

# Taking our science to the 2017 ASCO Annual Meeting

#### **Investor science event**

Chicago, IL, USA 05 June 2017



#### **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; effects of patent litigation in respect of IP rights; 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 that R&D will not yield new products that achieve commercial success; the risk of delay to new product launches; the risk that new products do not perform as we expect; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the risks from pressures resulting from generic competition; the impact of competition, price controls and price reductions; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the difficulties of obtaining and maintaining regulatory approvals for products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk of failure of critical processes affecting business continuity; economic, regulatory and political pressures to limit or reduce the cost of our products; failure to achieve strategic priorities or to meet targets or expectations; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; the risk of substantial product liability claims; 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 impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; taxation risks; exchange rate fluctuations; 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 impact of failing to attract and retain key personnel and to successfully engage with our employees; the risk of misuse of social medial platforms and new technology; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.

#### **Speakers and Q&A participants**



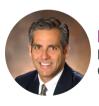
Pascal Soriot
Executive Director and
Chief Executive Officer



Sean Bohen
Executive Vice President,
Global Medicines Development
and Chief Medical Officer



Jamie Freedman
Executive Vice President and
Head, Oncology Business Unit



Rob lannone Head of Immuno-Oncology, Global Medicines Development



Susan Galbraith
Head of Oncology,
Innovative Medicines Biotech
Unit



Klaus Edvardsen Head of Oncology, Global Medicines Development



**David Berman** Head of Oncology, MedImmune



# **Agenda**



Welcome



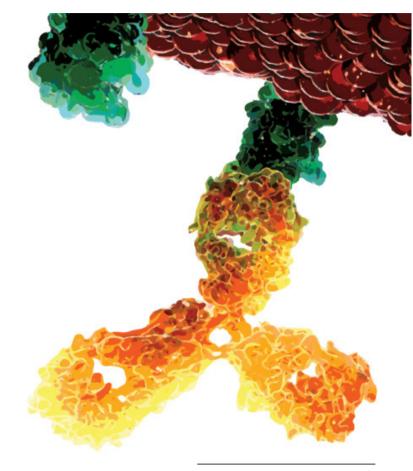
**Strategy** 



Pipeline and news flow



**Summary and Q&A** 



Antibody that blocks inhibitory signals from the tumour to cells of the immune system, resulting in enhanced antitumour immunity



#### **Key Phase III medicines & lifecycle**

#### Pipeline will determine the rate of growth

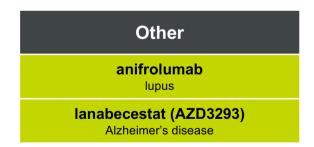
Oncology
<b>Imfinzi</b> <sup>1</sup> multiple cancers
Imfinzi + treme multiple cancers
<b>acalabrutinib</b> blood cancers
moxetumomab leukaemia
selumetinib thyroid cancer
<b>Lynparza</b> <sup>1,2</sup> multiple cancers
Tagrisso <sup>1</sup> lung cancer

- 1. Life-cycle development programme.
- 2. Under regulatory review in major jurisdiction. Status as of 5 June 2017.

Cardiovascular & Metabolic
Diseases

ZS-92
hyperkalaemia

roxadustat2
anaemia



Respiratory

benralizumab
severe, uncontrolled asthma² / COPD

tralokinumab
severe, uncontrolled asthma

PT010
COPD / asthma



#### **Key Phase III medicines & lifecycle**

#### Oncology has a transformative potential

#### Focus today

# Imfinzi¹ multiple cancers Imfinzi + treme multiple cancers acalabrutinib blood cancers moxetumomab leukaemia selumetinib thyroid cancer Lynparza¹,² multiple cancers Tagrisso¹ lung cancer

- 1. Life-cycle development programme.
- 2. Under regulatory review in major jurisdiction. Status as of 5 June 2017.

#### Cardiovascular & Metabolic Diseases ZS-9<sup>2</sup> hyperkalaemia

# Other anifrolumab lupus lanabecestat (AZD3293) Alzheimer's disease

# Respiratory benralizumab severe, uncontrolled asthma² / COPD tralokinumab severe, uncontrolled asthma PT010 COPD / asthma



# **Agenda**



Welcome



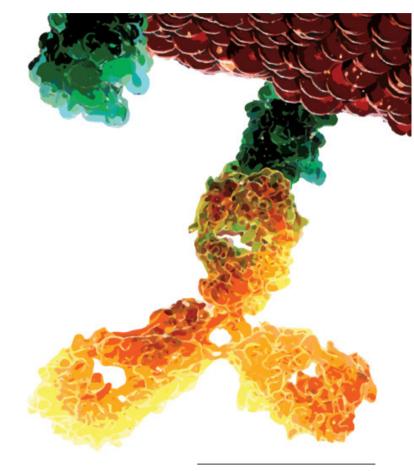
**Strategy** 



Pipeline and news flow



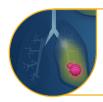
**Summary and Q&A** 



Antibody that blocks inhibitory signals from the tumour to cells of the immune system, resulting in enhanced antitumour immunity



#### Delivering the Oncology strategy at a fast pace



**Establishing leadership in lung cancer** 



**Emerging as a leader in Immuno-Oncology** 



Advancing *Lynparza* and the DDR<sup>1</sup> portfolio 'beyond BRCA<sup>2</sup>'



**Developing Haematology** 





#### Establishing leadership in lung cancer

#### Unique opportunity across all disease stages



#### Non-small cell lung cancer

(~85% of all lung cancers)

#### EGFRm / T790M<sup>1</sup> opportunity

(~15-20% of patients, double in Asia)

#### IO<sup>2</sup> market opportunity

(~75-80% of patients)

Stage I-III (early / non-metastatic)

Stage IV (metastatic)



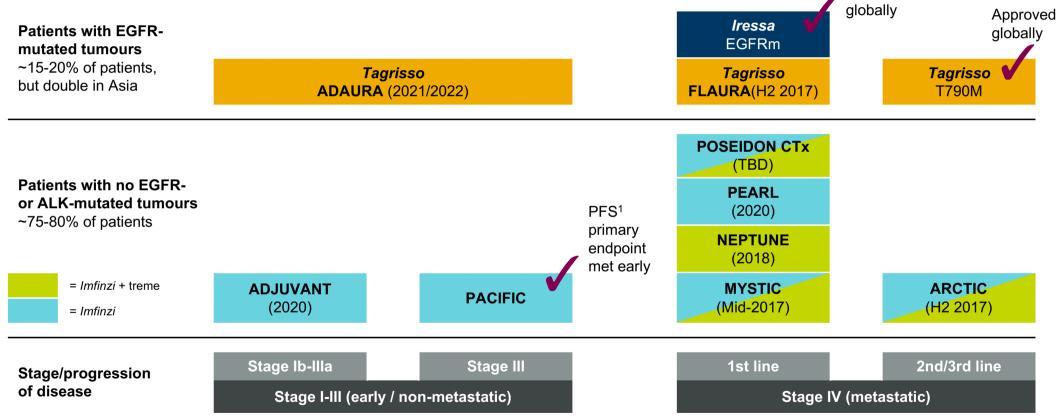
<sup>1.</sup> EGFRm / T790M = Epidermal Growth Factor Receptor mutation / The T790M mutation substitutes a threonine (T) with a methionine (M) at position 790 of exon 20, affecting the ATP binding pocket of the EGFR kinase domain.

2. IO = Immuno-Oncology.

NSCLC staging details: https://www.cancer.org/cancer/non-small-cell-lung-cancer/detection-diagnosis-staging/staging.html. Source: AstraZeneca epidemiology data.

# AstraZeneca in non-small cell lung cancer (NSCLC)

Overview of approved medicines and ongoing Phase III trials





1. PFS = Progression-Free Survival.
( ) = First data anticipated.

Source: AstraZeneca epidemiology data.

#### Tagrisso: Become the treatment of choice

#### Potential to transform EGFRm NSCLC outcomes





#### **Extend**

as the backbone therapy for all EGFRm patients; in early disease and via combinations with other mechanisms



#### **Expand**

the benefit of *Tagrisso* to 1L and adjuvant EGFRm NSCLC as the new treatment of choice

#### **Establish**

Tagrisso as the new standard of care for EGFR T790M-positive NSCLC at first progression



#### Imfinzi: Ongoing development programme

#### Potential for 1L differentiation with tremelimumab

#### Lung cancer

NSCLC and small-cell lung cancer (SCLC)

















Head and neck cancer





**Bladder cancer** 



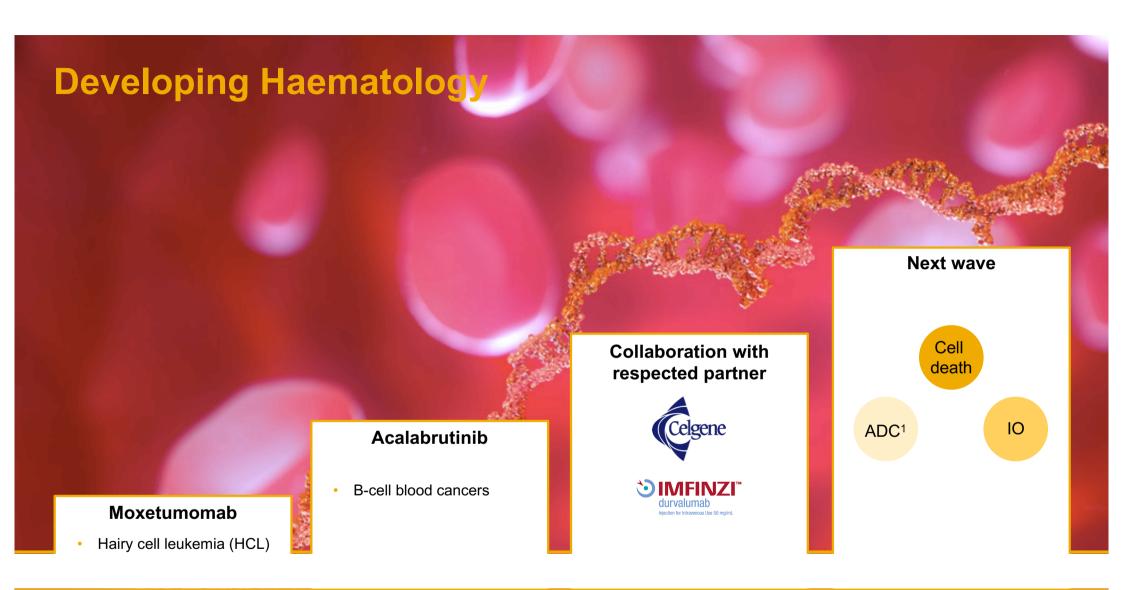
Other cancers





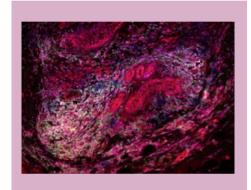




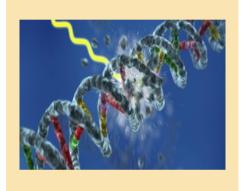


# Oncology: Scientific leadership around four key platforms

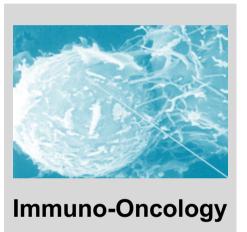
# Opportunity for novel combinations

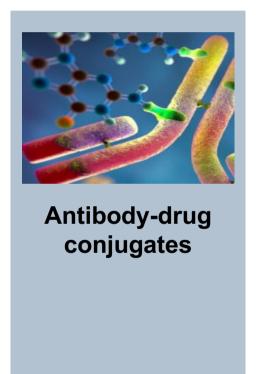


**Tumour drivers** and resistance



DNA damage response







# **Agenda**



Welcome



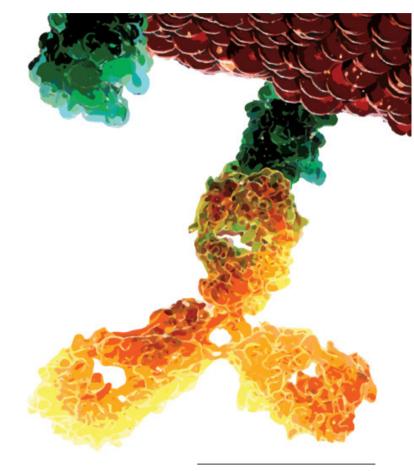
Strategy



Pipeline and news flow



Summary and Q&A

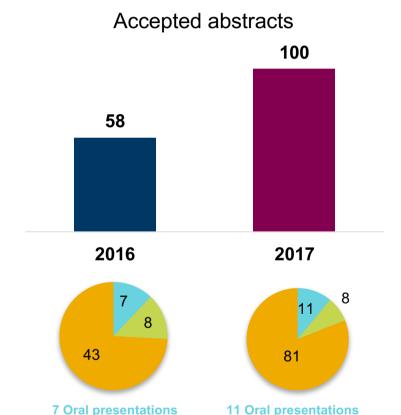


Antibody that blocks inhibitory signals from the tumour to cells of the immune system, resulting in enhanced antitumour immunity



# **ASCO Annual Meeting presence almost doubled**

#### Relevance of AstraZeneca in Oncology is fast increasing



8 Poster discussions

81 Posters

**100** company-sponsored and supported **abstracts** at ASCO. This includes **five 'Best of ASCO'** presentations, and a total of **11 oral presentations** and **eight poster discussions**.

#### Highlights

- Lynparza
  - Phase III OlympiAD BRCAm mBC
  - Phase III SOLO-2 BRCAm OC HRQOL
- Tagrisso
  - Phase III AURA3 NSCLC CNS disease
- Imfinzi
  - Study 1108 monotherapy; updates in bladder cancer and NSCLC



Source: AstraZeneca analysis based on ASCO abstract acceptances.

43 Posters

8 Poster discussions

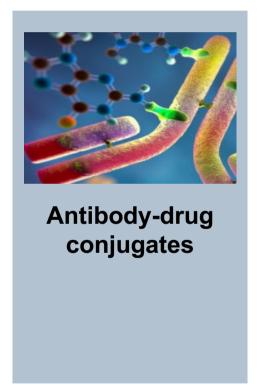
# Oncology: Scientific leadership around four key platforms

#### Opportunity for novel combinations





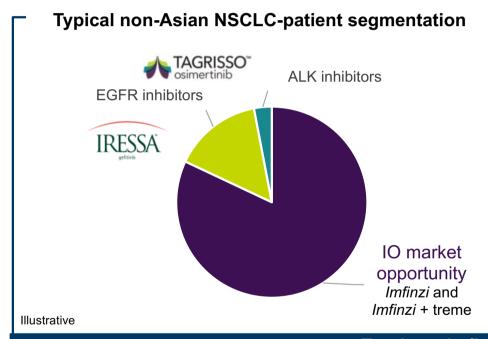


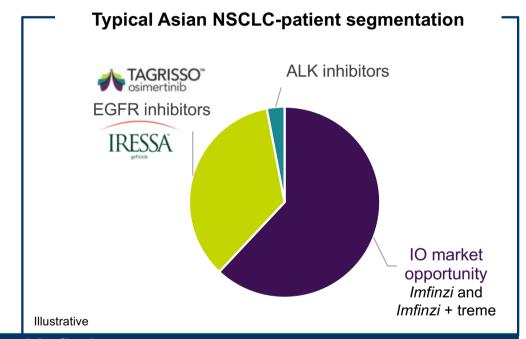




# **NSCLC: Stage IV metastatic disease**

#### Potential to benefit the majority of patients



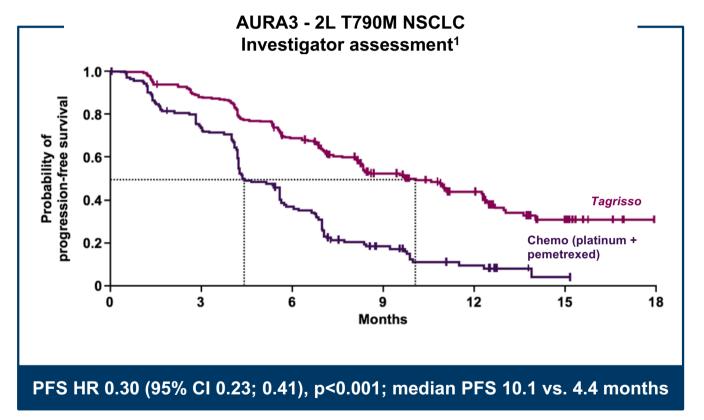


Tagrisso, Imfinzi and Imfinzi + treme:
Unique opportunities to benefit NSCLC patients and create significant value



#### **Tagrisso**

#### First randomised Phase III trial to demonstrate superiority



PFS by investigator	Tagrisso (N=279)	Chemo (N=140)	
HR (95% CI)	<b>0.30</b> (0.23; 0.41) p<0.001		
Median PFS, months (95% CI)	10.1 (8.3; 12.3)	4.4 (4.2; 5.6)	
With CNS metastases			
PFS by investigator	Tagrisso (N=93)	Chemo (N=51)	
HR (95% CI)	<b>0.32</b> (0.21; 0.49) p<0.001		
Median PFS, months (95% CI)	8.5 (6.8; 12.3)	4.2 (4.1; 5.4)	
AURA3: Similar PFS hazard ratio with or without brain metastases			

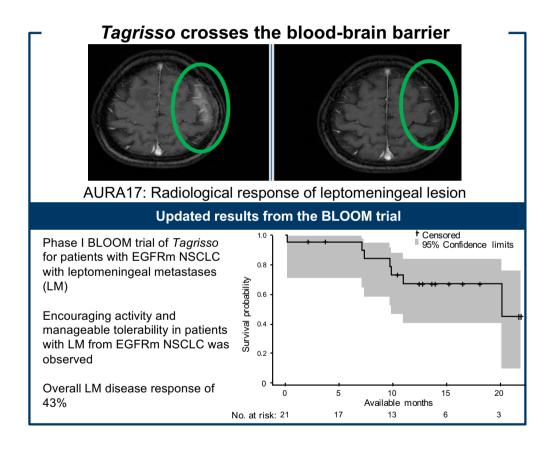
Source: WCLC 2016, abstract PL03.03.

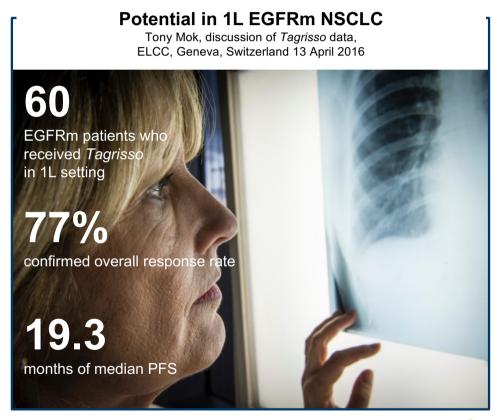


<sup>1.</sup> Analysis of PFS by BICR was consistent with the investigator-based analysis: HR 0.28 (95% CI 0.20; 0.38), p<0.001; median PFS 11.0 vs. 4.2 months.

#### **Tagrisso**

#### Encouraging long-term CNS benefit supports 1L use







#### **Tagrisso**

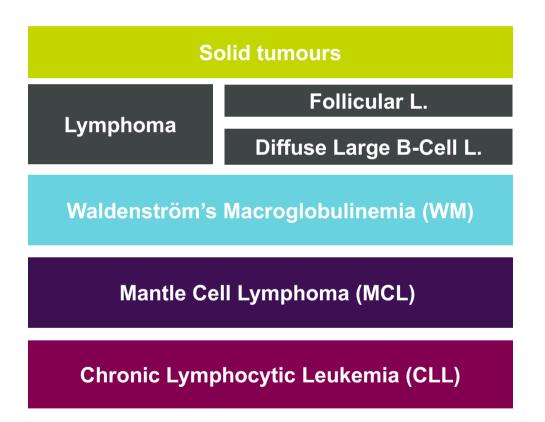
#### Potential to transform EGFRm NSCLC outcomes





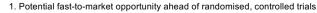
#### **Acalabrutinib**

#### Extensive clinical trial programme underway



#### 21 clinical trials underway with +2,000 patients - excerpts:

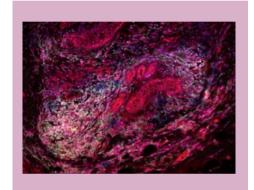
Indication	Line of therapy; trial design	Phase
CLL	Front line acalabrutinib + obinutuzumab vs. obinutuzumab + chlorambucil vs. acalabrutinib	III
	Relapsed/refractory acalabrutinib vs. ibrutinib	III
	Relapsed/refractory acalabrutinib vs. investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab	III
	Relapsed/refractory, ibrutinib-intolerant acalabrutinib	II
MCL	Front line, previously untreated acalabrutinib + bendamustine + rituximab vs. bendamustine + rituximab	III
	Relapsed/refractory acalabrutinib	II
WM	Relapsed/refractory acalabrutinib	lb/II
	Pivotal Phase II data anticipated H1 2017 <sup>1</sup>	





# Oncology: Scientific leadership around four key platforms

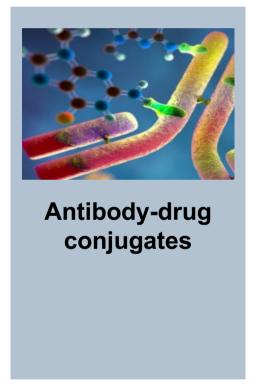
# Opportunity for novel combinations



**Tumour drivers** and resistance



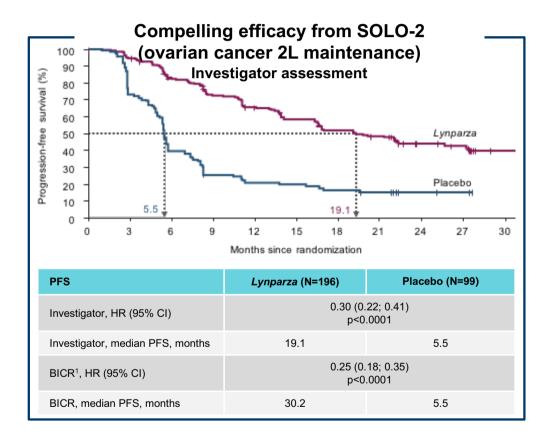






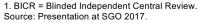
#### Lynparza: Ovarian cancer

#### Compelling efficacy and safety



#### Compelling safety data, patient convenience

% (events, n)	Anemia Grade ≥3	Neutropenia Grade ≥3	Thrombocytopenia Grade ≥3
SOLO-2	19.5% (38)	5.1% (10)	1.0% (2)
Interpretation	>10%	<10%	<<10%
AS	ARIB PARIS SULVEY OF THE SECOND SULVEY OF THE SECON		
Reducing burden for patients; from 16 capsules to 4 tablets			





# **Lynparza:** Breast cancer OlympiAD study design

- · HER2-negative metastatic breast cancer
  - ER+ and/or PR+ or
  - TNBC
- Deleterious or suspected deleterious gBRCAm
- ≤2 prior chemotherapy lines in metastatic setting
- Prior anthracycline and taxane
- HR+ disease progressed on
   ≥1 endocrine therapy, or not suitable
- If prior platinum use
  - No evidence of progression during treatment in the advanced setting
  - ≥12 months since (neo)adjuvant treatment

Olaparib 300 mg tablets bd

2:1 randomization

Chemotherapy treatment of physician's choice (TPC)

- Capecitabine
- Eribulin
- Vinorelbine

Treat until progression

#### **Primary endpoint**

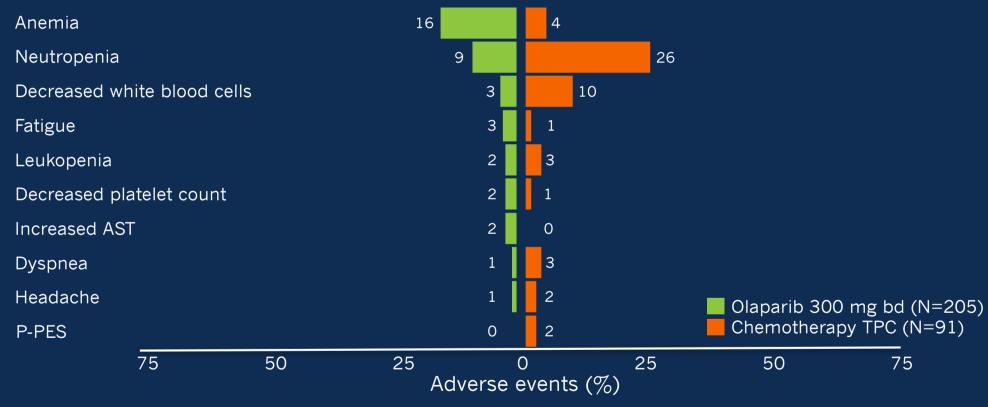
Progression-free survival (RECIST 1.1, BICR)

#### **Secondary endpoints**

- Overall survival
- Time to second progression or death
- · Objective response rate
- Global HRQoL (EORTC-QLQ-C30)
- Safety and tolerability

BICR, blinded independent central review; ER, estrogen receptor; HRQoL, health-related quality of life; PR, progesterone receptor; RECIST, response evaluation criterial in solid tumors; TNBC, triple negative breast cancer

# Lynparza: Breast cancer Grade ≥3 adverse events in ≥2% patients in either arm



MedDRA preferred terms for adverse events have been combined for 1) anemia and 2) neutropenia ALT, alanine aminotransferase; AST, aspartate aminotransferase; P-PES, Palmar-plantar erythrodysesthesia syndrome

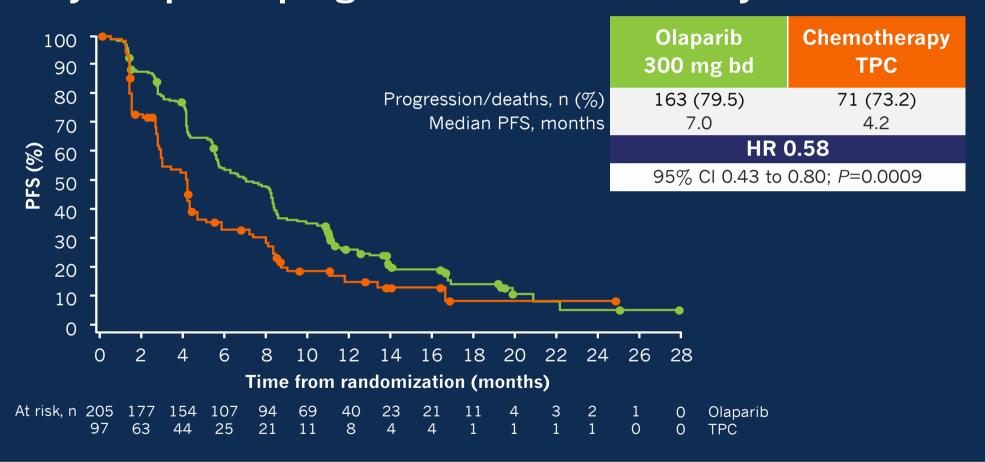
27ESENTED AT: ASCO ANNUAL MEETING '17

#ASCO17

Presented by: Mark Robson, MD

6/4/2017

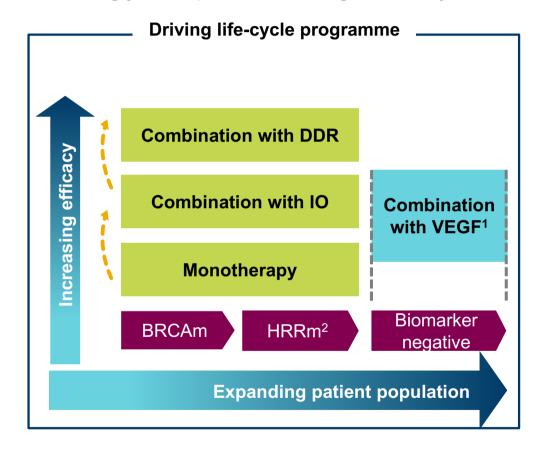
# Lynparza: Breast cancer Primary endpoint: progression-free survival by BICR

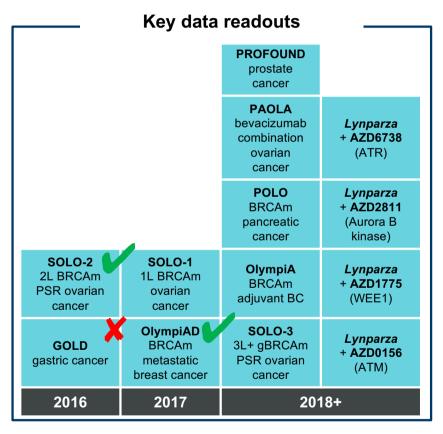


28 SENTED AT: ASCO ANNUAL MEETING '17 #ASCO17

### Lynparza: Expanding beyond BRCA

#### Strategy; expected regulatory submissions





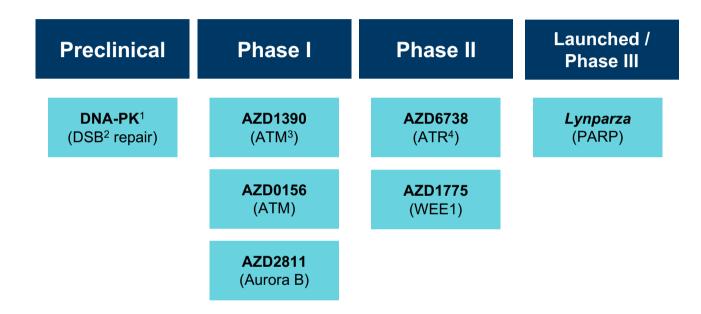


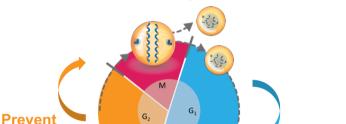
<sup>1.</sup> VEGF = Vascular Endothelial Growth Factor.

<sup>2.</sup> HRRm = Homologous Recombination Repair mutations.

#### **DNA** damage response (DDR)

#### Deep portfolio from preclinical to launch





**Effect is manifest in M phase** 

repair

G1 = Gap/growth phase I S = DNA replication phase G2 = Gap/growth phase II M = Cell division phase \ = Cell cycle checkpoint

**Maximise** damage

#### Uniquely placed to explore full range of opportunities in DDR

1. DNA-PK = DNA-dependent Protein Kinase.

2. DSB = Double Strand Break.

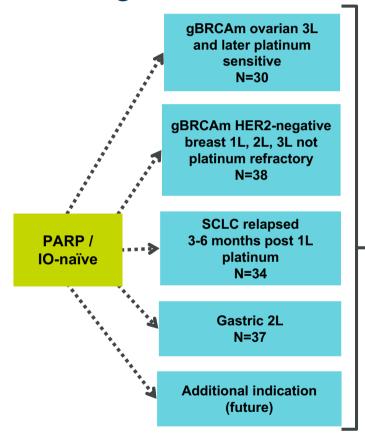
3. ATM = Ataxia-Telangiectasia Mutated.

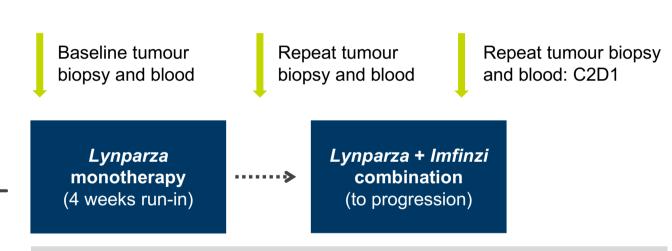
4. ATR = Ataxia-Telangiectasia and Rad3-related.



# Lynparza + Imfinzi (MEDIOLA trial)

Leading with novel anti-PDL1 plus targeted-therapy combinations





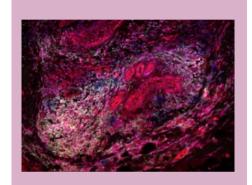
#### **Key features:**

- Phase II proof-of-concept basket trial
- Dose finding established in National Cancer Institute (NCI) D081KC00001
- Rigorous translational science

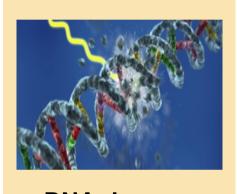


# Oncology: Scientific leadership around four key platforms

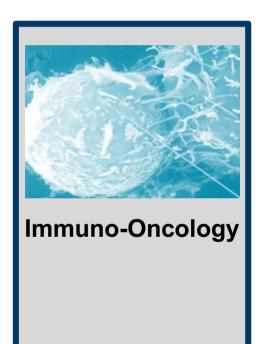
Opportunity for novel combinations

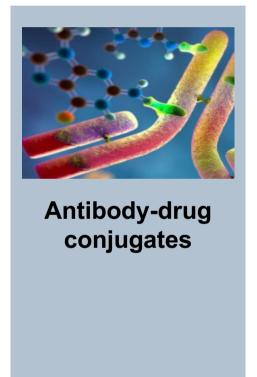


**Tumour drivers** and resistance



DNA damage response

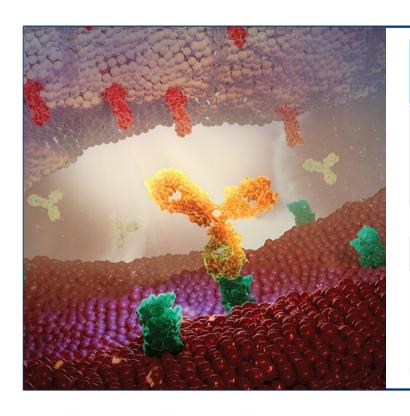






#### Imfinzi: Bladder cancer 2L

# First approval; compelling data



	All patients N=182	PD-L high N=95	PD-L1 low/negative N=73	PD-L1 NE <sup>1</sup> N=14
Objective Response Rate (ORR) by BICR, n (%) (95% confidence interval [CI])	31 (17.0%) (11.9, 23.3)	25 (26.3%) (17.8, 36.4)	3 (4.1%) (0.9, 11.5)	3 (21.4%) (4.7, 50.8)
Complete Response	5	3	1	1
Partial Response	26	22	2	2
Median Duration of Response (DoR) (Range, months)	Not reached (0.9+2, 19.9+)	Not reached (0.9+, 19.9+)	Not reached (1.9+, 12.3)	Not reached (2.3+, 2.6)



<sup>1.</sup> NE = Not Evaluable.

<sup>2. &#</sup>x27;+' = censored value.

Source: *Imfinzi* US prescribing information.

#### Imfinzi: Stage III NSCLC

#### PACIFIC trial: First and only IO medicine with PFS

#### **PACIFIC**



#### **News Release**



**Regulatory News Service** 

This announcement contains inside information

12 May 2017 07:00 BST

IMFINZI SIGNIFICANTLY REDUCES THE RISK OF DISEASE WORSENING OR DEATH IN THE PHASE III PACIFIC TRIAL FOR STAGE III UNRESECTABLE LUNG CANCER

Imfinzi met a primary endpoint of statistically-significant and clinically-meaningful progression-free survival (PFS) in 'all-comer' patients with locally-advanced, unresectable (Stage III) non-small cell lung cancer in a planned interim analysis

Imfinzi is the first immuno-oncology medicine to show superior PFS in this setting

Plans for regulatory submission under active discussion with authorities

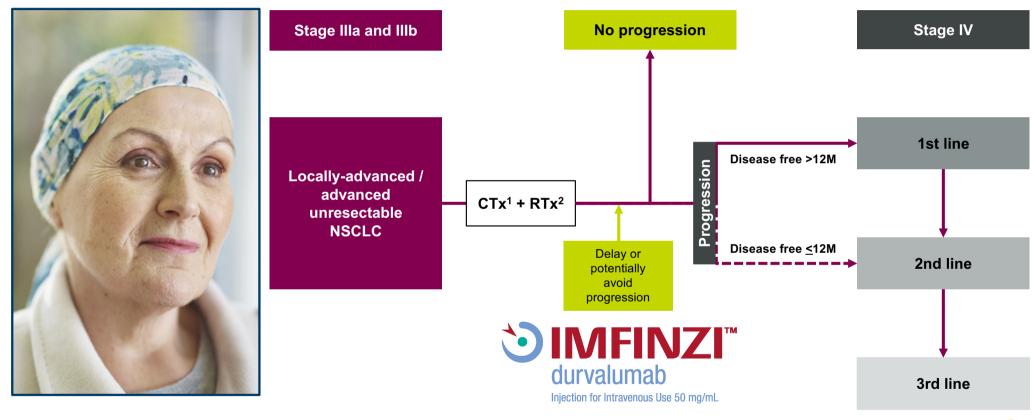
AstraZeneca and MedImmune, its global biologics research and development arm, today announced positive results for the Phase III PACIFIC trial, a randomised, double-blinded, placebo-controlled multi-centre trial of *Imfinzi* (durvalumab) as sequential treatment in patients with locally-advanced, unresectable (Stage III) non-small cell lung cancer (NSCLC) who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy.

- ~100,000 patients are diagnosed with Stage III lung cancer each year in G7; about half being unresectable
- Trial will continue for overall survival with final overall survival data currently expected in 2019
- 2-3 years ahead of competitors



#### Imfinzi: Stage III NSCLC

# PACIFIC trial: Statistically-significant and clinically-meaningful PFS



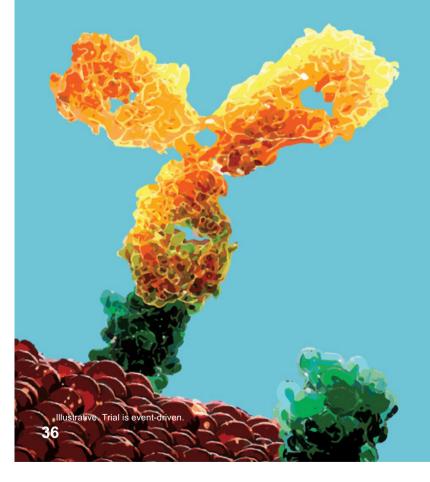
<sup>1.</sup> CTx = Chemotherapy.



<sup>2.</sup> RTx = Radiation therapy.

# Imfinzi: Stage IV NSCLC

# MYSTIC trial: Multiple potential outcomes



	2017	2018
Primary endpoints		
Imfinzi + treme combo PFS in 'expressers'	Mid-2017 PFS final analysis	
Imfinzi + treme combo OS in 'expressers'		terim analyses OS final analysis
Imfinzi OS in 'expressers'	OS in	terim analyses OS final analysis

## Imfinzi: Stage Ib-IV NSCLC

## Extensive Phase III programme

	ADJUVANT	PACIFIC	MYSTIC	NEPTUNE	PEARL	POSEIDON	ARCTIC
	Stage lb-Illa	Stage III unresectable	Stage IV / 1L EGFR/ALK wt Non-sq / sq <sup>2</sup>	Stage IV / 1L EGFR/ALK wt Non-sq / sq	Stage IV / 1L EGFR/ALK wt Non-sq / sq PD-L1 expr.	Stage IV / 1L EGFR/ALK wt Non-sq / sq	Stage IV / 3L EGFR/ALK wt Non-sq / sq PD-L1 low
Trial design	Randomised, controlled	Randomised, controlled	Randomised, controlled	Randomised, controlled	Randomised, controlled	Randomised, controlled	Randomised, controlled
	<i>Imfinzi</i> vs placebo	<i>Imfinzi</i> vs placebo	<i>Imfinzi</i> , <i>Imfinzi</i> + treme vs SoC	Imfinzi + treme vs SoC	<i>Imfinzi</i> vs SoC	Imfinzi + SoC, Imfinzi + treme + SoC vs SoC	Imfinzi, treme, Imfinzi + treme vs SoC
Primary endpoint(s)	DFS <sup>1</sup>	PFS OS	PFS OS	os	PFS OS	PFS	PFS OS
Data readout	2020	PFS 2019 (final OS)	Mid-2017 (PFS) 2018 (final OS)	2018	2020	TBD	H2 2017
Recruitment status	Ongoing	Fully recruited	Fully recruited	Fully recruited	Ongoing	Ongoing	Fully recruited

<sup>1.</sup> DFS = Disease-Free Survival.

<sup>2.</sup> Non-sq / sq = Non-squamous / squamous (histology).

## Imfinzi: Key news flow Mono and combo w/treme

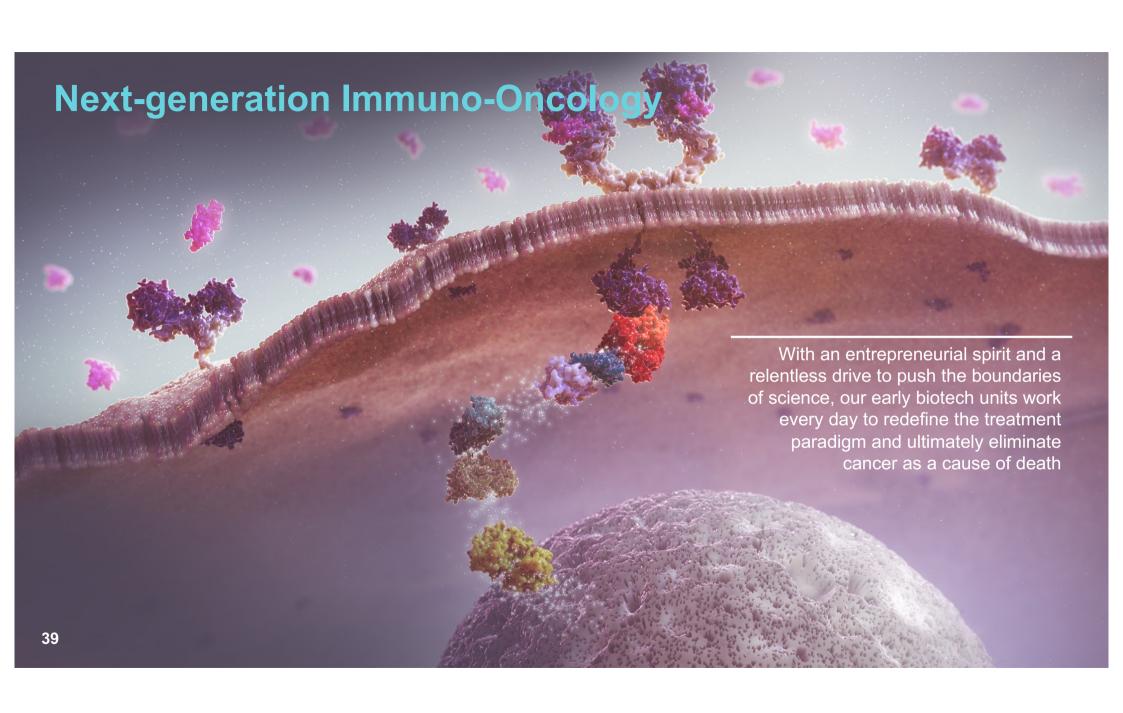
= Imfinzi = Imfinzi +/- treme	= fully recruited			2
Bladder cancer (UC¹)			DANUBE 1L	
Head and neck cancer		KESTREL 1L	<b>EAGLE</b> 2L	
Lung cancer (NSCLC)				POSEIDON 1L IO-IO-CTx triple
			NEPTUNE 1L (final OS)	<b>PEARL</b> 1L (Asia)
	MYSTIC 1L (PFS)	ARCTIC 3L PD-L1 low/neg.	MYSTIC 1L (final OS)	<b>ADJUVANT</b> Adjuvant
	Mid 2017	H2 2017	2018	2018+

Potential leadership in IO & IO-IO combinations across multiple cancer types



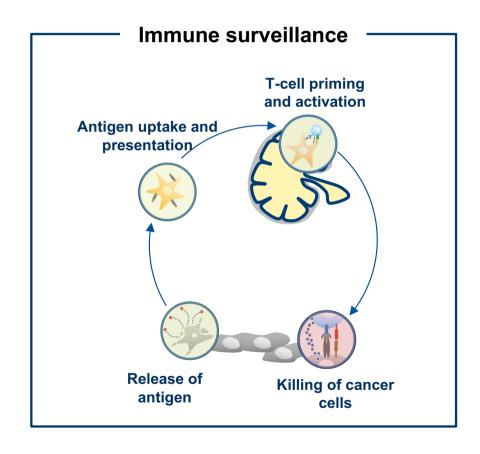
<sup>1.</sup> Urothelial Carcinoma.

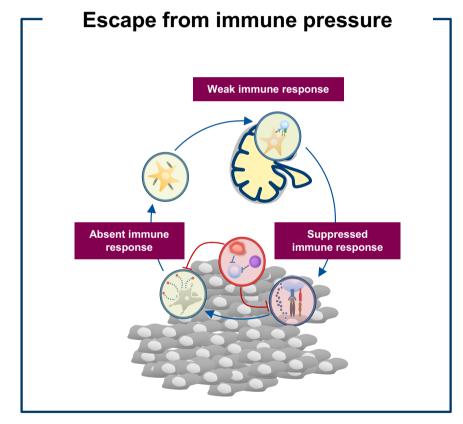
<sup>2.</sup> Global trial excluding China.



## **Next-generation Immuno-Oncology**

## Cancer may arise when tumour cells escape immune pressure

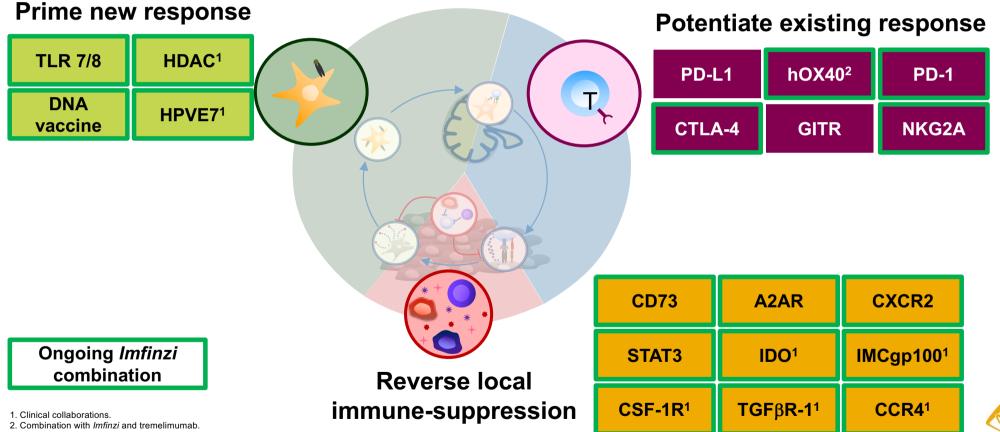






## **Next-generation Immuno-Oncology**

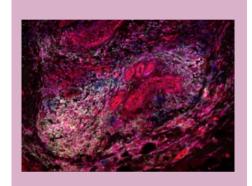
Broad IO clinical programme to enhance anti-tumor immunity



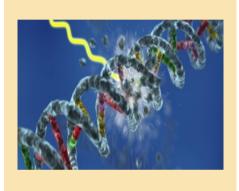


## Oncology: Scientific leadership around four key platforms

## Opportunity for novel combinations

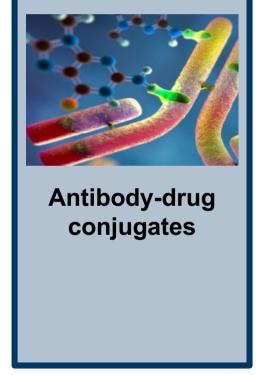


**Tumour drivers** and resistance



DNA damage response

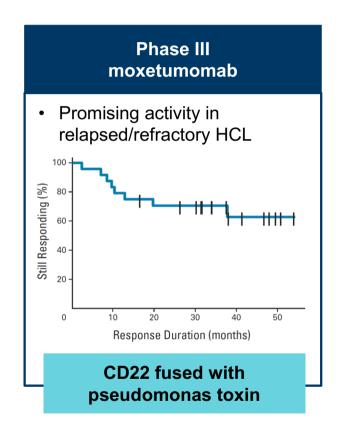


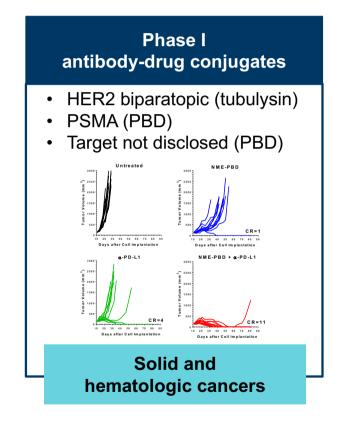


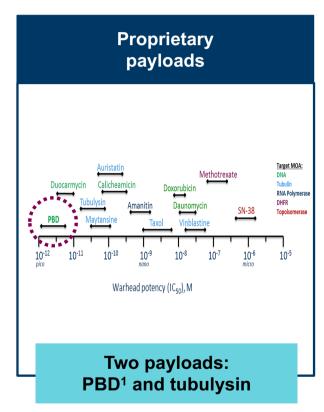


## ADC: Growing antibody-drug conjugate programme

## Now four clinical-stage programmes









<sup>1.</sup> PBD = Pyrrolobenzodiazepine. Source: AstraZeneca data on file; ASCO 2015, abstract 7079.

# Transformative potential of Oncology PACIFIC Phase III trial only one opportunity

#### **Faslodex**

breast cancer 1L Reg. decisions

#### Lynparza

ovarian cancer 2L Reg. decision (US)

#### acalabrutinib

blood cancer Phase II/reg. submission (US)<sup>1</sup>

#### Lynparza

ovarian cancer 2L Reg. submission (EU)

#### **Imfinzi**

lung cancer Stage III Reg. submission (US)

#### Lynparza

breast cancer Reg. submissions

### Major Oncology milestones over the 2017-2018 timeframe

Imfinzi +/- treme lung cancer 1L Phase III MYSTIC Imfinzi +/- treme lung cancer 3L Phase III ARCTIC Imfinzi +/- treme
head/neck cancer 1L

Phase III **KESTREL** 

Imfinzi + treme

lung cancer 1L
Phase III NEPTUNE

Imfinzi +/- treme head/neck cancer 2L Phase III EAGLE

#### **Tagrisso**

lung cancer 1L Phase III FLAURA Lynparza

ovarian cancer 1L Phase III moxetumomab

leukaemia Phase III Imfinzi +/- treme

bladder cancer
Phase III DANUBE

selumetinib thyroid cancer Phase III



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

Timeline based on Q1 2017 Results forthcoming major news flow; the exact location of each box is approximate.

## **Agenda**



Welcome



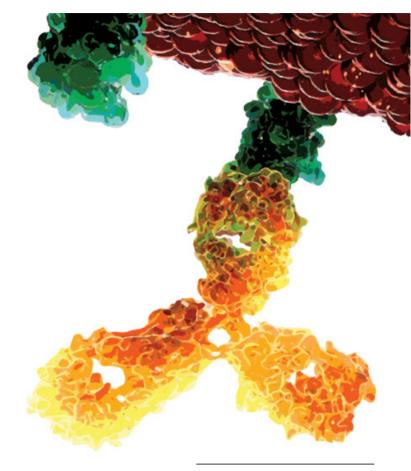
Strategy



Pipeline and news flow



**Summary and Q&A** 



Antibody that blocks inhibitory signals from the tumour to cells of the immune system, resulting in enhanced antitumour immunity



## **Summary**

- 1 Significant progress made in Oncology strategy execution
- 2 Lynparza and DDR portfolio expanding beyond ovarian cancer and BRCA
- 3 Establishing lung cancer leadership through *Tagrisso* and *Imfinzi* +/- treme
- 4 Development of Haematology gaining momentum
  - 5 Oncology pipeline with transformative potential



### **Questions & answers**

Please press \*1 on your phone if you wish to ask a question or use the dedicated Q&A facility on the webcast

- Pascal Soriot, moderator
- Sean Bohen
- Jamie Freedman
- Rob lannone
- Klaus Edvardsen
- Susan Galbraith
- David Berman



Investor science event expected to end at 8:30 PM CDT Food and drinks are available outside - please join us!



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# Taking our science to the 2017 ASCO Annual Meeting

#### **Investor science event**

Chicago, IL, USA 05 June 2017

