

# Q1 2016 Results

**Media Teleconference**

09:00 BST

29 April 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 yield 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 anti-competitive 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 media 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.



# Q1 2016: Good start to the year; advancing the strategy

- **Continued delivery**
  - Total Revenue +5%; Growth Platforms +6%
  - Core SG&A cost decline, slower Core R&D cost growth despite M&A
  - Four regulatory approvals, four regulatory designations
- **Advancing the strategy**
  - Sharpening focus on main therapy areas:  
Oncology, Respiratory, Cardiovascular & Metabolic Disease
  - Driving productivity improvements: \$1.1bn annual savings from end 2017



# Q1 2016: Pipeline headlines

## Four approvals; four designations

- **Regulatory approvals**
  - **Bevespi Aerosphere** (PT003) - COPD (US)
  - **Zurampic** - gout (EU)
  - **Brilique** - prior-MI (EU)
  - **Tagrisso** - lung cancer (JP)
- **Regulatory designations**
  - Breakthrough Therapy:  
**durvalumab** - bladder cancer (US)
  - Orphan Drug: **acalabrutinib** - blood cancers (EU)  
**MEDI-551** - neuromyelitis optica (US)
  - Fast Track: **MEDI8852** - hospitalised influenza (US)







## Potential regulatory submissions of new medicines

<b>acalabrutinib</b> (blood cancer)
<b>roxadustat</b> (anaemia) (CN)
<b>benralizumab</b> (severe asthma)
<b>2016</b>

<b>durva + treme</b> (lung, head & neck, pancreatic cancers)
<b>durvalumab</b> (lung, head & neck cancer)
<b>moxetumomab</b> (leukaemia)
<b>selumetinib</b> (lung cancer)
<b>2017</b>



# Growth Platforms: Resilient performance despite challenging conditions

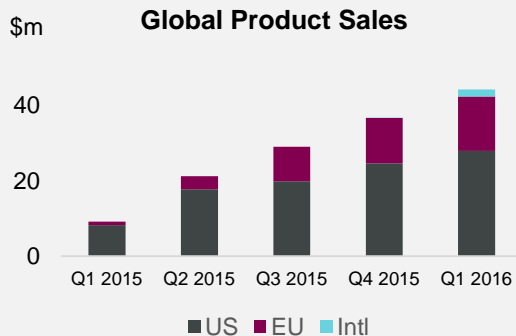
	Q1 2016 \$m	% change	% Total Revenue
<b>Growth Platforms</b>	3,435	+6	56
 <b>Respiratory</b>	1,207	+2	-
 <b>Brilinta/Brilique</b>	181	+46	-
 <b>Diabetes</b>	578	+23	-
 <b>Emerging Markets</b>	1,465	+6	-
 <b>Japan</b>	429	(7)	-
 <b>New Oncology</b>	99	n/m	-

Absolute values at actual exchange rates. Growth rates at CER



# New Oncology Launches progressing well

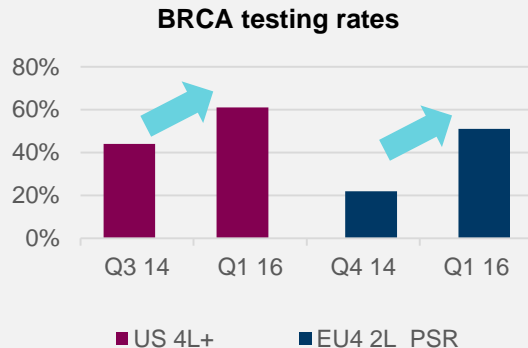
## Lynparza (ovarian cancer)



- Global Product Sales \$44m
- Launched in 21 countries; regulatory reviews ongoing in 14



## Steady increase in ovarian cancer patients with known BRCA status

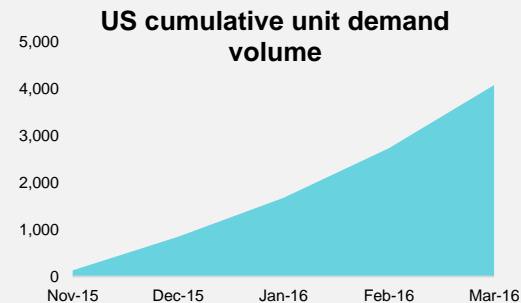


- US: Steady growth in testing rates
- EU: Half of eligible patients know BRCA status

US: 4th line+ patients  
EU4 (France, Germany, Italy & Spain): 2nd line platinum-sensitive recurrent patients

Source: IPSOS Oncology monitor

## Tagrisso (lung cancer)



- Global Product Sales \$51m
- Testing rates growing rapidly in markets where launched
- FDA approval of ctDNA test expected Q2 2016



Absolute values at actual exchange rates



# Advancing strategy: Sharpening focus, enhancing operational effectiveness, adjusting the cost structure

## ACTIONS

1. Sharpening **focus** on main therapy areas;  
**prioritise** investment; **increase** for Oncology
2. **Reduce** Core SG&A costs
  - Global, regional and country levels
  - Greater use of shared services
3. **Reshape** manufacturing
  - Streamline costs; implement biologics capacity build
4. Continue overall **productivity** and **simplification** efforts across business & R&D

## FINANCIAL IMPLICATIONS

- Once implemented end 2017 **annual benefit** of **~\$1.1bn** versus FY 2015, primarily in Core SG&A
- Mitigating the growth of Core R&D costs from an accelerating pipeline
- **Restructuring** charges of **~\$1.5bn**, virtually all cash

2016 guidance unchanged



# FY 2016 guidance & capital-allocation priorities

## FY 2016 guidance

Total Revenue

Low to mid single-digit percentage decline

Core EPS

Low to mid single-digit percentage decline

## Capital-allocation priorities

Investment in the business

Progressive dividend policy

Strong, investment-grade credit rating

Earnings-accretive opportunities





# Pipeline

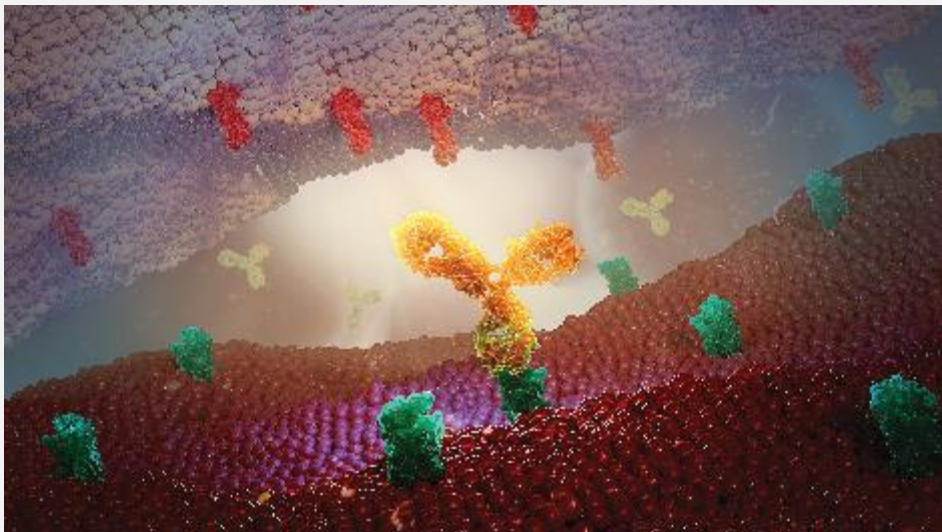
## Sean Bohan

EVP, Global Medicines Development & Chief Medical Officer



# Key regulatory designations received in the period<sup>1</sup>

## Recognition of pipeline quality and progress continued



- Breakthrough Therapy: **durvalumab** - bladder cancer (US)
- Orphan Drug:
  - **Acalabrutinib** (chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma (SLL); mantle cell lymphoma (MCL); lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia, WM) (EU)
  - **MEDI-551** - neuromyelitis optica (US)
- Fast Track: **MEDI8852** - hospitalised influenza A (US)

<sup>1</sup>. Status since the prior results announcement on 4 February 2016



# Q1 late-stage pipeline headlines

## Respiratory, Inflammation & Autoimmunity (RIA)

- **Symbicort** - COPD: Approval pressurised metered-dose inhaler (pMDI) (EU)
- **Bevespi** - COPD: Approval (US)
- **Zurampic** - gout: Approval (EU)



## Cardiovascular & Metabolic Disease (CVMD)

- **Brilique**
  - post-MI: Approval (EU)
  - stroke: SOCRATES missed primary endpoint

## Infection, Neuroscience & Gastrointestinal (ING)

- **AZD3293** - Alzheimer's disease: Phase II safety interim met; un-gating Phase III programme

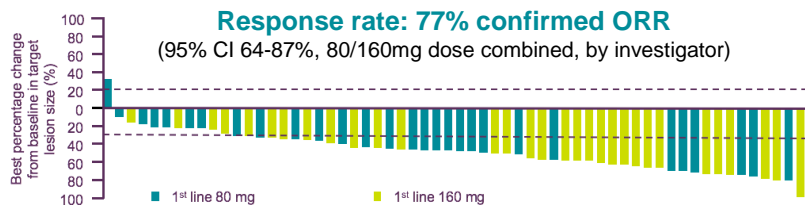
## Oncology

- **Tagrisso** - lung cancer:
  - Approval (JP)
  - CAURAL trial will not re-start
  - FLAURA 1st-line trial fully recruited
  - encouraging 1st-line data at ELCC
- **tremelimumab** - mesothelioma: DETERMINE trial did not meet primary endpoint
- **durva + treme** trial started: Phase II unresectable liver cancer

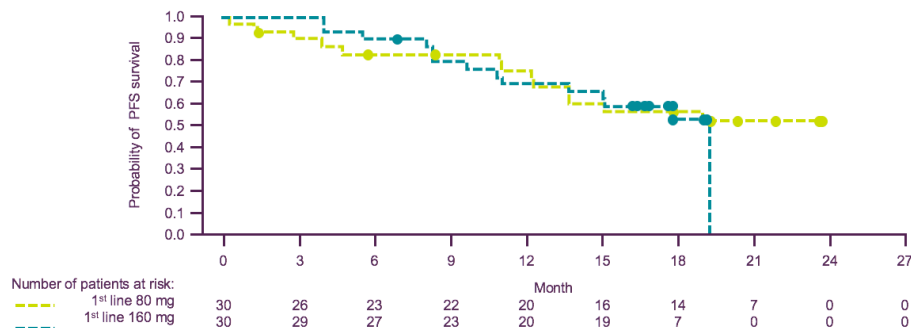


# Tagrisso Phase I efficacy updates

## Encouraging first-line activity continues



**Progression-free survival: 19.3 months**  
(95% CI 13.7-NC, 80/160mg dose combined, by investigator)



**TAGRISSO™**  
osimertinib



# Pipeline newsflow in 2016-2017

## Realising potential of new medicines

	Q2 2016	H2 2016	H1 2017
<b>Regulatory decisions</b>	<b>ZS-9</b> - hyperkalaemia (US)	<b>saxa/dapa</b> - type-2 diabetes (EU) <b>cediranib</b> - ovarian cancer (EU) <b>CAZ AVI</b> - serious infections (EU)	<b>brodalumab</b> - psoriasis (US, EU) <b>ZS-9</b> - hyperkalaemia (EU)
<b>Regulatory submissions</b>	<b>saxa/dapa</b> - type-2 diabetes (US)	<b>Bevespi Aerosphere</b> - COPD (EU) <b>benralizumab</b> - severe asthma (US, EU)  <b>roxadustat</b> - anaemia (CN) <b>acalabrutinib</b> - blood cancer (US)	<b>Brilinta/Brilique</b> - PAD  <b>Lynparza</b> - gastric, breast, ovarian (2nd line) cancers <b>selumetinib</b> - lung cancer <b>durvalumab</b> - H&N cancer (HAWK)
<b>Key data readouts</b>	<b>benralizumab</b> - severe asthma  <b>Lynparza</b> - gastric cancer	<b>Brilinta/Brilique</b> - PAD <sup>1</sup> <b>Lynparza</b> - breast, ovarian (2nd line) cancers <b>selumetinib</b> - lung cancer <b>durvalumab</b> - H&N cancer (HAWK) <b>acalabrutinib</b> - blood cancer	<b>Lynparza</b> - ovarian cancer (1st line) <b>durvalumab</b> - lung cancer (PACIFIC) <b>durva + treme</b> - lung cancer (MYSTIC, ARCTIC) - head and neck cancer (CONDOR)

1. PAD = Peripheral Arterial Disease



# Closing

**Pascal Soriot**

Chief Executive Officer



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