

# FY 2020 results

Conference call and webcast for investors and analysts



## Forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act of 1995, AstraZeneca (hereafter 'the Group') provides 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 the Group believes its 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 the Group undertakes no obligation to update these forward-looking statements. The Group identifies 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 the Group's control, include, among other things: the risk of failure or delay in delivery of pipeline or launch of new medicines; the risk of failure to meet regulatory or ethical requirements for medicine development or approval; the risk of failure to obtain, defend and enforce effective intellectual property (IP) protection and IP challenges by third parties; the impact of competitive pressures including expiry or loss of IP rights, and generic competition; the impact of price controls and reductions; the impact of economic, regulatory and political pressures; the impact of uncertainty and volatility in relation to the UK's exit from the EU; the risk of failures or delays in the quality or execution of the Group's commercial strategies; the risk of failure to maintain supply of compliant, quality medicines; the risk of illegal trade in the Group's medicines; the impact of reliance on third-party goods and services; the risk of failure in information technology, data protection or cybercrime; the risk of failure of critical processes; any expected gains from productivity initiatives are uncertain; the risk of failure to attract, develop, engage and retain a diverse, talented and capable workforce, including following the Alexion Pharmaceuticals, Inc. (hereafter 'Alexion') transaction; the risk of failure to adhere to applicable laws, rules and regulations; the risk of the safety and efficacy of marketed medicines being questioned; the risk of adverse outcome of litigation and/or governmental investigations, including relating to the Alexion transaction; the risk of failure to adhere to increasingly stringent anti-bribery and anti-corruption legislation; the risk of failure to achieve strategic plans or meet targets or expectations; the risk of failure in financial control or the occurrence of fraud; the risk of unexpected deterioration in the Group's financial position; the impact that the COVID-19 global pandemic may have or continue to have on these risks, on the Group's ability to continue to mitigate these risks, and on the Group's operations, financial results or financial condition; the risk that a condition to the closing of the transaction with Alexion may not be satisfied, or that a regulatory approval that may be required for the transaction is delayed or is obtained subject to conditions that are not anticipated; the risk that the Group is unable to achieve the synergies and value creation contemplated by the Alexion transaction, or that the Group is unable to promptly and effectively integrate Alexion's businesses; and the risk that management's time and attention are diverted on transaction-related issues or that disruption from the Alexion transaction makes it more difficult to maintain business, contractual and operational relationships. Nothing in this document, or any related presentation/webcast, should be construed as a profit forecast.



## Forward-looking statements, proposed acquisition of Alexion

#### Important additional information

In connection with the proposed transaction, the Group intends to file a registration statement on Form F-4 with the SEC, which will include a document that serves as a prospectus of the Group and a proxy statement of Alexion (the 'proxy statement/prospectus'), Alexion intends to file a proxy statement with the SEC (the 'proxy statement') and each party will file other documents regarding the proposed transaction with the SEC. Investors and security holders of Alexion are urged to carefully read the entire registration statement and proxy statement/prospectus or proxy statement and other relevant documents filed with the SEC when they become available, because they will contain important information. A definitive proxy statement/prospectus or a definitive proxy statement will be sent to Alexion's shareholders. Investors and security holders will be able to obtain the registration statement and the proxy statement/prospectus or the proxy statement free of charge from the SEC's website or from the Group or Alexion as described in the paragraphs below.

The documents filed by the Group with the SEC may be obtained free of charge at the SEC's website at www.sec.gov. These documents may also be obtained free of charge on the Group's website at http://www.astrazeneca.com under the tab 'Investors'.

The documents filed by Alexion with the SEC may be obtained free of charge at the SEC's website at www.sec.gov. These documents may also be obtained free of charge on Alexion's internet website at http://www.alexion.com under the tab, 'Investors' and under the heading 'SEC Filings' or by contacting Alexion's Investor Relations Department at investorrelations@alexion.com.

#### Participants in the solicitation

The Group, Alexion and certain of their directors, executive officers and employees may be deemed participants in the solicitation of proxies from Alexion shareholders in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the shareholders of Alexion in connection with the proposed transaction, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the proxy statement/prospectus or proxy statement when it is filed with the SEC. Information about the directors and executive officers of Alexion and their ownership of Alexion shares is set forth in the definitive proxy statement for Alexion's 2020 special meeting of shareholders, as previously filed with the SEC on March 26, 2020. Free copies of these documents may be obtained as described in the paragraphs above.



## **Speakers**



Pascal Soriot
Executive Director and
Chief Executive Officer



Dave Fredrickson
Executive Vice President,
Oncology Business Unit



Ruud Dobber
Executive Vice President,
BioPharmaceuticals
Business Unit



Mene Pangalos Executive Vice President, BioPharmaceuticals R&D



Marc Dunoyer
Executive Director and
Chief Financial Officer



Pam Cheng
Executive Vice President,
Operations & IT (for Q&A)



Leon Wang
Executive Vice President,
International and China
President (for Q&A)



## Agenda

**Overview** 

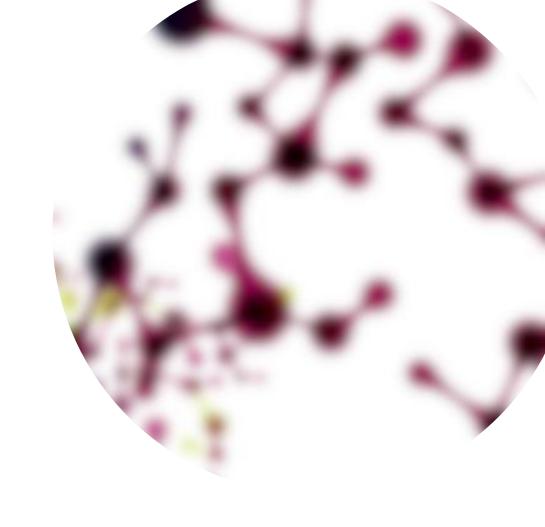
**Oncology** 

**BioPharmaceuticals, Emerging markets** 

**Finance** 

Pipeline update, news flow

**Closing and Q&A** 





## FY 2020: strong and resilient double-digit performance

#### **Key highlights**

**Total revenue** up by 10%, continuing double-digit trajectory underpinned by focused R&D and SG&A investment

**Revenue growth**: new medicines<sup>1</sup> +33%. Oncology +24% and New CVRM<sup>2</sup> +9%. Respiratory & Immunology stable and Emerging markets +10%, despite COVID-19<sup>3</sup> impact to *Pulmicort* 

Core operating profit up by 17% despite lower core OOI<sup>4</sup> (-2%) Core EPS<sup>5</sup> \$4.02 (+18%), including 20% tax rate

Cash improving, including net cash inflow from operating activities at \$4.8bn

**Pipeline** progress underpinning future double-digit revenue growth **ESG**<sup>6</sup>: COVID-19 vaccine authorised with supplies ramping up

**2021 guidance**: **total revenue** increase by a low teens percentage, accompanied by faster growth in **core EPS** to \$4.75 to \$5.00



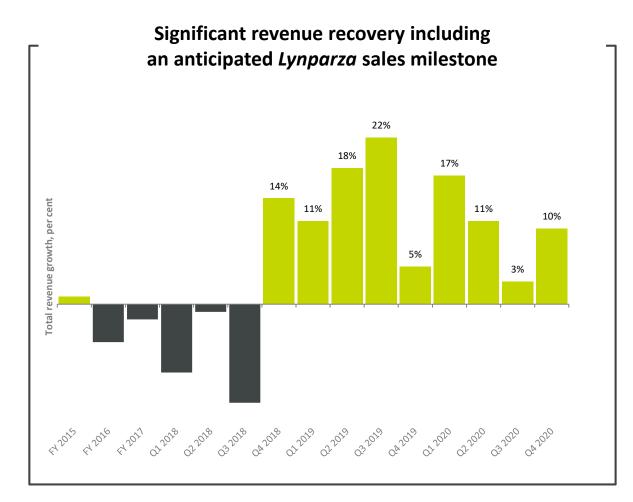
Strong progress in the late-stage pipeline Important milestones since the last results update

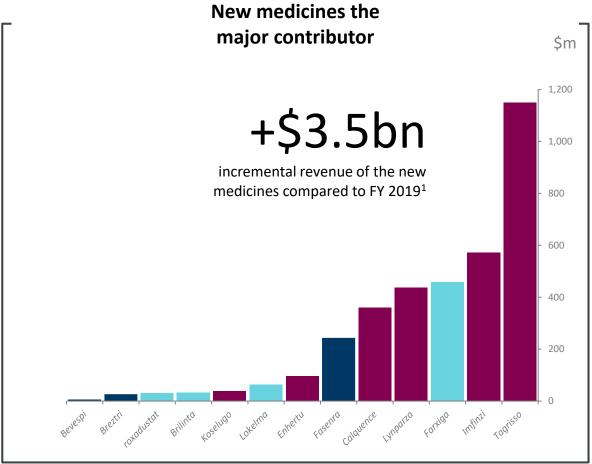
#### Medicine **Indication (geography)** adjuvant NSCLC1 (EGFRm2) (US) Regulatory **Tagrisso** new Q4W<sup>3</sup> dosing (US, EU) Imfinzi approvals ovarian cancer (1st line<sup>4</sup>, HRD+<sup>5</sup>) (PAOLA-1) (EU, JP) Lynparza prostate cancer (2nd line<sup>6</sup>, BRCAm<sup>7</sup>) (EU, JP) pancreatic cancer (1st line, BRCAm) (JP) gastric cancer (2nd line+, HER2+8) (US) Enhertu breast cancer (3rd line<sup>9</sup>, HER2+) (EU) Calquence CLL<sup>10</sup> (EU, JP) Forxiga HF<sup>11</sup> CVOT<sup>12</sup> (EU, JP, CN) stroke (THALES) (US) Brilinta Symbicort mild asthma (CN) Trixeo COPD<sup>13</sup> (EU) COVID-19 Vaccine COVID-19 (UK; authorisation for emergency supply, EU; conditional marketing authorisation) AstraZeneca **Regulatory submission** adjuvant NSCLC (EGFRm) (EU) Tagrisso prostate cancer (2nd line, BRCAm) (CN) acceptances and/or Lynparza CKD<sup>14</sup> (US, JP; priority reviews, EU, CN) submissions Farxiga anifrolumab lupus (SLE<sup>15</sup>) (JP) **Major Phase III data** Imfinzi biliary tract cancer: Orphan Drug Designation (US) readouts or other Imfinzi + treme head & neck cancer (1st line): Phase III primary endpoint not met significant liver cancer: orphan designation (EU) tremelimumab CLL (R/R<sup>16</sup>) (ELEVATE R/R): Phase III primary endpoint met developments Calquence severe asthma: Phase III primary endpoint met tezepelumab 1. Non-small cell lung cancer 2. Epidermal growth factor receptor mutation 3. Once every four weeks 4. 1st treatment in the metastatic setting 5. Homologous recombination deficiency positive 6. 2nd treatment

in the metastatic setting 7. Breast cancer susceptibility gene 1/2 mutation 8. Human epidermal growth factor receptor 2 positive 9. 3rd treatment in the metastatic setting 10. Chronic lymphocytic leukaemia 11. Heart failure 12. CV outcomes trial 13. Chronic obstructive pulmonary disease 14. Chronic kidney disease 15. Systemic lupus erythematosus 16. Relapsed/refractory. Status as of 11 February 2021.

#### **FY 2020:** total revenue +10%

#### New medicines continued to grow





Oncology New CVRM Respiratory & Immunology

Absolute values at CER. 1. Total revenue for *Tagrisso*, *Imfinzi*, *Farxiga*, *Lynparza*, *Calquence*, *Fasenra*, *Enhertu*, *Lokelma*, *Koselugo*, *Brilinta*, roxadustat, *Breztri* and *Bevespi*.



## FY 2020: diversified and double-digit growth

#### Oncology, US, Emerging markets drove performance

# Growth across therapy areas

# Growth across geographies

	Q4 2020 \$m	growth %	ratio %	FY 2020 \$m	growth %	ratio %		Q4 2020 \$m	growth %	ratio %	FY 2020 \$m	growth %	ratio %
Total revenue	7,410	10	100	26,617	10	100	Total revenue	7,410	10	100	26,617	10	100
Oncology	3,270	23	44	11,455	24	43	US	2,388	15	32	8,833	13	33
							EMs <sup>1</sup>	2,244	8	30	8,711	10	33
New CVRM	1,252	7	17	4,702	9	18	- EMs ex China	882	7	12	3,336	9	13
Respiratory & Immunology	1,534	(2)	21	5,375	(0)	20	- China	1,362	9	18	5,375	11	20
							Europe	1,831	12	25	5,540	9	21
Other medicines	1,354	2	18	5,085	(2)	19	Established rest of world	947	(1)	13	3,533	5	13



## Accelerating the expansion into immunology

Alexion: immune-mediated rare disease global leader



Compelling scientific complementarity and synergy

Combination of two science- and patient-centric organisations

Further-sustained, industry-leading double-digit revenue growth

Improved profitability and strengthened cash flow





## Agenda

**Overview** 

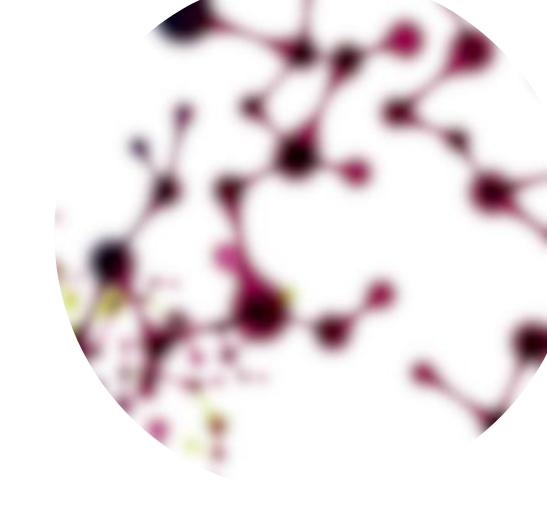
#### **Oncology**

**BioPharmaceuticals, Emerging markets** 

**Finance** 

Pipeline update, news flow

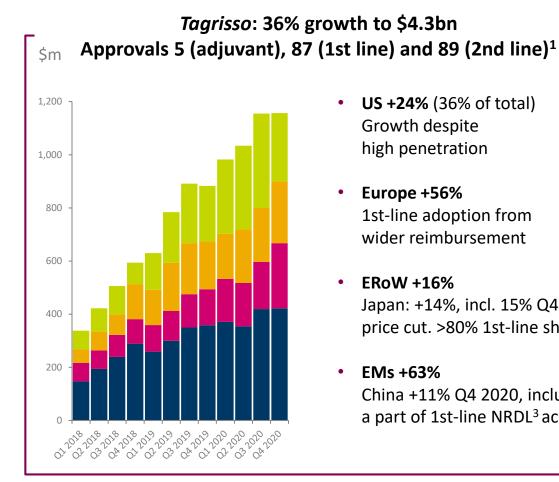
Closing and Q&A



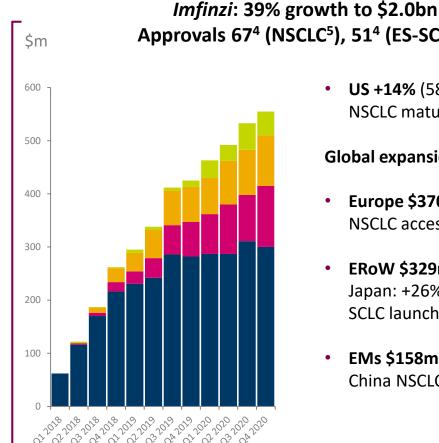


## Tagrisso and Imfinzi

### Global growth boosted by Europe and EMs



- **US +24%** (36% of total) Growth despite high penetration
- **Europe +56%** 1st-line adoption from wider reimbursement
- **ERoW +16%** Japan: +14%, incl. 15% Q4 2019 price cut. >80% 1st-line share<sup>2</sup>
- EMs +63% China +11% Q4 2020, including a part of 1st-line NRDL<sup>3</sup> accrual



Approvals 67<sup>4</sup> (NSCLC<sup>5</sup>), 51<sup>4</sup> (ES-SCLC<sup>6</sup>)

Global expansion; ex US \$857m

NSCLC matured; SCLC grew

**US +14%** (58% of total)

- Europe \$370m NSCLC access drove growth
- ERoW \$329m Japan: +26%; NSCLC matured; SCLC launched
- EMs \$158m China NSCLC launch progressed

US Europe Established Rest of World (ERoW) EMs

Total revenue at actual exchange rates; changes at CER and for FY 2020, unless stated otherwise.

- 1. Reimbursement in three, 40 and 66 countries, respectively.
- 2. Market research, December 2020.
- 3. National Reimbursement Drug List.

#### **US Europe ERoW EMs**

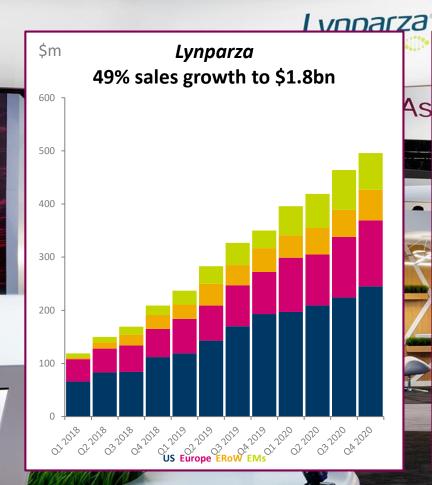
Total revenue at actual exchange rates; changes at CER and for FY 2020, unless stated otherwise.

- 4. Reimbursement in 28 and five countries, respectively
- 5. Here unresectable, Stage III NSCLC.
- 6. Extensive-stage small cell lung cancer.



## Lynparza

# The globally-leading PARP<sup>1</sup> inhibitor



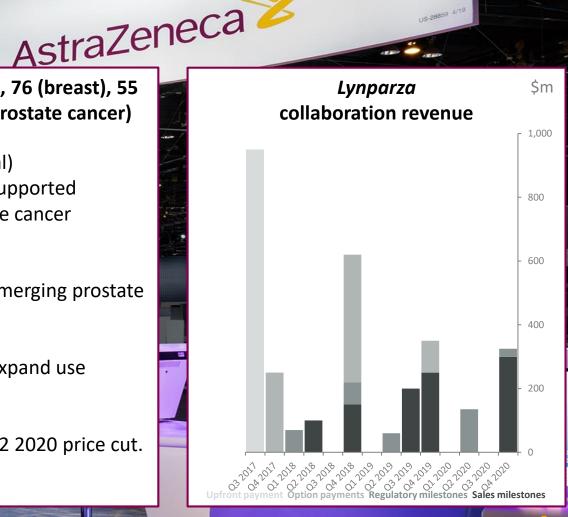
Approvals 78 (ovarian), 76 (breast), 55 (pancreatic) and 49 (prostate cancer)

- US +40% (49% of total)
   1st-line OC<sup>2</sup> growth supported
   by new use in prostate cancer
- Europe +51%

  1st-line OC growth; emerging prostate
- EMs +108%
  OC launch; NRDL to expand use

2. Ovarian cancer.

ERoW +32%
 Japan: +27%; ~14% Q2 2020 price cut.
 OC uptake continued



Collaboration revenue at actual exchange rate

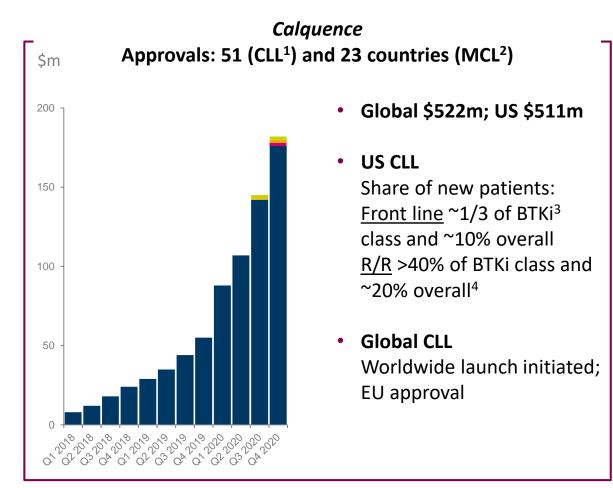
Collaboration with Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada. \$3.1bn revenue recorded; \$4.6bn future potential.

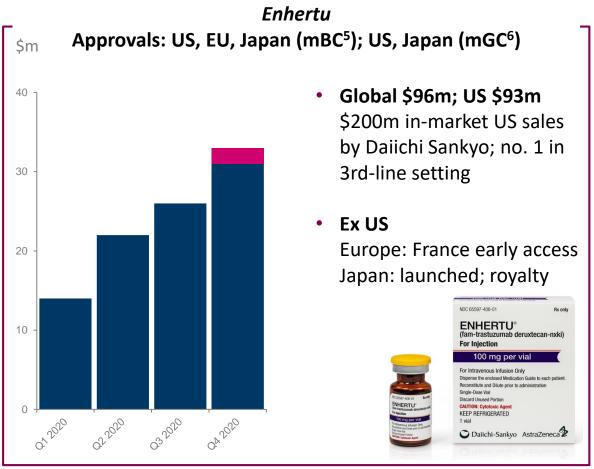
oduct sales at actual exchange rates; changes at CER and for FY 2020, unless stated thereign 1. Poly ADP riboso polymorase

otherwise. 1. Poly ADP ribose polymerase

## Calquence and Enhertu

#### Calquence accelerated; Enhertu launch continued





**US Europe ERoW EMs** 

Total revenue at actual exchange rates.

<sup>3.</sup> Bruton tyrosine kinase inhibitor 4. IQVIA market research.



Collaboration revenue at actual exchange rates.

5. Metastatic breast cancer (3L, HER2+) 6. Metastatic gastric cancer (3L/2L+, HER2+).

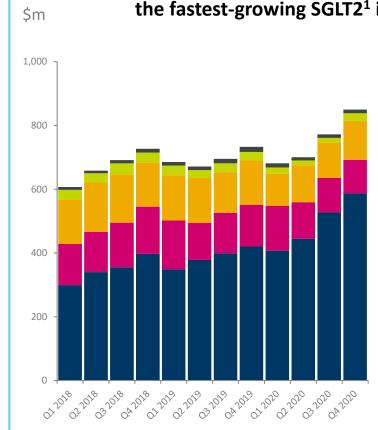


<sup>1.</sup> Chronic lymphocytic leukaemia 2. Mantle cell lymphoma (R/R)

#### **BioPharmaceuticals: New CVRM**

#### Farxiga inflection point; strong progress

Diabetes/HF: 9% growth driven by *Farxiga*, continued the fastest-growing SGLT2<sup>1</sup> in the fastest-growing T2D<sup>2</sup> class<sup>3</sup>



Farxiga +30%

US +6% Strong market growth offset by some price

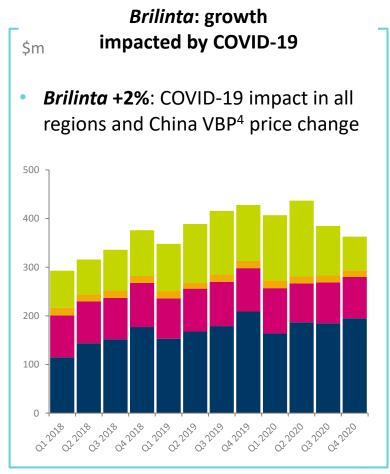
Ex US (71% of total)
Europe +35%
Strong volume growth; SGLT2
leadership in several markets

EMs +55% Leading SGLT2; benefit from NRDL

Farxiga Onglyza Bydureon Byetta Other

Total revenue at actual exchange rates; changes at CER and for FY 2020, unless stated otherwise.

- 1. Sodium-glucose co-transporter 2 (inhibitor).
- 2. Type-2 diabetes.
- 3. IQVIA market research.

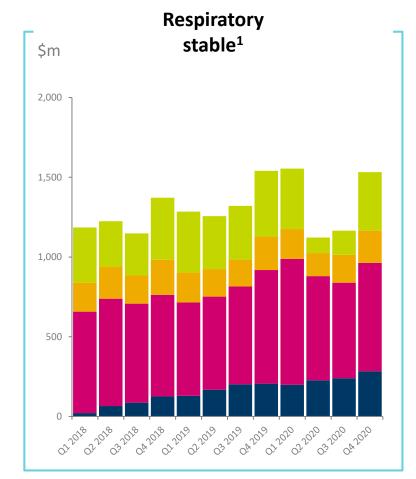


**US Europe ERoW EMs** 

Total revenue at actual exchange rates; changes at CER and for FY 2020, unless stated otherwise. 4. Volume-based procurement.



# BioPharmaceuticals: Respiratory & Immunology Solid growth excluding the COVID-19 impact to *Pulmicort*



#### Fasenra Symbicort Other Pulmicort

Total revenue at actual exchange rates; changes at CER and for FY 2020, unless stated otherwise. 1. 12% growth excluding *Pulmicort*.

## Encouraging growth everywhere except EMs; *Pulmicort* impact in China

- **US +18%**Symbicort (+23%); market, volume and price growth. Fasenra (+25%)
- Europe +5%

  Symbicort (+2%). Growth
  boost by Fasenra (+70%)
- ERoW +1%
   Japan: -14%; lower Symbicort
   volume/price. Fasenra (+14%)

EMs -18%
Pulmicort (\$798m, -33%) lower paediatric nebulisation use in China (1/2 of market) due to COVID-19; a recovery seen in Q4 in surgery

Maintenance use with *Symbicort* (\$567m, +9%) continued forward



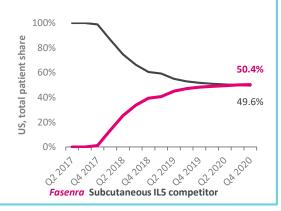


# BioPharmaceuticals: new launch medicines

#### Portfolio of new medicines across uses and markets

## Fasenra Severe asthma

- Europe \$203m (+70%);
   Japan \$100m (+14%)
   Leading biologic medicine in many markets<sup>1</sup>
- US \$603m (+25%)
  Leading novel biologic<sup>1</sup>



Total revenue at actual exchange rates. 1. Market shares are total patient share in severe, uncontrolled asthma; specialty pharmacies and 'buy and bill' market, IQVIA market research.

## *Breztri* COPD

- EMs \$14m
   Ongoing launch in China;
   Q4 impact by NRDL accrual
- Japan \$9m
   ~1/4 of new patients<sup>2</sup>;
   year-end Ryotanki<sup>3</sup> lift
- US \$5m
   Early launch;
   efficacy resonates with prescribers

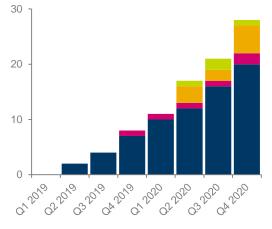


- 2. IQVIA market research.
- 3. Ryotanki: regulation in Japan that restricts prescriptions for medicines in their first year on the market to just two weeks.

#### *Lokelma* Hyperkalaemia

Global \$76m; US \$57m
 US market leadership<sup>4</sup>;
 COVID-19 market impact

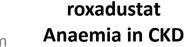
Japan accelerated; early sales in China and Europe



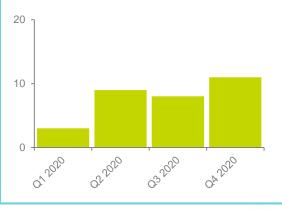
#### **US Europe ERoW EMs**

Śm

Total revenue at actual exchange rates. 4. Market leadership in new-to-medicine patients, IQVIA market research.



- EMs \$30m
   China launch progressed;
   \$73m in-market sales; tens of '000s of patients treated
- US
   Regulatory decision Q1 '21

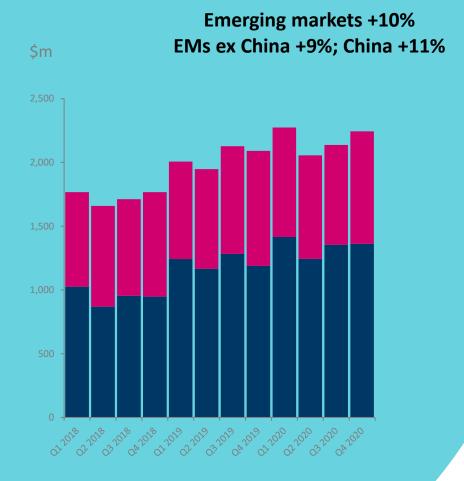


**EMs** 

Collaboration revenue at actual exchange rates.



# Emerging markets Diverse and solid growth



China EMs ex China

Total revenue at actual exchange rates; changes at CER and for FY 2020, unless stated otherwise.

# Performance driven by new medicines +59% (33% of total revenue; \$1.1bn<sup>1</sup> incrementally)

Oncology +36%: *Tagrisso* (\$1.2bn); March 2021 NRDL inclusion

**New CVRM** +31%: *Forxiga* (+55%); *Brilinta* (+4%)

**Respiratory & Immunology** -18%: *Pulmicort* COVID-19 hit (\$798m, -33%), but *Symbicort* continued up (\$567m, +9%)

- Diversified growth: AP<sup>2</sup> +6%, MEA<sup>3</sup> +1%, LA<sup>4</sup> +13%, Russia +42%
- Major 2020 NRDL inclusions: Lynparza, Forxiga, roxadustat
   Major 2020 VBP inclusions: Brilinta, legacy GI medicines<sup>5</sup>

Revenue anticipated to continue growing ahead of the long-term ambition of mid to high single-digit growth



## Agenda

**Overview** 

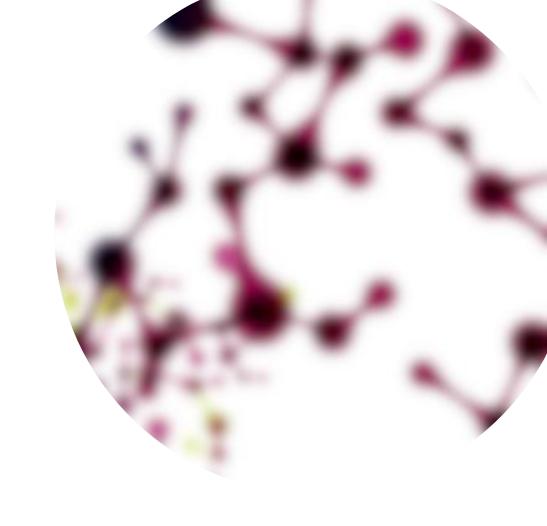
Oncology

**BioPharmaceuticals, Emerging markets** 

#### **Finance**

Pipeline update, news flow

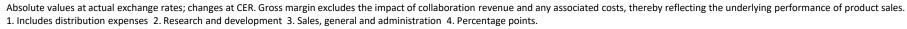
Closing and Q&A





# Reported profit and loss

	FY 2020 \$m	change %	% total revenue	Q4 2020 \$m	change %	% total revenue
Total revenue	26,617	10	100	7,410	10	100
- product sales	25,890	11	97	7,011	11	95
- collaboration revenue	727	(11)	3	399	(4)	5
Gross margin	79.5%	0.5 pp <sup>4</sup>		78.2%	1.1 pp	
Operating expenses <sup>1</sup>	17,684	(2)	66	5,038	(5)	68
- R&D² expenses	5,991	(1)	23	1,719	19	23
- SG&A <sup>3</sup> expenses	11,294	(3)	42	3,210	4	43
Other operating income	1,528	(1)	6	640	29	9
Operating profit	5,162	81	19	1,487	183	20
Tax rate	19.7%			13.9%		
EPS	\$2.44	142		\$0.78	249	





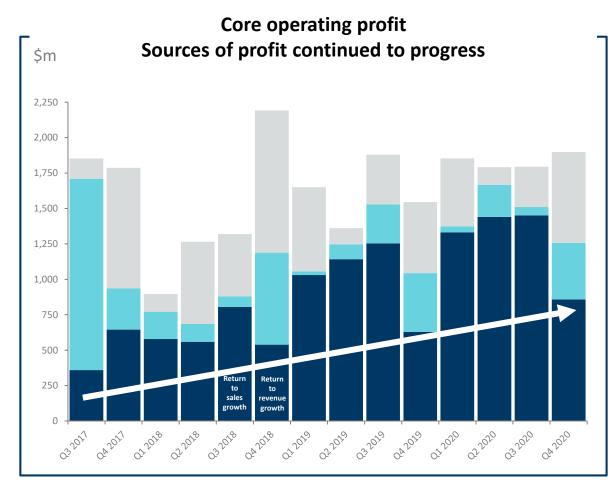
## Core profit and loss

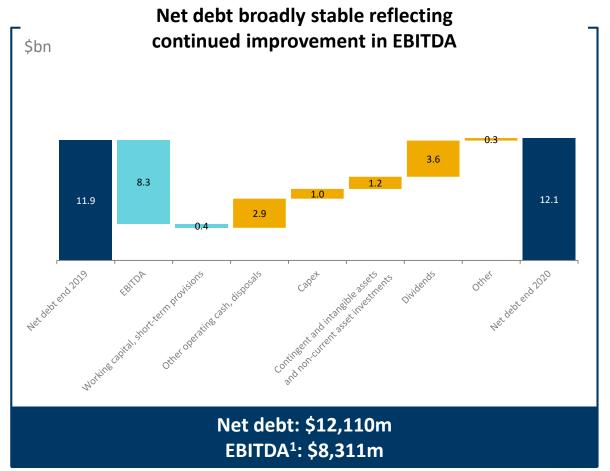
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- product sales	25,890	11	97	7,011	11	95
- collaboration revenue	727	(11)	3	399	(4)	5
Gross margin	80.0%	0.3 pp		78.6%	2.0 pp	
Operating expenses	15,633	6	59	4,654	8	63
- R&D expenses	5,872	10	22	1,707	12	23
- SG&A expenses	9,362	4	35	2,838	6	38
Other operating income	1,531	(2)	6	642	29	9
Operating profit	7,340	17	28	1,899	28	26
Tax rate	20.1%			17.6%		
EPS	\$4.02	18		\$1.07	24	



## Analysis: core operating profit and net debt

#### Increasing operating leverage and cash flow progress





Residual Collaboration revenue (CR) Core OOI

Earnings before interest, tax, depreciation and amortisation; last four quarters.
 AstraZeneca credit ratings: Moody's: short-term rating P-2, long-term rating A3, outlook negative.
 Standard & Poor's: short-term rating A-2, long-term rating BBB+, outlook positive.

Absolute values at actual exchange rates.

## Financial priorities

#### FY 2020 results underpinned the strategic journey

#### **Deleveraging/dividend growth**

- As cash flow improves, deleveraging and progressive dividend policy
- Unchanged priorities for capital allocation

#### **Cash-flow growth**

- 2020: continued improvement in cash-flow metrics; dividend cover
- 2021: anticipate further improvement in cash flow



Revenue growth

+10% growth in total revenue in 2020

#### **Operating leverage**

- **59%** ratio of core operating expenses to total revenue (vs. 60% in 2019)
- 17% growth in core operating profit
- 28% core operating profit margin despite 2% lower core OOI



## 2021 guidance

### **Total revenue**

increase by a low teens percentage

### **Core EPS**

faster growth to \$4.75 to \$5.00



## 2021 and beyond: the acquisition of Alexion

#### Accelerating the strategic and financial development

#### Compelling scientific complementarity and synergy

- Increased immunology presence: complement system platform, currently applied in rare diseases
- Pipeline boosted with 11 molecules across 20+ programmes
- Leveraging AstraZeneca's precision-medicine capabilities

#### Combination of two science- and patient-centric organisations

- Focus on science and innovation
- Patient-centric organisations with high-touch patient support services

#### Further-sustained, industry-leading revenue growth

- Attractive growth in specialty and highly-specialised/rare-disease care
- Leverage AstraZeneca's global geographical reach to accelerate Alexion medicines
- Double-digit average annual revenue growth through 2025

#### Improved profitability and strengthened cash flow

- Core operating margin significantly enhanced in the short term, and with continued margin expansion thereafter
- Synergies c.\$500m per year by the end of the third year following completion
- Double-digit percentage core EPS accretion anticipated in the first three years following completion
- Strong cash flow, rapid debt deleveraging with an ambition to increase the dividend
- Strong, investment-grade credit rating to provide strategic and financial flexibility



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**Overview** 

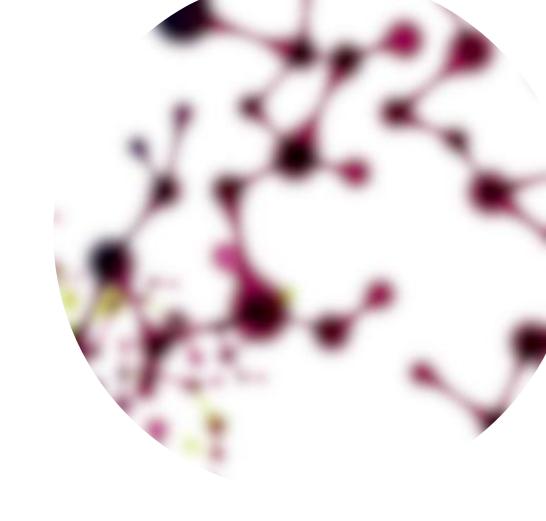
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**BioPharmaceuticals, Emerging markets** 

**Finance** 

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## Continuing response to COVID-19

### Advancing vaccine, antibody, other options

## COVID-19 Vaccine AstraZeneca

- Late-stage trials recruited; >55k participants
- UK emergency use authorisation;
   EU conditional marketing authorisation
- US Phase III and additional data from pooled Oxford trials during Q1 2021

**Granted conditional approval or emergency use in >50 countries** 

# AZD7442 long-acting antibody (LAAB) combo

- PROVENT and STORMCHASER
   Phase III trial in pre- and post exposure prophylaxis; 300mg IM¹
   dose; potential for 12 months
   protection
- TACKLE Phase III trial of 600mg IM in outpatient setting and collaborator trials

First data in H1 2021



- Farxiga DARE-19 Phase III trial
- MEDI3506
   ACCORD Phase II trial
- Symbicort
   INHASCO Phase IIIa trial
- Pulmicort
   TACTIC-COVID Phase IIIa trial
   STOIC Phase II trial positive

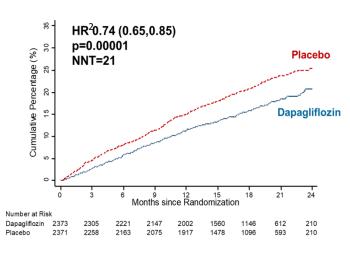
First data in H1 2021



## Building new standard of care: Farxiga From T2D to HF and CKD

#### **DAPA-HF Phase III trial**

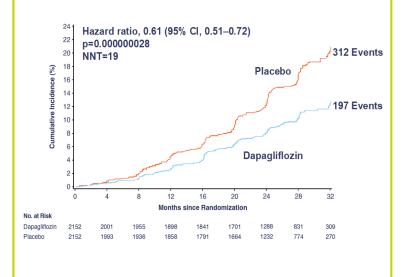
HFrEF<sup>1</sup>: 26% risk reduction in primary endpoint



Now approved in **US, EU and Japan** 

#### DAPA-CKD Phase III trial

First SGLT2 inhibitor with benefit in patients with and without T2D



All secondary endpoints met, including all-cause mortality

- New DAPA-MI<sup>3</sup> Phase III trial achieved first patient dosed
- New Phase II trial of Farxiga + AZD9977 in CKD in H1 2021
- DELIVER Phase III trial in HFpEF<sup>4</sup> with data in H2 2021



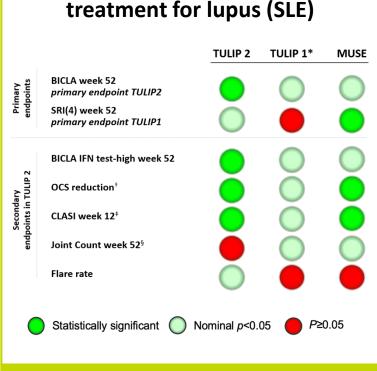
New and upcoming milestones

<sup>3.</sup> Myocardial infarction.

<sup>1.</sup> Heart failure with reduced ejection fraction 2. Hazard ratio. Source: Hot Line Session 1, European Society of Cardiology 2019.

# Building new standard of care: anifrolumab The first new medicine for lupus (SLE) in 10 years

# Potential first-in-class treatment for lupus (SLE)



# Consistency across multiple key endpoints at 300mg dose

Source: abstract L17, American Congress on Rheumatology (ACR), 2019; Arthritis Rheum (69):376–86, 2017; Lancet Rheumatology, 2019.

\* Data generated using the revised restriction medication rules † in patients with OCS ≥10 mg/d at baseline ‡CLASI analysis includes patients with baseline inc LASI score ≥10. § In TUILP¹ and MUSE trials, joint activity was assessed in patients with 28 swollen and ≥8 tender joints. In the TUILP¹ trial joint activity was assessed in patients with ≥6 swollen and ≥6 tender joints. OCS = oral corticosteroid.

# Pooled analysis of the TULIP trial programme at ACR 2020

Early and sustained reduction in the activity of skin disease



 Improvements in multiple organs and reduction in disease flares while sustaining steroid reduction

Potentially the first new medicine for lupus (SLE) in over 10 years

# Regulatory and clinical status

- Regulatory submissions US, EU, JP
- Long-term safety results due 2022
- Ongoing developments
  - subcutaneous formulation
  - lupus nephritis
  - cutaneous lupus erythematosus
  - myositis

Regulatory decisions anticipated in H2 2021



### BioPharmaceuticals: 'What's next'

#### Expanding pipeline, including immunology

#### What's next

Phase I/II new medicines, selected

MEDI3506 Now PIIb	MEDI3506 Now PII in
(IL33¹ mAb²) ✓	(IL33 mAb) asthma√
DKD³	asthma, COPD, AD <sup>11</sup> , COVID-19
<b>cotadutide</b>	<b>AZD1402</b>
(GLP-1 <sup>4</sup> /glucagon co-agonist)	(IL4R $lpha^{12}$ antagonist)
NASH <sup>5</sup> , DKD	asthma
AZD4831 Plla avail-	<b>AZD0449, AZD4604</b>
(MPO <sup>6</sup> inhibitor) able √	(inhaled JAK <sup>13</sup> inhibitors)
HFpEF	asthma
AZD5718 Now PII in  (FLAP <sup>7</sup> inhibitor) CKD ✓  CKD ✓	<b>MEDI7352</b> (NGF <sup>14</sup> TNF <sup>15</sup> bispecific fusion protein) pain
<b>AZD9977 + Farxiga</b>	<b>AZD2693</b>
(MCR <sup>9</sup> modulator + SGLT2)	(PNPLA3 <sup>16</sup> inhibitor)
HF with CKD	NASH
<b>zibotentan + <i>Farxiga</i></b> (ETR <sup>10</sup> antagonist + SGLT2) CKD	AZD8233 Now (PCSK9 <sup>17</sup> ASO <sup>18</sup> ) PII ✓ dyslipidaemia

#### What's now

#### Phase III new medicines

<b>roxadustat</b>	<b>PT027</b>
anaemia in CKD	asthma
nirsevimab	<b>tezepelumab</b>
respiratory syncytial virus	severe asthma
<b>brazikumab</b>	anifrolumab
inflammatory bowel disease <sup>19</sup>	lupus (SLE)

#### Phase III lifecycle management, major

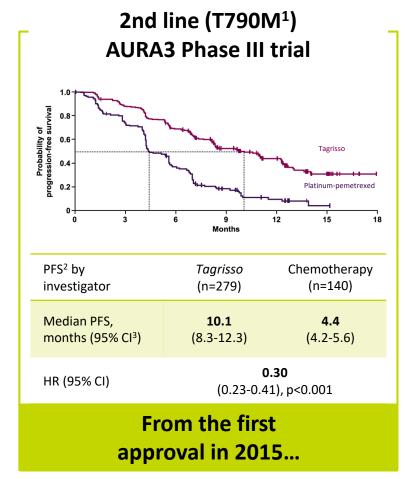
	<b>Fasenra</b> multiple indications
New PIII  Farxiga in MI ✓  multiple indications	<b>Breztri/Trixeo</b> asthma

<sup>1.</sup> Interleukin-33 2. Monoclonal antibody 3. Diabetic kidney disease 4. Glucagon-like peptide-1 5. Non-alcoholic steatohepatitis 6. Myeloperoxidase 7. 5-Lipoxygenase-activating protein 8. Coronary artery disease 9. Mineralocorticoid receptor 10. Endothelin receptor 11. Atopic dermatitis (eczema) 12. Interleukin-4 receptor alpha 13. Janus kinase 14. Nerve growth factor 15. Tumour necrosis factor 16. Patatin-like phospholipase domain-containing protein 3 17. Proprotein convertase subtilisin/kexin type 9 18. Antisense oligonucleotide 19. Trial technically classified as Phase II.

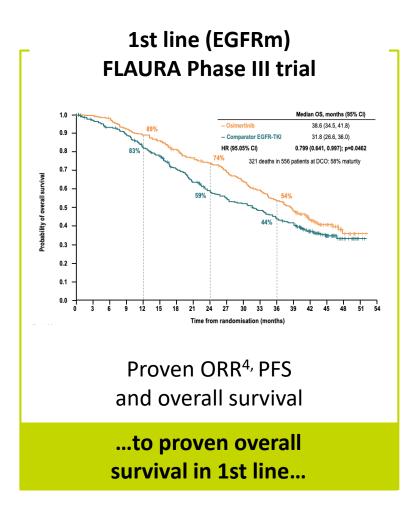


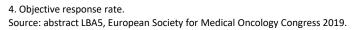
## Building new standard of care: Tagrisso

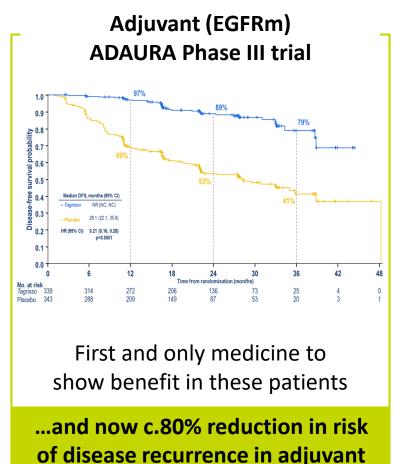
#### Moving into earlier lines of NSCLC, reshaping the standard of care



1. Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation 2. Progression-free survival. 3. Confidence interval. Source: abstract PL03.03, WCLC 2016.



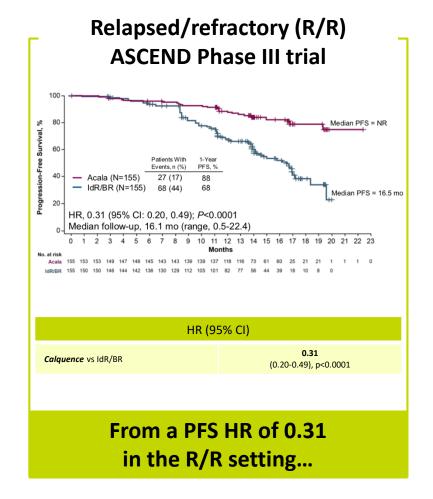


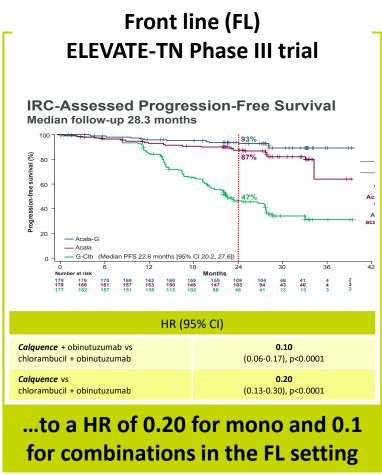


Source: abstract LBA5, ASCO 2020. Stage IB to IIIA; disease-free survival by investigator assessment.



# Building new standard of care: Calquence All data in CLL support a best-in-class potential





#### BTK inhibitor head-to-head ELEVATE-RR Phase III trial

- First Phase III trial to evaluate two BTK inhibitors head to head in R/R CLL
- Met primary endpoint of noninferior PFS
- Superior safety on key measure of lower atrial fibrillation (AFib)

Non-inferiority on PFS and superiority on AFib

Source: abstract 31, The American Society of Hematology, 2019.

# Oncology: 'What's next' Solid pipeline moving forward

#### What's next

Phase I/II new medicines, selected

<b>adavosertib</b>	<b>ceralasertib</b>
(WEE1 <sup>1</sup> inhibitor)	(ATR <sup>7</sup> inhibitor)
uterine, ovarian cancer	solid tumours, blood cancers
<b>oleclumab</b>	AZD4635
(CD73 <sup>2</sup> mAb)	(A2AR <sup>8</sup> inhibitor)
solid tumours	solid tumours
AZD4573	<b>MEDI5752</b>
(CDK9 <sup>3</sup> inhibitor)	(PD-1 <sup>9</sup> /CTLA4 <sup>10</sup> mAb)
blood cancers	solid tumours
<b>MEDI2228</b>	AZD2811
(BCMA <sup>4</sup> ADC <sup>5</sup> )	(Aurora B inhibitor)
blood cancers	solid tumours, blood cancers
<b>AZD5991</b>	AZD0466
(MCL1 <sup>6</sup> inhibitor)	(Bcl-2 <sup>11</sup> /xL)
blood cancers	solid tumours, blood cancers

#### What's now

#### Phase III new medicines

datopotamab deruxtecan lung cancer	camizestrant (AZD9833) breast cancer
<b>monalizumab</b>	<b>capivasertib</b>
head & neck cancer	breast, prostate cancer
savolitinib	<b>tremelimumab</b>
NSCLC <sup>12</sup>	multiple cancers

#### Phase III lifecycle management, major

	<i>Lynparza</i> multiple cancers
<b>Tagrisso</b>	<i>Enhertu</i>
NSCLC	multiple cancers
<i>Imfinzi</i>	<b>Calquence</b>
multiple cancers	multiple cancers

<sup>1.</sup> Tyrosine kinase WEE1 2. 5'-nucleotidase 3. Cyclin-dependent kinase 9 4. B-cell maturation antigen 5. Antibody drug conjugate 6. Induced myeloid leukaemia cell differentiation protein 7. Ataxia telangiectasia and rad3-related kinase 8. Adenosine A2A receptor 9. Programmed cell death protein 1 10. Cytotoxic T-lymphocyte-associated protein 4 11. B-cell lymphoma 2 12. Potentially pivotal Phase II.



## Late-stage pipeline events in the 2021-2022 timeframe

#### Busy news flow continues; Phase III readouts increase into 2021

		H1 2021	H2 2021	2022
/ \	gulatory ecision	Tagrisso - adjuvant NSCLC (EGFRm) (CN) Lynparza - breast cancer (BRCAm) (CN) Koselugo - neurofibromatosis type 1 (NF1) (EU) Farxiga - CKD (US) Brilique/Brilinta - CAD/T2D CVOT (EU, JP, CN) Brilique - stroke (THALES) (EU) roxadustat - anaemia in CKD (US) Symbicort - mild asthma (EU)	Tagrisso - adjuvant NSCLC (EGFRm) (EU) Lynparza - prostate cancer (2L) (CN)  Forxiga - CKD (EU, JP, CN) Brilinta - stroke (THALES) (CN)  anifrolumab - lupus (SLE) (US, EU, JP)	<i>Imfinzi</i> - ES-SCLC (CN)
sub and	egulatory bmission d/or ceptance	Imfinzi unresectable, Stage III NSCLC (PACIFIC-2) Calquence - CLL (R/R) (ELEVATE R/R)  Fasenra - nasal polyps tezepelumab - severe asthma  COVID-19 Vaccine AstraZeneca - SARS-CoV-2 (US, JP) AZD7442 - SARS-CoV-2	Imfinzi - NSCLC (1L) (PEARL) Imfinzi +/- treme - NSCLC (1L) (POSEIDON) Imfinzi +/- treme - liver cancer (1L) Lynparza - adjuvant breast cancer Lynparza - prostate cancer (1L, castration-resistant) Enhertu - breast cancer (2L, HER2+)	Imfinzi - limited-stage SCLC Imfinzi - liver cancer (locoregional) Imfinzi - biliary tract cancer Lynparza - ovarian cancer (3L, BRCAm) Enhertu - breast cancer (3L, HER2+) (Phase III) Enhertu - breast cancer (HER2 low) Calquence - CLL (CN) Koselugo - NF1 (JP, CN) Farxiga - HF (HFpEF) roxadustat - anaemia in myelodysplastic syndrome PT027 - asthma
	y Phase III ta readouts	Imfinzi - unresectable, Stage III NSCLC (PACIFIC-2) Imfinzi +/- treme - NSCLC (1L) (POSEIDON) (OS) Lynparza - adjuvant breast cancer COVID-19 Vaccine AstraZeneca - SARS-CoV-2 AZD7442 - SARS-CoV-2	Imfinzi - NSCLC (1L) (PEARL) Imfinzi +/- treme - liver cancer (1L) Lynparza - prostate cancer (1L, castration-resistant) Enhertu - breast cancer (3L, HER2+) (Phase III) Enhertu - breast cancer (2L, HER2+) Enhertu - breast cancer (HER2 low) Farxiga - HF (HFpEF) PT027 - asthma	Imfinzi - limited-stage SCLC Imfinzi - liver cancer (locoregional) Imfinzi - biliary tract cancer roxadustat - anaemia in myelodysplastic syndrome nirsevimab - respiratory syncytial virus



## Agenda

**Overview** 

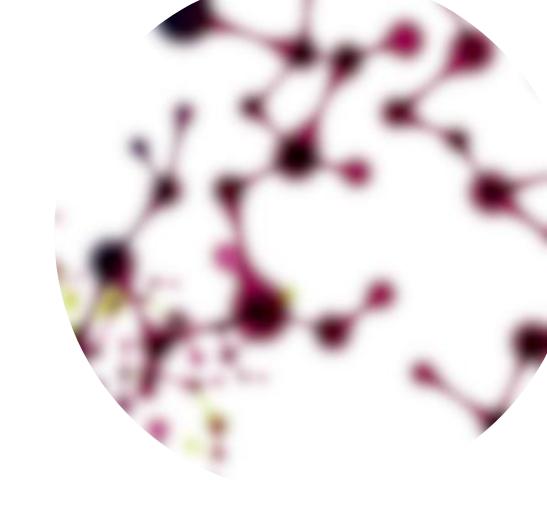
Oncology

**BioPharmaceuticals, Emerging markets** 

**Finance** 

Pipeline update, news flow

**Closing and Q&A** 





## AstraZeneca in summary

### Pipeline-driven transformation



#### **Global presence**

Balanced specialty and primary-care franchises<sup>1</sup>

Leading emerging markets presence with R&D base



#### **Strong pipeline**

22 Phase III medicines and significant lifecycle projects

Advancing early- and mid-stage pipeline



#### **Improving financials**

Eight blockbuster medicines

Returned to durable revenue and earnings growth

Focus on operating leverage and cash flow

Innovative medicines in Oncology and BioPharmaceuticals<sup>2</sup> Experienced and proven team







#### Now launched:

#### AIR

As part of ongoing efforts to make sustainability data transparent and accessible, the new <u>Analyst Interactive Reporting</u> (AIR) centre provides sustainability data in a single platform, covering global information from key performance indicators for Access to healthcare, Environmental protection and Ethics and transparency

astrazeneca.com/investors/air

## Appendix: 'What's next'

## Next key milestone by project

Oncology				
Project	Target	Phase	Indication	Next milestone
adavosertib	WEE1	II	uterine, ovarian cancer	Phase III start
ceralasertib	ATR	II	solid tumours blood cancers	Phase II data
oleclumab	CD73	II	solid tumours	Phase II data
AZD4635	A2AR	II	solid tumours	Phase II data
AZD4573	CDK9	II	blood cancers	Phase II data
MEDI5752	PD-1/ CTLA4	L	solid tumours	Phase II start 2021
MEDI2228	ВСМА	I	blood cancers	Phase II start 2021
AZD2811	Aurora B	L	solid tumours blood cancers	Phase II start 2021
AZD5991	MCL1	I	blood cancers	Phase II start 2021
AZD0466	Bcl-2/xL	1	solid tumours blood cancers	Phase I data 2021 Phase I start 2021

BioPharmaceuticals: CVRM							
Project	Target	Phase	Indication	Next milestone			
cotadutide	GLP-1/ glucagon	II	NASH DKD	Phase IIb data H2 2021 Phase II data 2022			
AZD4831	MPO	II	НҒрЕҒ	Phase IIb start H1 2021			
AZD5718	FLAP	II	CKD CAD	Phase IIb data 2022 Phase IIa data H1 2021			
AZD9977 + Farxiga	MCR + SGLT2	I	HF with CKD	Phase II start H1 2021			
zibotentan + <i>Farxiga</i>	ETR + SGLT2	-	CKD	Phase II start H1 2021			
AZD2693	PNPLA3	I	NASH	Phase I data H2 2021			
AZD8233	PCSK9	II	dyslipidaemia	Phase II data H2 2021			
BioPharmaceutic	als: Respi	ratory &	Immunology				
MEDI3506	IL33	l II	COPD asthma, AD, COVID-19, DKD	Phase I data 2021 Phase II data through 2021			
AZD1402	IL4Rα	ı	asthma	Phase II start H1 2021			
AZD0449 AZD4604	JAK	I	asthma	Phase II start H1 2021 Phase I start H1 2021			
MEDI7352	NGF TNF	1/11	Pain	Phase II start, Phase II data			



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