  Calquence - chronic lymphocytic leukaemia  Brilinta - CAD/type-2 diabetes CVOT
. Cardiovascular outcomes trial.		anifrolumab - lupus	Farxiga - heart failure lanabecestat - Alzheimer's disease

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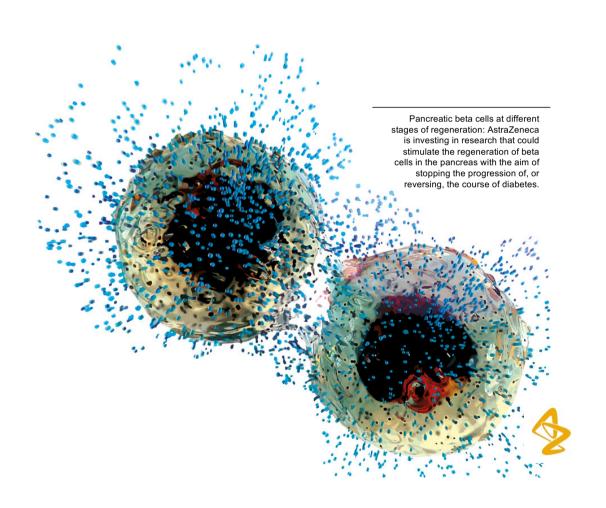
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**Closing and Q&A** 



# Encouraging launches underpin 2018 return to growth Financials on track - commercial execution - guidance reiterated

- Financials on track
  - Product Sales as anticipated
    - Strong execution of launches; offset by tail of Crestor EU/JP and divestments
  - Total Revenue impacted by lower Initial Externalisation Revenue
  - Core operating expenses declined by 1%
- Newer medicines delivered \$0.4bn in additional sales vs. Q1 2017 and 66% growth
  - Lynparza, Tagrisso, Imfinzi all very strong
  - CVRM blockbusters Brilinta and Farxiga continued growth
  - Respiratory competitive, but Fasenra off to a rapid start
  - China maintained fast growth
- Pipeline continued to deliver important news flow
- 2018 guidance reiterated





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  - China maintained fast growth
- Pipeline continued to deliver important news flow
- 2018 guidance reiterated





# Q1 2018 Results

Conference call and webcast for investors and analysts

18 May 2018

