

# A pipeline-driven transformation

SEB Nordic Seminar 2018

09 January 2018



# 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 anti-competitive 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 media 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.



# Agenda

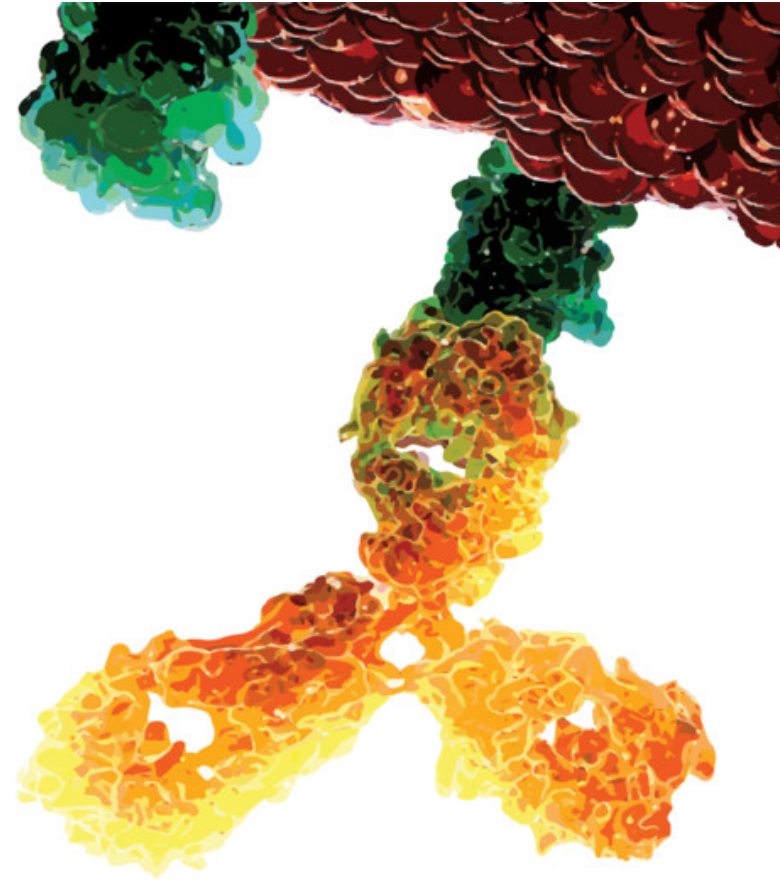
## Strategy status

## Opportunities in 2018

-Business

-Pipeline & news flow

## Summary



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



# Strategic priorities

1

**Achieve  
scientific  
leadership**

2

**Return  
to growth**

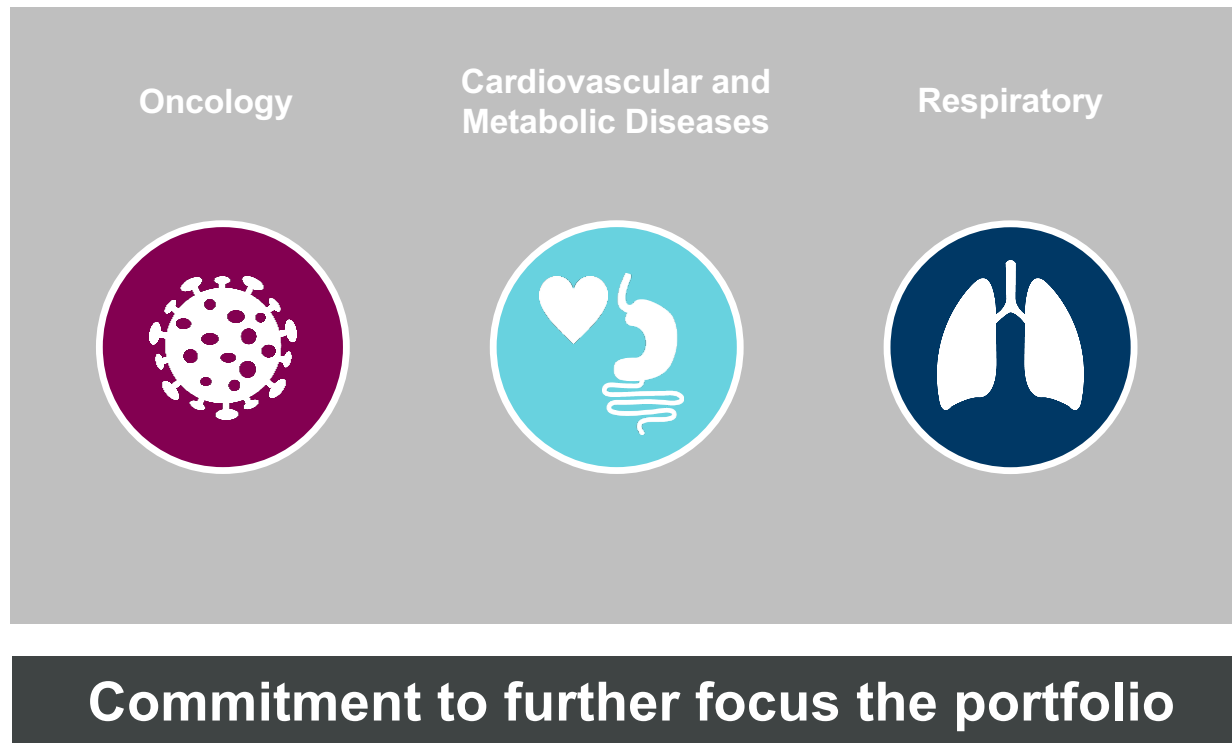
3

**Be a great  
place to work**



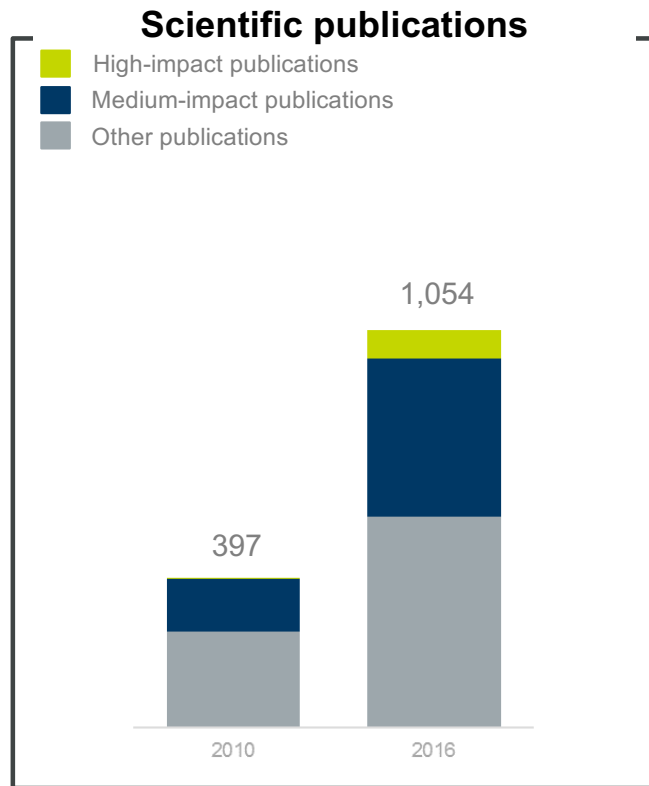
# Focused strategy

## Three therapy areas

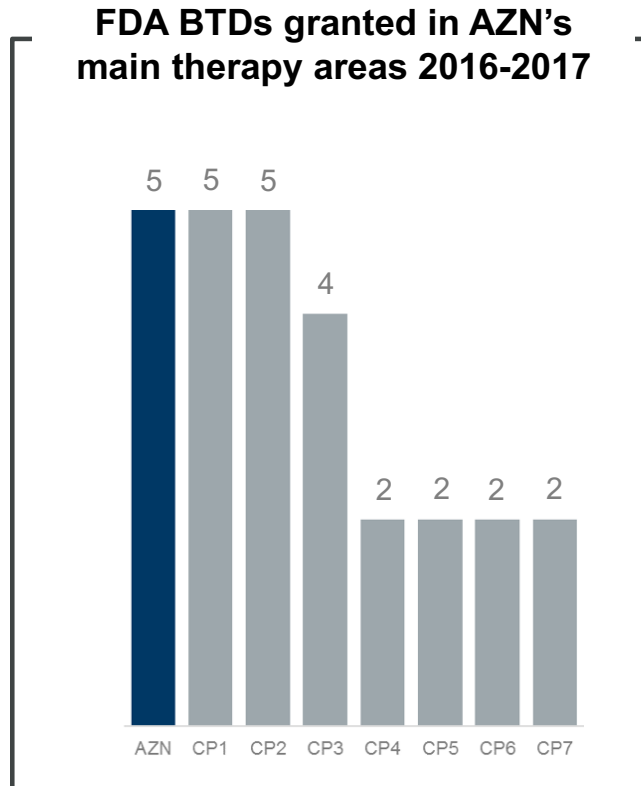


# R&D productivity: Sustainable progress

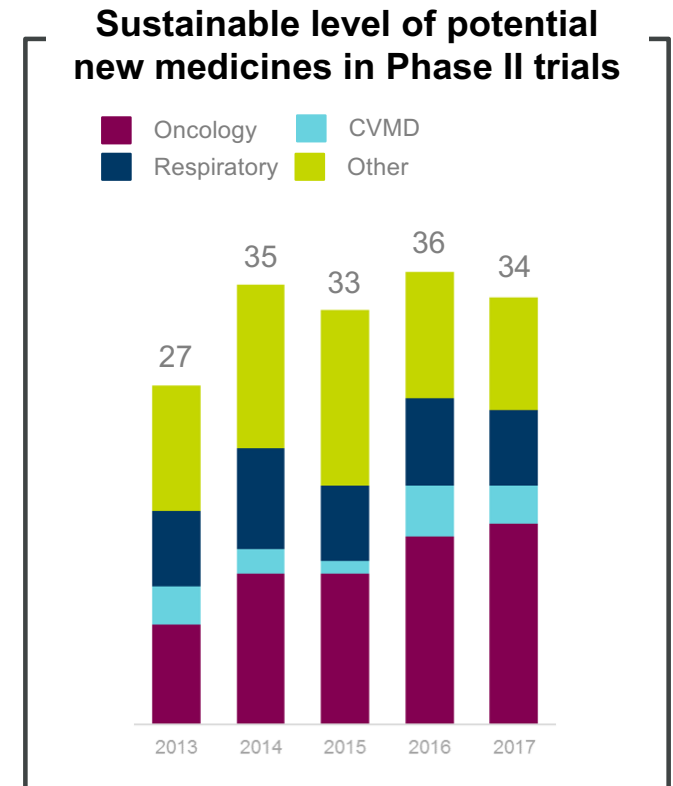
## A new AstraZeneca with science-based culture



Source: Internal analysis. High-impact (rating > 15); medium-impact (rating > 5); other (rating < 5).



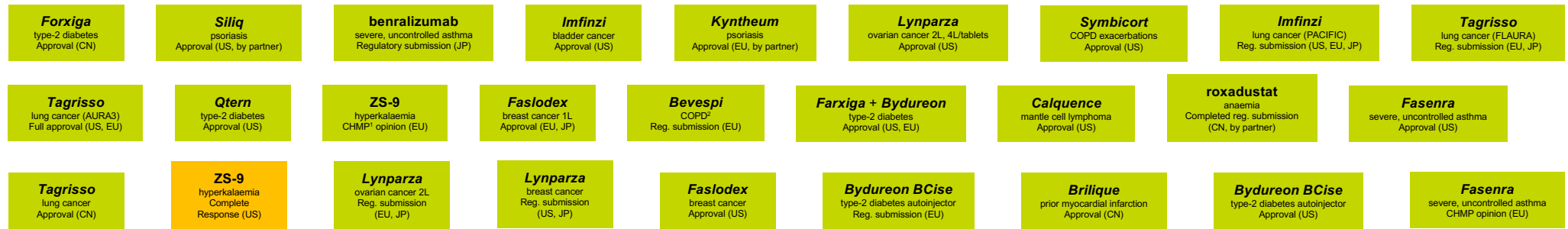
AstraZeneca (AZN) and industry peers/competitors (CP) 1-7.  
Source: Internal analysis based on focr.org. Includes Breakthrough Therapy Designations (BTD) in the three main AstraZeneca therapy areas.



# Late-stage pipeline news flow

## Unprecedented activity level in '17

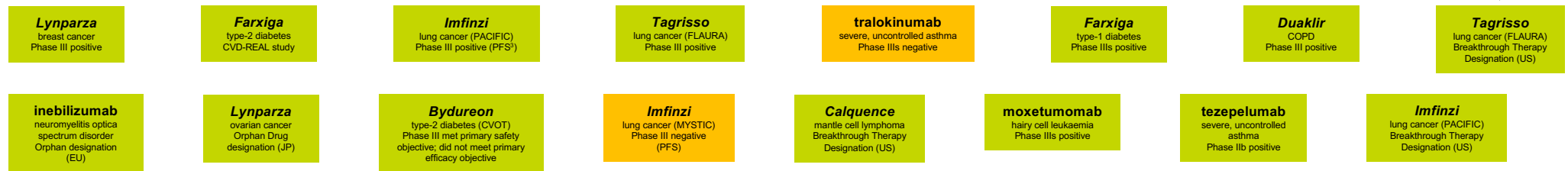
1  
Achieve scientific leadership



Regulatory actions

**Significant patient benefits anticipated to support return to growth**

Data & designations

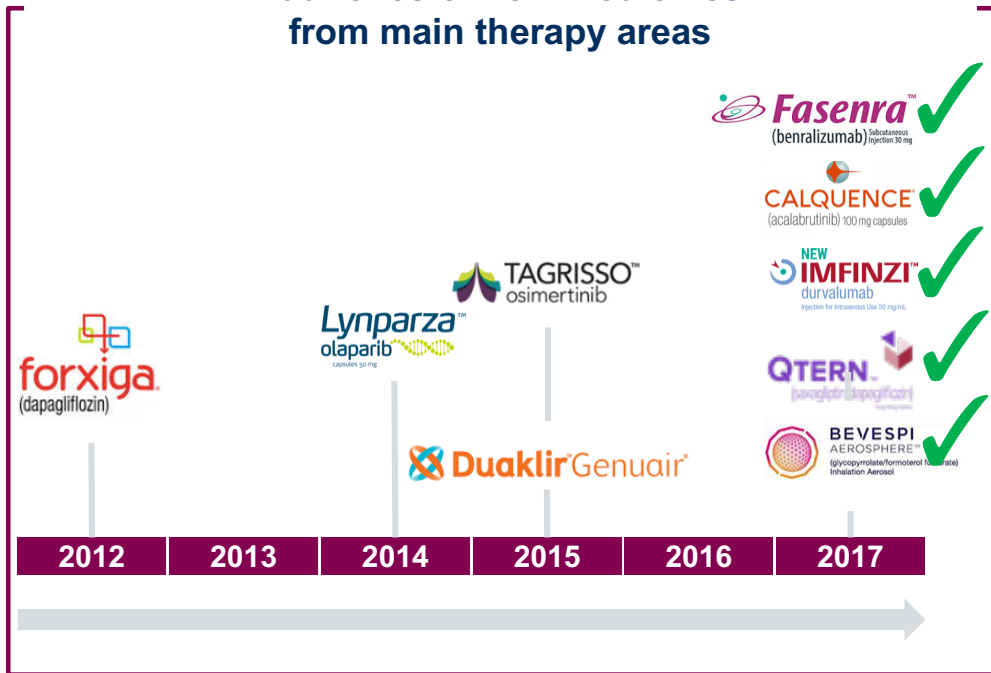


1. The Committee for Medicinal Products for Human Use.  
2. Chronic obstructive pulmonary disease.  
1. Progression-free survival.  
Status as of 14 December 2017. **Favourable** / unfavourable news.

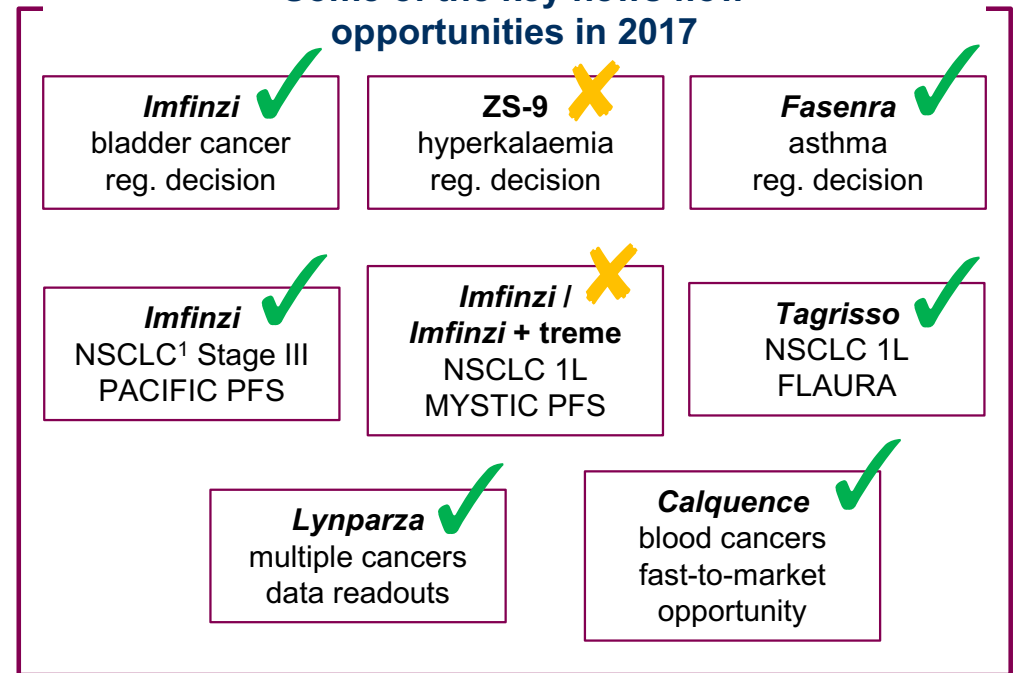


# 2017: Already a defining year

## Launches of new medicines from main therapy areas



## Some of the key news flow opportunities in 2017



1. Non-small cell lung cancer.

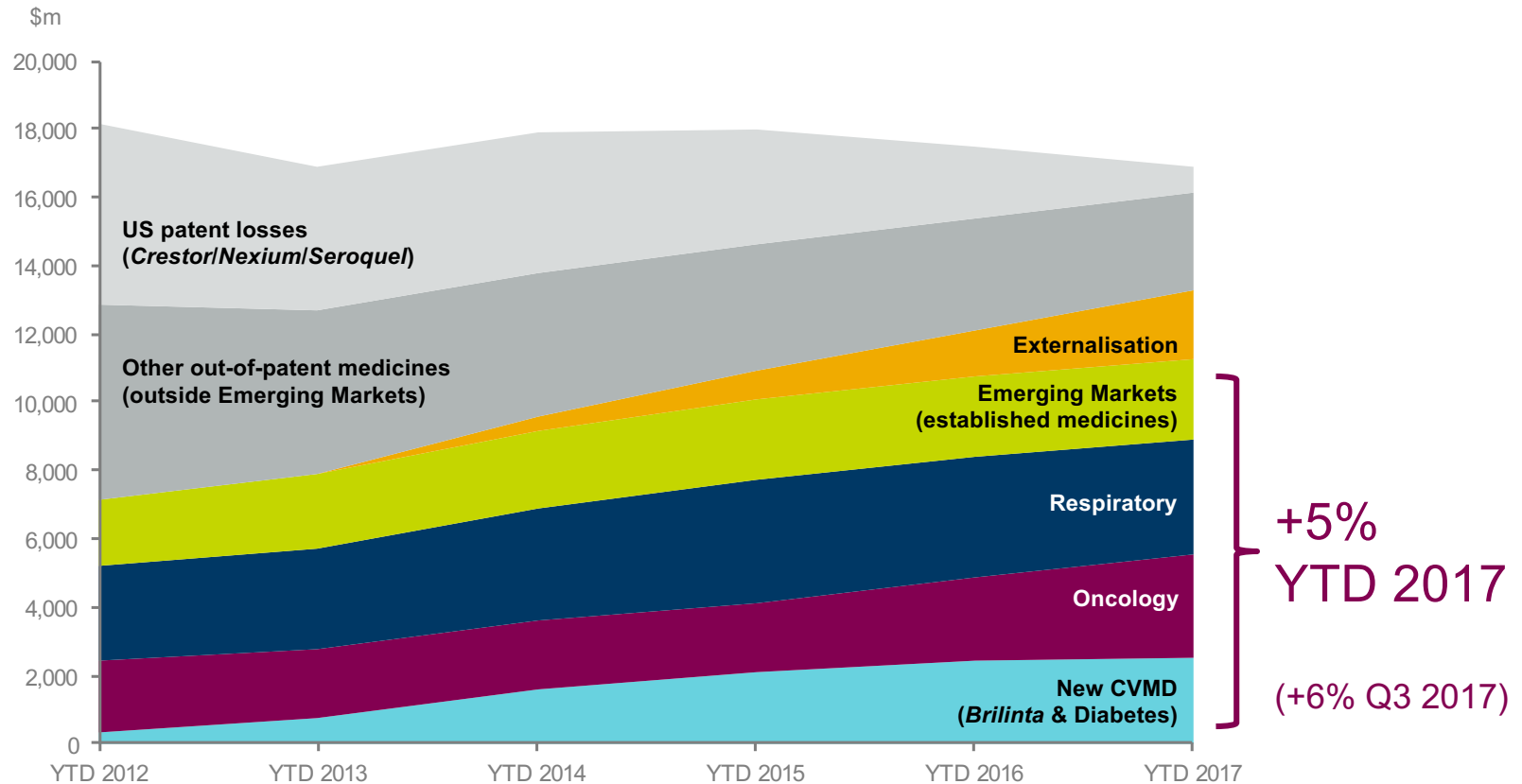




# Product Sales: An inflection point approaching

## A new AstraZeneca is emerging from the patent losses

2  
Return to growth








Absolute values and change at CER.



# Growth Platforms: Solid Q3 with improving performance

2  
Return to growth

	Q3 2017 \$m	% change	% Total Revenue	% Product Sales	YTD 2017 \$m	% change	% Total Revenue	% Product Sales
<b>Growth Platforms</b>	3,760	6	60	77	11,055	4	66	75
 <b>Emerging Markets</b>	1,515	10	-	-	4,519	7	-	-
 <b>Respiratory</b>	1,092	(2)	-	-	3,372	(3)	-	-
 <b>New CVMD</b>	873	7	-	-	2,543	5	-	-
 <b>Japan</b>	578	4	-	-	1,645	5	-	-
 <b>New Oncology</b>	339	73	-	-	876	97	-	-

Total Product Sales for Growth Platforms are adjusted to remove duplication on a medicine and regional basis.  
Product Sales values at actual exchange rates; change at CER.



# Core Profit & Loss



	YTD 2017 \$m	% change	% Total Revenue	Q3 2017 \$m	% change	% Total Revenue
<b>Total Revenue</b>	<b>16,688</b>	<b>(3)</b>	<b>100</b>	<b>6,232</b>	<b>10</b>	<b>100</b>
- Product Sales	14,665	(8)	88	4,882	(2)	78
- Externalisation Revenue	2,023	50	12	1,350	n/m	22
Gross Margin	81.8%	(1) pp	-	79.6%	(4) pp	-
R&D Expenses	3,956	(2)	24	1,339	-	21
SG&A Expenses	5,678	(5)	34	1,950	4	31
Other Operating Inc. & Exp.	1,101	94	7	143	32	2
Tax Rate	18%	-	-	17%	-	-
<b>EPS</b>	<b>\$2.98</b>	<b>(7)</b>		<b>\$1.12</b>	<b>(17)</b>	

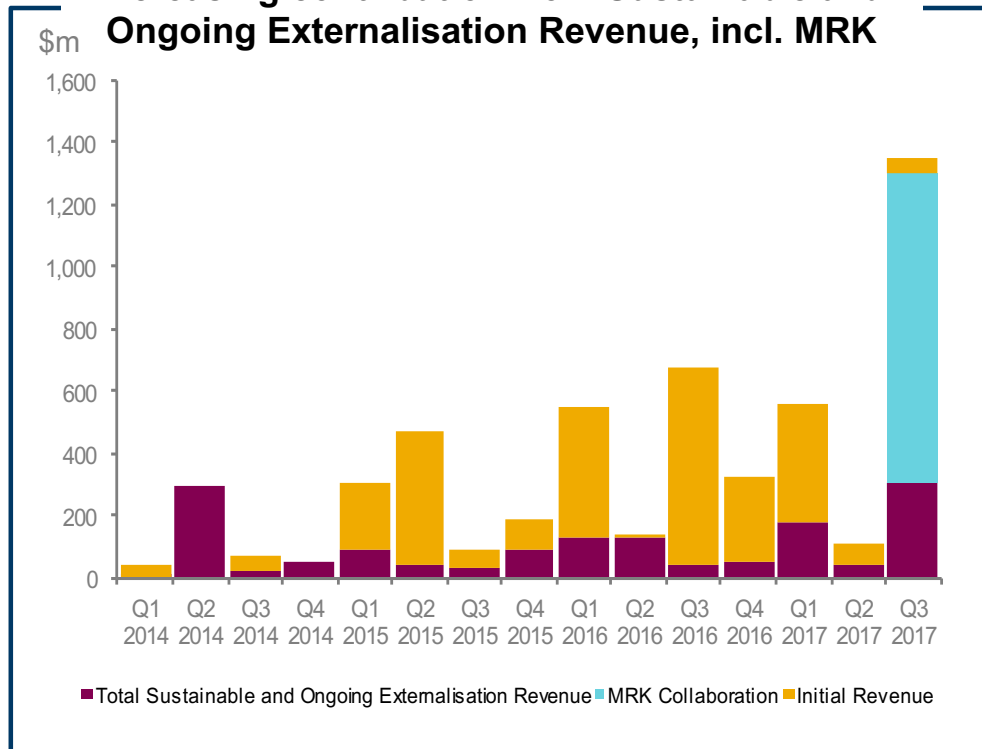
Absolute values at actual exchange rates; change at CER.  
Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales.



# Externalisation Revenue

## Sustainable income increased

Increasing contribution from Sustainable and Ongoing Externalisation Revenue, incl. MRK



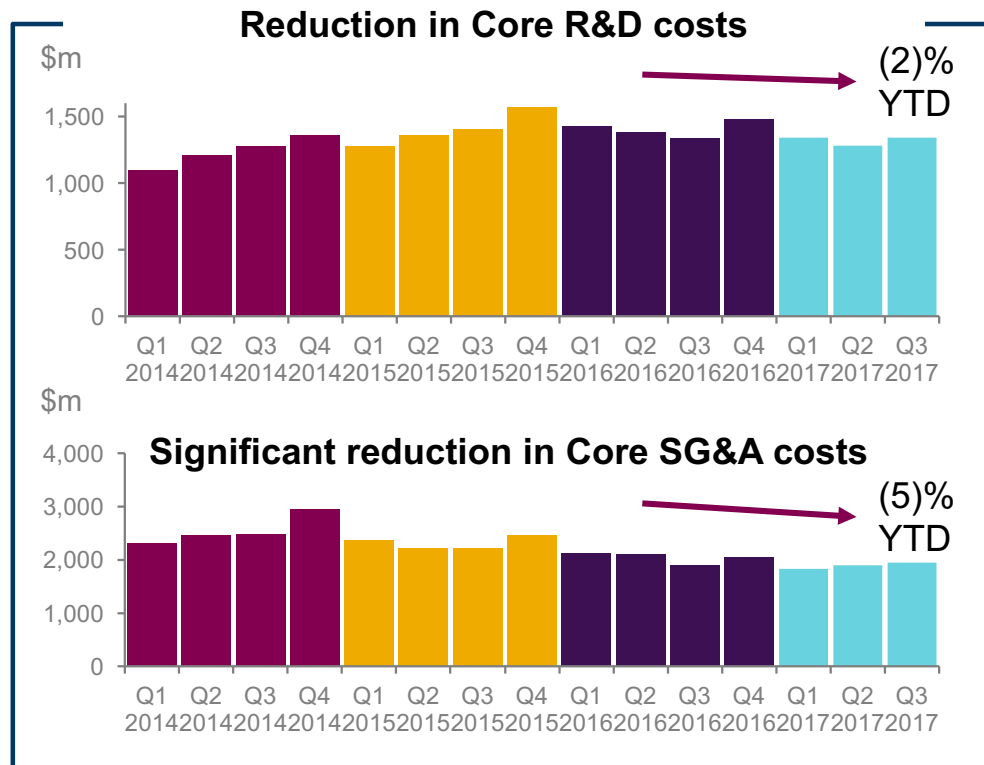
### Key observations

- Sustainable and Ongoing Externalisation Revenue annualising at >\$500m in 2017
- MRK collaboration expected to provide further and increasing income in the years to come
  - \$1.6bn this year - \$1bn in Externalisation Revenue
  - \$750m option payments in 2017-2019
  - Regular milestones; approval (~1/3) and sales-related (~2/3); mono and combo therapy
  - First milestone anticipated in 2018

Absolute values at actual exchange rates.



# Continued progress and focus on cost discipline



## Continued reduction in Core costs

- Reduction in Core R&D costs
  - YTD 2017: Down by 2%
  - FY 2017: Core R&D costs are expected to be broadly in line with those in FY 2016
- Significant reduction in Core SG&A costs
  - YTD 2017: Down by 5%
  - Q3 2017: Continued cost discipline; increase of 4% reflects comparative period, early investment in upcoming launches and Emerging Markets/China

Absolute values at actual exchange rates; change at CER.



# FY 2017 guidance and capital-allocation priorities

Guidance	
<b>Total Revenue</b> Low to mid single-digit percentage decline	<b>Core EPS</b> Towards the favourable end of a low to mid teens percentage decline

Capital-allocation priorities
Investment in the business
Progressive dividend policy
Strong, investment-grade credit rating
Immediately earnings-accretive, value-enhancing opportunities



# Agenda

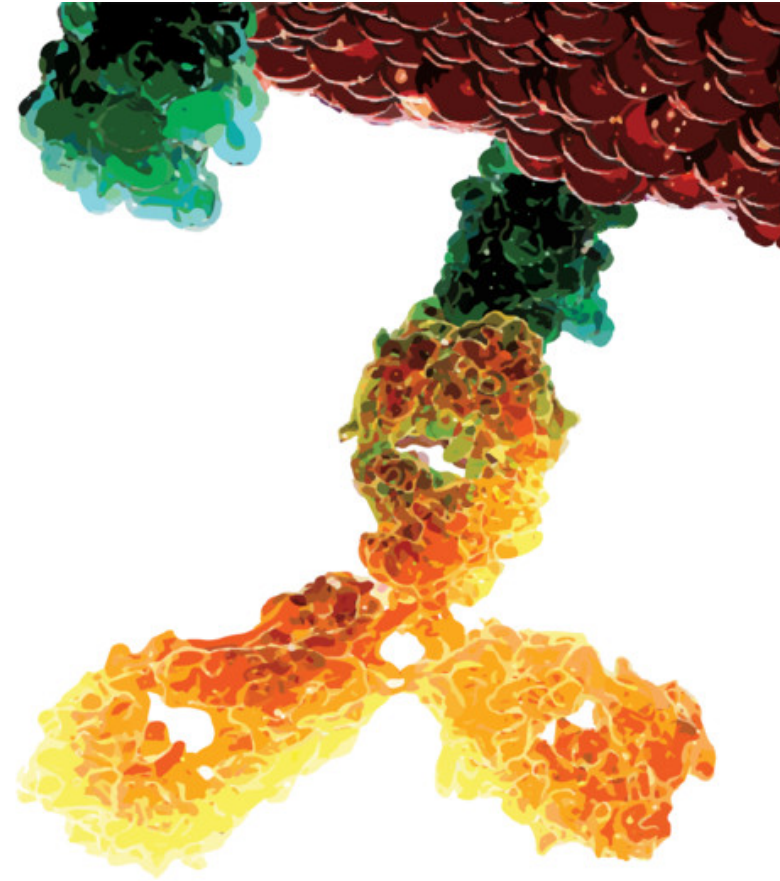
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**-Pipeline & news flow**

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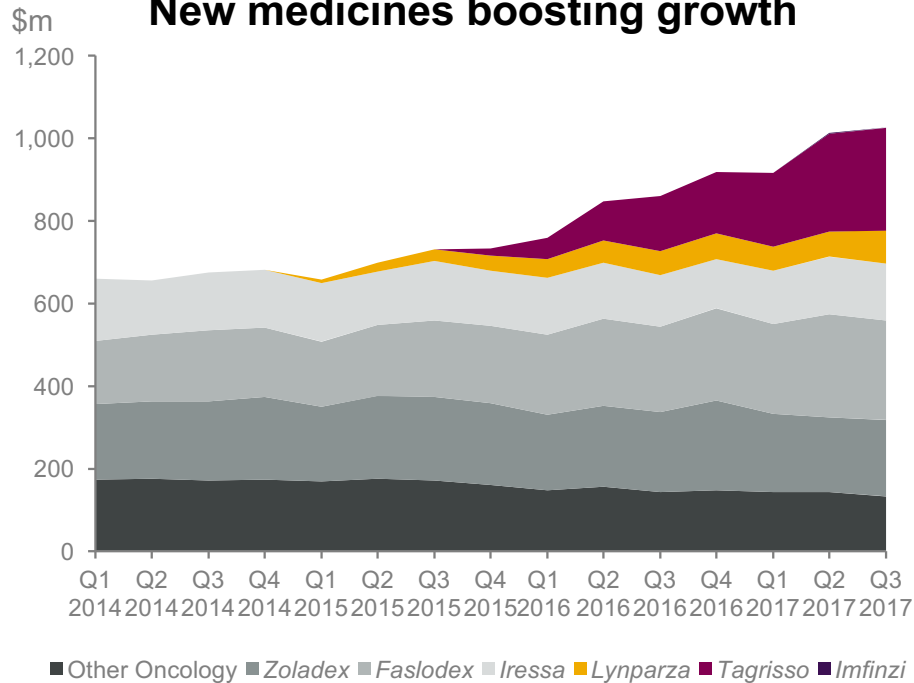
Antibody that blocks inhibitory signals from the tumour to cells of the immune system, resulting in enhanced anti-tumour immunity



# Oncology

Quarterly sales now >\$1bn

**Oncology Product Sales**  
**New medicines boosting growth**



- **Total Oncology +19%**
  - Already 20% of total Product Sales
- **Six new medicines 2014-2020 with four delivered**
  - *Lynparza*
  - *Tagrisso*
  - *Imfinzi*: Strategic US launch May 2017 in bladder cancer 2L enabling awareness, account openings and formulary access. Steady progress; mid-single digit share of new patients / shared 3rd market position
  - *Calquence*: Entry into blood cancers

Absolute values at CER.





# Lynparza

## Global leader in DNA damage response

### Back to strong growth

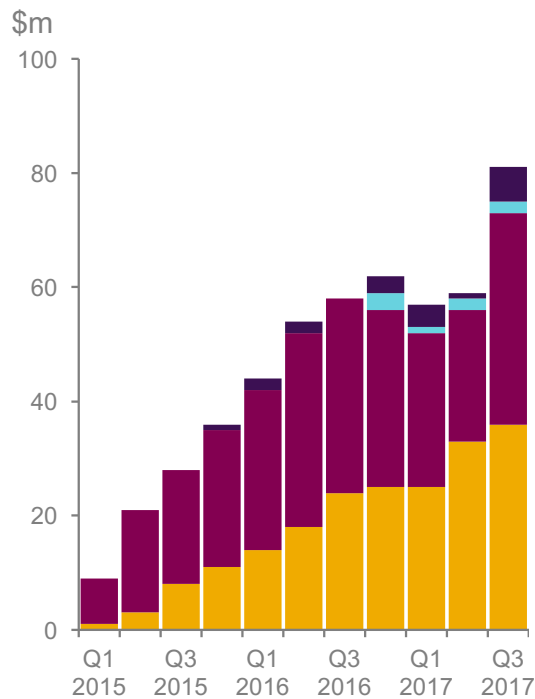


Chart legend: Europe US Established Rest of World Emerging Markets

Absolute values at actual exchange rates.

### US returned to growth in Q3

- **Europe**  
Steady progress in 2L ovarian cancer, despite capsule label
- **US**  
Returned to growth in Q3; strong launch of tablets and new broad label in OC<sup>1</sup>
- **Next commercial milestones**
  - Tablets in Europe (H1 2018)
  - BC<sup>2</sup> launch in US (H1 2018)
  - First launch in Japan; OC (H1 2018)
  - 2018 followed by BC (H2 2018)

1. Ovarian cancer.  
2. Breast cancer.

### MRK collaboration status since H1 2017 Results announcement

- Joint Steering Committee and subteams created and agreed commercial and development plans
- Collaboration infrastructure set up and agreed
- MRK sales reps will start promoting *Lynparza* in early 2018

AstraZeneca

MERCK  
INVENTING FOR LIFE



# Lung cancer: *Tagrisso* and *Imfinzi*

Quickly progressing with making medicines available to patients

## Tagrisso

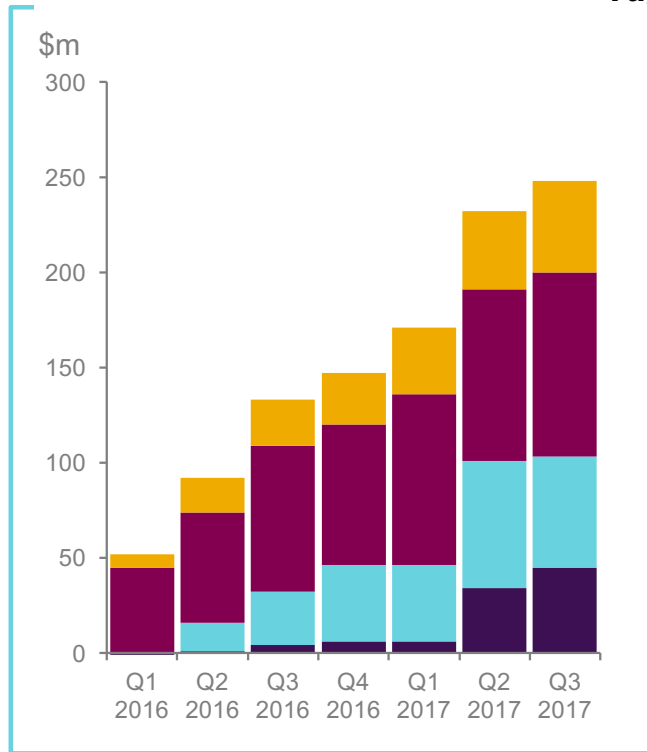


Chart legend: **Emerging Markets** Established Rest of World **US** **Europe**

Absolute values at actual exchange rates.

- **US**  
Higher testing rates underpinned growth
- **Europe**  
Positive reimbursement decision in Germany
- **Japan**  
Testing rates >90%, 2L T790M penetration ~80%
- **Emerging Markets**  
China launch progressing well

## Imfinzi

Locally-advanced, unresectable NSCLC

8

Regulatory submissions<sup>1</sup>

Other Q3 achievements

- ESMO presentation/NEJM publication
- Global early-access programme initiated



Imfinzi is not yet approved in lung cancer.

1. US, EU, Japan, Switzerland, Canada, Australia, Brazil, South Korea.



# Agenda

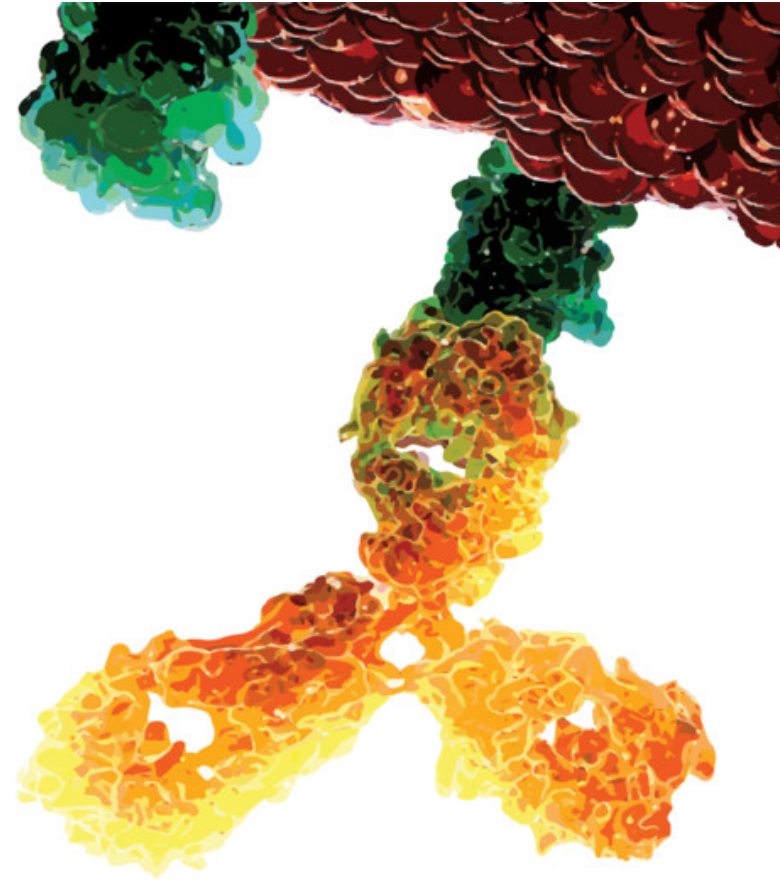
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Antibody that blocks inhibitory signals from the tumour to cells of the immune system, resulting in enhanced anti-tumour immunity



# Late-stage pipeline and key lifecycle medicines

## Significant opportunities exist in all three therapy areas

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

Cardiovascular and Metabolic Diseases
<b>ZS-9</b> <sup>2</sup> hyperkalaemia
<b>roxadustat</b> <sup>2</sup> anaemia

Respiratory
<b>Fasenra</b> <sup>1</sup> severe, uncontrolled asthma <sup>2</sup> / COPD
<b>PT010</b> COPD / asthma
<b>tezepelumab</b> severe, uncontrolled asthma





Other
<b>anifrolumab</b> lupus
<b>lanabecestat</b> Alzheimer's disease

1. Lifecycle development programme.  
2. Under regulatory review in major jurisdiction.  
Status as of 14 December 2017.



# Oncology

## Strategic priorities support the return to growth

Multiple cancers	Lung cancers	Blood cancers
 <ul style="list-style-type: none"><li>• Ovarian and breast cancers</li><li>• Lifecycle programme (2018+), incl. prostate cancer</li><li>• Merck collaboration</li></ul>	 <ul style="list-style-type: none"><li>• 2nd line / T790Mm<sup>1</sup></li><li>• 1st line / EGFRm<sup>2</sup></li><li>• Adjuvant EGFRm (2022+)</li></ul>	  <ul style="list-style-type: none"><li>• Locally-advanced/Stage III, unresectable NSCLC<sup>3</sup></li><li>• Lifecycle programme (2018+)</li><li>• First AstraZeneca medicine in blood cancer</li><li>• MCL<sup>4</sup> initial indication</li><li>• Lifecycle programme (2019+)</li></ul>

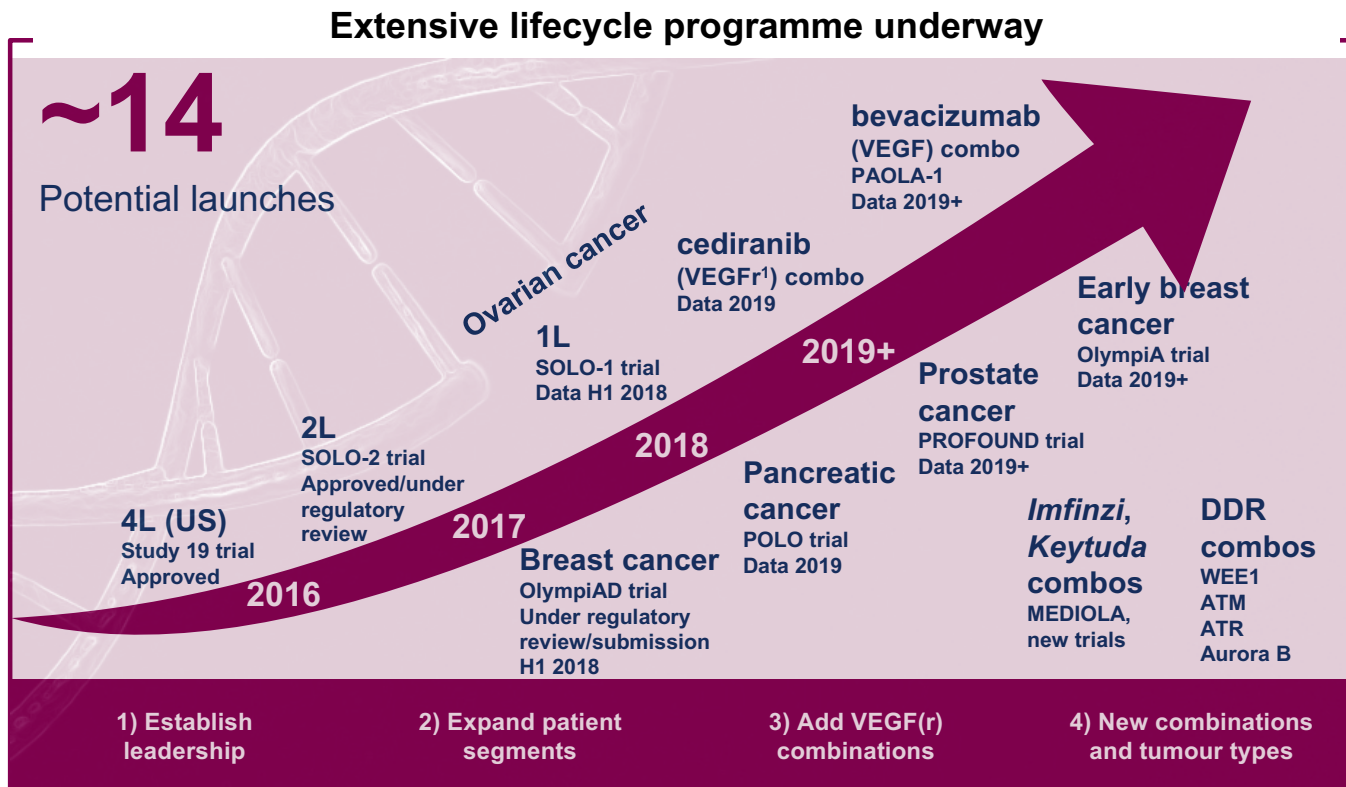
### Rich and early pipeline, including combinations

1. Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.  
2. Epidermal growth factor receptor mutation.  
3. Non-small cell lung cancer.  
4. Mantle cell lymphoma.  
( ) First / next data anticipated.



# Lynparza

## Significant opportunity to further expand through Merck collaboration



- Status of Merck collaboration**
- Collaboration infrastructure set up and agreed
  - Joint steering committee and subteams created
  - Agreed development plans
  - More new trials expected to be announced in H1 2018
- AstraZeneca   **MERCK**  
INVENTING FOR LIFE

1. Vascular endothelial growth factor (receptor).



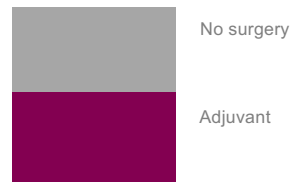
# Lung cancer: *Tagrisso* and *Imfinzi*

## Early-stage disease

## Late-stage disease

Stage I-III  
Total 155k patients

*Tagrisso's*  
ADAURA trial  
*Imfinzi's*  
ADJUVANT trial

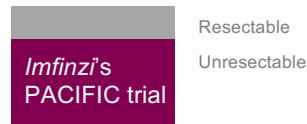


**80k**

adjuvant  
patients

Stage III  
Total 105k patients

*Imfinzi's*  
PACIFIC trial

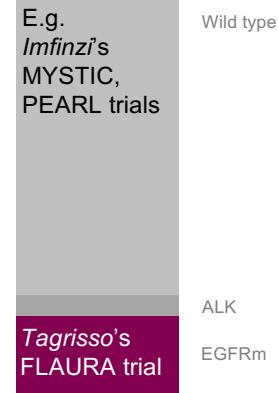


**76k**

unresectable  
patients

Stage IV 1st line  
Total 370k patients

E.g.  
*Imfinzi's*  
MYSTIC,  
PEARL trials

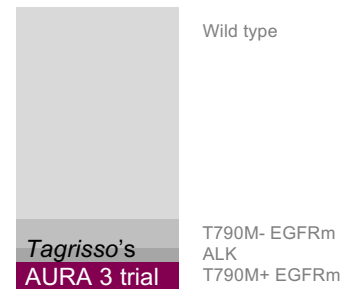


**70k**

1L EGFRm  
patients

Stage IV 2nd line  
Total 250k patients

*Tagrisso's*  
AURA 3 trial



**25k**

2L T790M EGFRm  
patients

Treated patients. Epidemiology: Internal estimates based on external market research, top eight countries, China generally includes a market-access adjustment.



# Farxiga

## Focus on establishing CV benefit in type-2 diabetes

### CVD-REAL

#### Real-world observational study

#### SGLT2 inhibitors vs other glucose-lowering medicines

**51%**

reduction in all-cause mortality

**39%**

reduction in risk of hospitalisation for heart failure

**46%**

risk of composite endpoint of hospitalisation for heart failure and death from any cause

Database	N	# of events	HR (95% CI)
US	143,264	424	0.44 (0.36, 0.54)
Norway	25,050	622	0.58 (0.50, 0.69)
Denmark	18,468	477	0.57 (0.48, 0.67)
Sweden	18,378	364	0.50 (0.41, 0.63)
UK	10,462	96	0.66 (0.44, 1.00)
Total	215,622	1983	<b>0.54 (0.48, 0.60)</b>

Hazard Ratio: 0.25    0.50    1.00    2.00  
 Favor SGLT2i ←    → Favor oGLD

### DECLARE Phase III trial

- Primary efficacy endpoints
  - Superiority for MACE (CV death, non-fatal myocardial infarction or non-fatal stroke)
  - Superiority for the composite endpoint of CV death or hospitalisation for heart failure
- Primary safety endpoint
  - Non-inferiority for MACE
- Data anticipated in H2 2018

**~17,000 patients**

including patients with multiple CV risk factors (~10,000) or established CVD (~7,000)










# Roxadustat

## Potential first-in-class oral HIF-PHD inhibitor for anaemia of CKD

### Phase III programme

Patient population	Company	Phase III trial
Anaemia in CKD patients not receiving dialysis	<b>FIBROGEN</b>	ANDES
	AstraZeneca 	OLYMPUS
	 astellas	ALPS
	 astellas	DOLOMITES
Anaemia in CKD in patients receiving dialysis	<b>FIBROGEN</b>	SIERRAS
	AstraZeneca 	ROCKIES
	 astellas	PYRENEES
Anaemia in newly-initiated dialysis patients	<b>FIBROGEN</b>	HIMALYAS

### Targeting a competitive medicine profile

#### Non-dialysis patients (against placebo)

- Superior haemoglobin increase
- Non-inferior on major adverse CV events (MACE) based on pooled analysis<sup>1</sup>

#### Dialysis patients (against erythropoietin)

- Non-inferior haemoglobin increase
- Non-inferior, potentially superior MACE; pooled analysis<sup>1</sup>

#### Regulatory status

- China rolling regulatory submission completed
- US regulatory submission anticipated in H2 2018

#### Lifecycle programme started

- Phase III in anaemia of myelodysplastic syndrome

1. The MACE endpoint is event-driven.  
In partnership with Fibrogen and their collaborator Astellas.



# Asthma: *Fasenra*

Targeted, anti-eosinophil medicine; recently launched in the US

***Fasenra* (benralizumab) received US FDA approval for severe eosinophilic asthma<sup>1</sup>**

**51%<sup>2</sup>**

reduction in the annual asthma exacerbation rate versus placebo

**159mL<sup>3</sup>**

Significant improvement in lung function as measured by forced expiratory volume in one second (FEV<sub>1</sub>) versus placebo

**75%<sup>5</sup>**

median reduction in daily OCS<sup>4</sup> use and discontinuation of OCS use in 52% of eligible patients



**Under regulatory review in the EU, Japan and several other countries with decisions anticipated in H1 2018**

**Lifecycle programme**

## **Asthma**

- Autoinjector; GRECO Phase III trial readout anticipated in H2 2018

## **COPD**

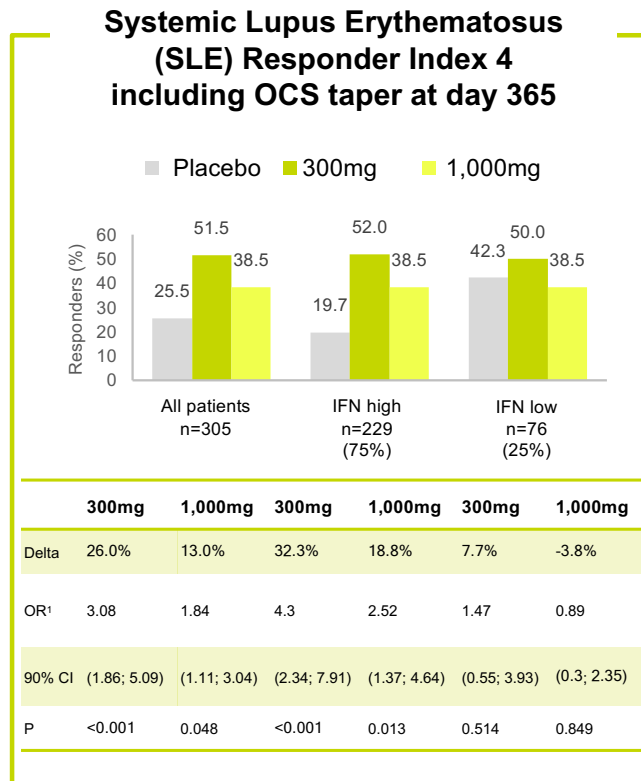
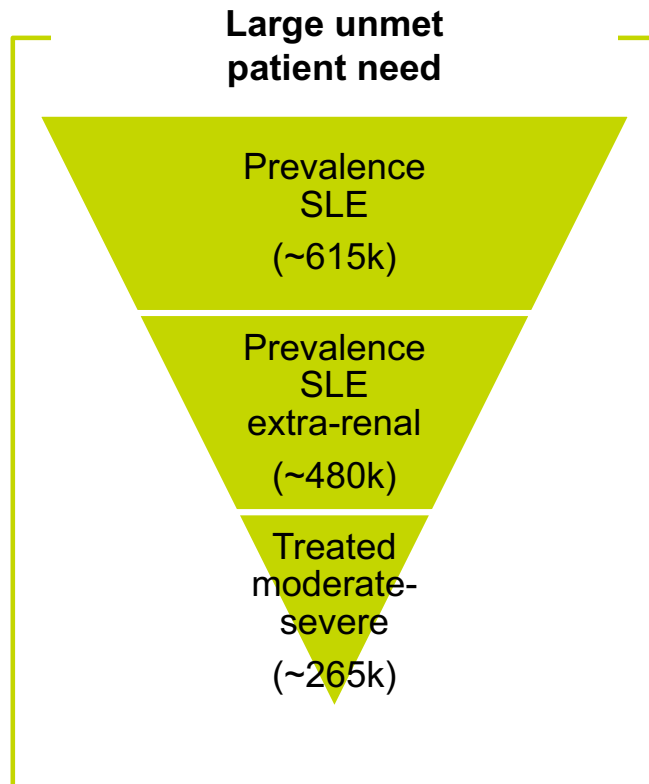
- Phase III VOYAGER programme is evaluating the efficacy and safety of *Fasenra* in patients with severe COPD
- Data readout anticipated in H2 2018

<sup>1</sup>. Based on the results from the Phase III trials SIROCCO, CALIMA and ZONDA. <sup>2</sup>. SIROCCO: 51% reduction in AER vs. placebo at week 48 (.74 vs 1.52). CALIMA: 28% reduction vs. placebo at week 56 (.73 vs 1.01). <sup>3</sup>. SIROCCO: At 48 weeks, an improvement in FEV<sub>1</sub> of 398mL (mean change from baseline) vs. 239mL for placebo, total of 159mL increase in FEV<sub>1</sub>. CALIMA: At 56 weeks, an improvement in FEV<sub>1</sub> of 330mL (mean change from baseline) vs. 215mL for placebo, for total of 116mL increase in FEV<sub>1</sub>. <sup>4</sup>. Oral corticoid steroid. <sup>5</sup>. Median reduction in OCS dose of 75% from baseline vs. 25% for placebo.  
Source: US prescribing information.



# Anifrolumab

## Lupus Phase III on track for H2 2018



**Phase III SLE programme now fully recruited**

- Phase III trials TULIP 1 and TULIP 2 both fully recruited
- Primary endpoints at 48 weeks driving data-readout timelines

**Lifecycle programme**

- Phase II subcutaneous administration trial fully recruited
- Phase II lupus nephritis trial ongoing

**Phase III data in H2 2018  
Regulatory submission in 2019**

Epidemiology: Internal estimates based on external market research, top eight countries.

1. Odds Ratio.  
Source: Furie R, et al., Arthritis & Rheumatology, 2016.



# Late-stage pipeline news flow 2018 & 2019

## Unlocking and realising potential of new medicine

	H1 2018	H2 2018	2019
<b>Regulatory decision</b>	<p><b>Lynparza</b> - ovarian cancer 2L (EU, JP) - breast cancer (US) <b>Tagrisso</b> - lung cancer (US) <b>Imfinzi</b> - lung cancer (PACIFIC) (US)</p> <p><b>Fasenra</b> - severe, uncontrolled asthma(EU,JP)</p>	<p><b>Lynparza</b> - breast cancer (JP) <b>Tagrisso</b> - lung cancer (EU, JP) <b>Imfinzi</b> - lung cancer (PACIFIC) (EU, JP)</p> <p><b>Bydureon BCise</b> - type-2 diabetes (EU)</p> <p><b>Bevespi</b> - COPD (EU)</p>	-
<b>Regulatory submission</b>	<p><b>Lynparza</b> - breast cancer (EU) <b>Imfinzi +/- treme</b> - lung cancer 3L (ARCTIC) <b>moxetumomab pasudotox</b> - hairy cell leukaemia 3L</p> <p><b>Bevespi</b> - COPD (JP) <b>Duaklir</b> - COPD (US)</p>	<p><b>Lynparza</b> - ovarian cancer 1L <b>Imfinzi + treme</b> - lung cancer 1L (NEPTUNE) <b>Imfinzi +/- treme</b> - lung cancer 1L (MYSTIC) - head &amp; neck cancer 1L, 2L (KESTREL, EAGLE) <b>selumetinib</b> - thyroid cancer</p> <p><b>roxadustat</b> - anaemia (US)</p> <p><b>PT010</b> - COPD</p>	<p><b>Lynparza</b> - pancreatic cancer 1L - ovarian cancer 3L <b>Imfinzi +/- treme</b> - lung cancer 1L (POSEIDON) - bladder cancer 1L (DANUBE)</p> <p><b>Brilinta</b> - CAD<sup>2</sup>/type-2 diabetes CVOT <b>Farxiga</b> - type-2 diabetes CVOT (DECLARE)</p> <p><b>Fasenra</b> - COPD <b>anifrolumab</b> - lupus</p>
<b>Key Phase III data readouts</b>	<p><b>Lynparza</b> - ovarian cancer 1L <b>Imfinzi +/- treme</b> - lung cancer 3L (ARCTIC) - lung cancer 1L (MYSTIC) (final OS) - head &amp; neck cancer 1L, 2L (KESTREL, EAGLE) <b>selumetinib</b> - thyroid cancer</p> <p><b>PT010</b> - COPD</p>	<p><b>Lynparza</b> - pancreatic cancer 1L <b>Imfinzi + treme</b> - lung cancer 1L (NEPTUNE)</p> <p><b>Farxiga</b> - type-2 diabetes CVOT<sup>1</sup> (DECLARE)</p> <p><b>Fasenra</b> - COPD</p> <p><b>anifrolumab</b> - lupus</p>	<p><b>Lynparza</b> - ovarian cancer 3L <b>Imfinzi</b> - lung cancer (PACIFIC) (final OS) <b>Imfinzi +/- treme</b> - lung cancer 1L (POSEIDON) - bladder cancer 1L (DANUBE) - liver cancer 1L (HIMALAYA) <b>Calquence</b> - chronic lymphocytic leukaemia</p> <p><b>Brilinta</b> - CAD/type-2 diabetes CVOT <b>Farxiga</b> - HF <b>lanabecestat</b> - Alzheimer's disease</p>

1. Cardiovascular outcomes trial.  
2. Coronary artery disease.  
Status as of 14 December 2017.



# Agenda

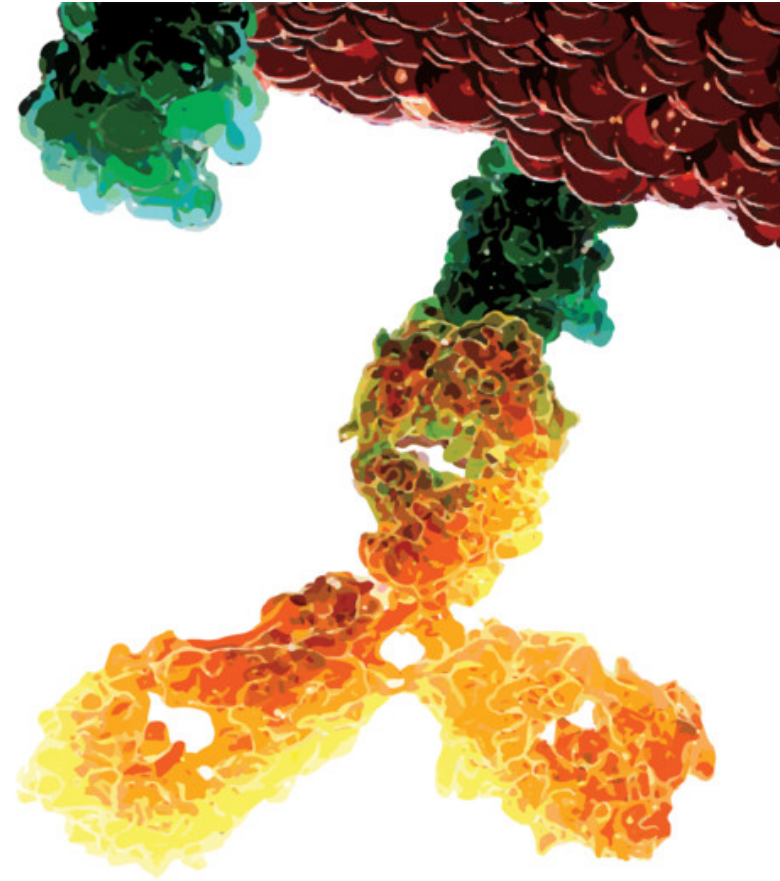
Strategy status

Opportunities in 2018

-Business

-Pipeline & news flow

Summary



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



# Pipeline-driven transformation gathers pace

## A new AstraZeneca is steadily emerging from 2017

Summary after the first  
nine months of 2017

- **YTD and Q3 2017 in line with expectations**
  - Financials on track
  - Guidance reiterated/updated
  - Unprecedented pipeline news flow
- **Business execution**
  - *Lynparza* back to US growth, *Tagrisso* excels, *Imfinzi* PACIFIC regulatory submissions, *Calquence* entry into blood cancers
  - Emerging Markets, *Brilinta* and *Farxiga* continued solidly
- **11 new potential medicines in Phase III/under registration ahead of busy news flow**



Q&A



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# A pipeline-driven transformation

SEB Nordic Seminar 2018

09 January 2018

