Meet AZN management: BioPharmaceuticals

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D

Ruud Dobber, Executive Vice President, BioPharmaceuticals Business Unit

25 March 2021

Interactive event for investors and analysts. This webinar is being recorded. https://astrazeneca.zoom.us/webinar/register/WN_bGgqh6nRS120V4JAbnFLvQ
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Agenda

BioPharmaceuticals Business Unit

BioPharmaceuticals R&D

COVID-19

Q&A
Chronic diseases are a staggering, growing burden to patients and society

<table>
<thead>
<tr>
<th>Disease</th>
<th>Global Prevalence</th>
<th>Mortality per year</th>
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<tbody>
<tr>
<td>T2 Diabetes</td>
<td>463 million²</td>
<td>1.6 million⁸</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>64 million³</td>
<td>50% die within 5 yrs⁸</td>
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<tr>
<td>Chronic Kidney Disease</td>
<td>840 million⁴</td>
<td>1.2 million¹⁰</td>
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<tr>
<td>Asthma</td>
<td>339 million⁵</td>
<td>400k¹¹</td>
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<tr>
<td>COPD</td>
<td>384 million⁶</td>
<td>3.1 million¹²</td>
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<tr>
<td>Lupus¹</td>
<td>5 million⁷</td>
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</table>

The ambition is to transform treatment for billions of people living with chronic diseases

Leading with an unmatched portfolio and growing pipeline

Unmatched portfolio

**CVRM**

- farxiga (dapagliflozin)
- BRILINTA, lixivaptan tablets

- Roxadustat Capsules

**R&I**

- BREZTRI AEROSPHERE® (budesonide/formoterol)
- Symbicort (budesonide/formoterol)
- Fasenra (benralizumab)

New CVRM and R&I today

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<tr>
<th>Phase III LCM</th>
<th>Phase III NME</th>
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<tr>
<td><strong>Farxiga</strong> DAPA-CKD</td>
<td>roxadustat®</td>
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<td>SGLT2</td>
<td>HIF-PH</td>
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<td>CKD</td>
<td>anaemia of CKD, MDS</td>
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<td><strong>Farxiga</strong> DAPA-MI</td>
<td><strong>PT027</strong></td>
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<td>SGLT2</td>
<td>ICS/SABA</td>
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<td>asthma</td>
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<td><strong>anifrolumab</strong> TULIP</td>
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<tr>
<td>SGLT2</td>
<td>Type I IFN receptor</td>
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<td>HfPEF²</td>
<td>SLE</td>
</tr>
<tr>
<td><strong>Fasenra</strong></td>
<td><strong>tezepelumab</strong>²</td>
</tr>
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<td>EDD³ diseases</td>
<td>TSLP</td>
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<tr>
<td></td>
<td>severe asthma</td>
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<td><strong>Fasenra</strong></td>
<td><strong>nirsevimab</strong>³</td>
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<td>IL5R COPD</td>
<td>mAb-YTE</td>
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<td>passive RSV immunisation</td>
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<td><strong>Breztri</strong></td>
<td>brazikumab</td>
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<td>LABA/LAMA/ICS asthma</td>
<td>IL23</td>
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<tr>
<td></td>
<td>Crohn’s disease</td>
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</table>

Portfolio tomorrow


Product Sales at actual exchange rates. Growth rate at CER.
Strong commercial execution

**T2D**¹ and **HF**²

**Severe asthma**

**Hyperkalaemia**

**Anaemia of CKD**

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**CKD³ under review**

**A leading biologic medicine⁴**

**Accelerated momentum**

**Strong start in China**

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**US** Europe **ERoW EM**

Product Sales at actual exchange rates. 1. Type-2 diabetes  2. Heart failure  3. Chronic kidney disease  4. Leading novel biologic medicine in severe asthma in many markets based on new to brand prescriptions. Market shares are total patient share in severe, uncontrolled asthma; specialty pharmacies and ‘buy and bill’ market, IQVIA market research.

Total revenue booked by AstraZeneca. Collaboration with FibroGen Inc. which booked in-market sales ($72.5m) in China in 2020.
**Emerging markets**

Footprint across four continents and over 70 countries

- **Russia & Eurasia**
  - c.5% of GDP
  - Four countries
  - c.1,300 employees

- **China & Hong Kong**
  - c.5% of GDP
  - >20,000 employees

- **Latin America**
  - c.10% of GDP
  - 23 countries
  - c.2,800 employees

- **Middle East & Africa**
  - c.17% of GDP
  - 30 countries
  - c.1,900 employees

- **Asia Area**
  - c.10% of GDP
  - Nine countries
  - c.3,600 employees

Emerging markets
Strong growth both in China and other EMs

**China**

+68%
Growth in New CVRM and R&I product sales

**EMs ex. China**

+56%
Growth in New CVRM and R&I product sales

**EMs ex. China: Forxiga**

Ranked #1
*Farxiga* is ranked as the number one SGLT2 inhibitor in nine EM ex. China countries

Product sales at actual exchange rates. Growth rates at CER.
Unique opportunity to transform kidney care by 2025

Underdiagnosed and undertreated

>2 billion
People at risk of developing CKD

+12%
Actual people diagnosed with CKD

Three thousand
Hospitals participating

800 thousand
Patients screened to date

50%
Screened patients that have elevated albumin-to-creatine ratio (ACR)

Transforming CKD management

Partnerships
Will increase treatment at Stage 3 by 2025
Transforming care for 1m patients with severe asthma by 2030
Aiming for biologics uptake similar to other inflammatory diseases

Headroom for growth

34 million
Patients with severe asthma\(^1\,^2\)

45% treated in primary care\(^3\)

15% eligible patients receive a biologic\(^3\,^4\)

Accelerating uptake and access

Digital
Activation and referral tools driving specialist treatment review

Enabling @home monitoring treatment

39 thousand
Patients enrolled

42% Patients self-administer Fasenra

Building the BioPharmaceuticals team of the future

Unmatched portfolio

Roxadustat Capsules

Transform treatment for billions of people living with chronic diseases

Reimagining healthcare delivery

Data analytics
Omnichannel
Go-to-market models

Strong & diverse talent pipeline

Building next generation capabilities in new specialty areas
Agenda

BioPharmaceuticals Business Unit

BioPharmaceuticals R&D

COVID-19

Q&A
AstraZeneca’s 5R framework has increased productivity

<table>
<thead>
<tr>
<th>Stage</th>
<th>Industry</th>
<th>AstraZeneca</th>
<th>BioPharmaceuticals</th>
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<tbody>
<tr>
<td>Preclinical</td>
<td>83%</td>
<td>93%</td>
<td>100%</td>
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<tr>
<td>Phase I</td>
<td>57%</td>
<td>69%</td>
<td>73%</td>
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<tr>
<td>Phase II</td>
<td>25%</td>
<td>26%</td>
<td>31%</td>
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<tr>
<td>Phase III</td>
<td>60%</td>
<td>68%</td>
<td>80%</td>
</tr>
<tr>
<td>Overall</td>
<td>31%</td>
<td>31%</td>
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</tr>
</tbody>
</table>

Source: AstraZeneca based on industry benchmarks (peer companies) provided by CMR International (Clarivate).
R&D productivity in 2020
Progress made across all R&D

123
high-impact journal\(^1\) manuscripts published in 2020 (vs. four in 2012)

39% increase in the number of Phase II projects from 2016-2020

890
journal publications overall in 2020 (vs. 367 in 2012)

15 projects with validated mechanism of action in 2016-2020

20 projects with regulatory designations in 2020

29 regulatory approvals in 2020

Benchmark: publications per $bn R&D spend\(^2\)

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1. High-impact peer-reviewed journals are those with an impact factor (IF) exceeding 15 using Thomson Reuters (TR) five year IF score.

2. TR five year IF. 3. High-quality peer-reviewed journals with IF ≥5 <15 using TR five year IF score. Contains exception list considered by AstraZeneca as high quality but has IF <5. Source: Scopus retrieval (algorithm includes journal publications up to Phase III), AstraZeneca analysis.
Focus areas to further improve productivity

- Enhancing disease understanding
- Broadening therapeutic platforms
- Predicting clinical outcomes
- Pioneering new approaches in the clinic

Data science and artificial intelligence (AI)
Identifying new targets through AI-enabled big data

Data collection

Identify top candidates

In vitro screening

In vivo validation

Selection of top candidates

Multiomics

AI and knowledge graphs

Podocytes – control

Podocytes – expression of novel gene

Control tubule

Target knockout tubule

Source: Groopman et al. NEJM (2019); Povysil et al. JAMA (2020); Kumar et al. American Society of Nephrology Congress October (2020).
A broad set of therapeutic platforms to target any biology

- **SMALL MOLECULES**
  - Small molecules
  - PROTACs
  - Zirconium cyclosilicate

- **ANTIBODY THERAPEUTICS**
  - Monoclonal antibody
  - Antibody drug conjugate
  - Bispecific antibody
  - Fragment antibody

- **CELL BASED THERAPEUTICS**
  - Cell therapy
  - In vivo expressed biologics (IVEBs)

- **PEPTIDE OR PROTEIN THERAPEUTICS**
  - Therapeutic proteins
  - Peptides
  - Anticalin protein

- **NUCLEOTIDE-BASED THERAPEUTICS**
  - Antisense oligonucleotide
  - Oligonucleotide conjugate
  - siRNA
  - mRNA

- **NUCLEOTIDE-BASED THERAPEUTICS**
  - Therapeutic gene editing
  - DNA

PROTACs = proteolysis targeting chimeras, siRNA = small interfering RNA, mRNA = messenger RNA, RNA = ribonucleic acid, DNA = deoxyribonucleic acid.
Novel PROTAC chemistry advances project portfolio

**Current status**

16
PROTAC projects

Five
Projects with in vivo efficacy

Five
E3 ligases enabled for project application

Three
Projects in lead optimisation

**Novel E3 ligand with reduced safety risk**

- **Traditional Thalidomide-like E3 ligand**
- **Novel E3 ligand**

**Potency**
- 260 nM
- 161 nM

**Stability**
- $T_{1/2} < 30$ min
- $T_{1/2} > 200$ h

**Racemisation**
- Yes
- No

**Teratogenic**
- Yes
- No

**In vivo activity of PROTACS for a cardiovascular target**

**Target Protein levels (AlphaLISA signal)**

**Heart**

- **Vehicle AZ14195842**
- **PROTAC**

**Patent applications filed in 2020**


Source: AstraZeneca data on file.

**significant in Welch test (p < 0.005).**
Cell therapy approaches focused on regeneration ongoing across all therapy areas

1. Human ventricular progenitor cells.
Source: Karl-Ludwig Laugwitz / Kenneth R. Chien.

Source: AstraZeneca data on file.

Heart stem cells formed from embryonic stem cells in six days

Day 0 → Day 3 → Day 6

HVP cells migrate to injury site after injection in damaged NHP² heart

24 hours post injection

HVP cells – attracted to injury site

48 hours post injection

Increased ejection fraction in infarcted mice at two months

**p < 0.01.
AI-led small molecule discovery is driving 70% efficacy
50% of small molecule projects are applying AI approaches

Predictive science continues to improve our clinical trial performance

Quantitative modelling can reduce study size, without impacting probability of success

Continuous monitoring can shorten trials and predict earlier success

Novel endpoints can predict and accelerate efficacy readouts

Advanced imaging can help elucidate potential for disease modification

Quantitative modelling
- Reduces study size without impacting probability of success

Continuous monitoring
- Shortens trials and predicts earlier success

Novel CompEx endpoints
- Predict and accelerate efficacy readouts

Advanced imaging
- Helps elucidate potential for disease modification

Sample size per arm in dose range finding study

Time in study

COPD with small airway disease

1. Composite exacerbation.
2. Chronic obstructive pulmonary disease.
Accelerating clinical efficiency through digital innovation

DAPA-MI\(^1\) is world’s first indication-seeking registry-based randomised controlled outcomes trial

- **Evaluating *Farxiga*** for prevention of heart failure and CV\(^2\) death following an acute MI
- **6,400 patients in only two countries rather than c.25**
- **60% reduction in patient burden index compared to DAPA-HF\(^4\) by using routinely collected clinical data from the registries**
- **Patient app for information sharing and data collection**
- **AI event adjudication**
  - Detection and self-report of events
  - Goal for adjudication in four minutes rather than current four months will accelerate future trial close out
- **50% per patient cost reduction without impacting timelines**

- **Accelerating and expanding patient recruitment**
  - Use of registries drives broader patient access, routine clinical follow up and aims to reduce recruitment times by a third
- **Reducing patient and investigator burden**
  - Health and trial information, patient reported outcomes and medication use

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### Overall BioPharmaceuticals pipeline

**Innovation to fuel sustainable growth**

<table>
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<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Under Review</th>
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<tr>
<td>AZD0284</td>
<td>anifrolumab Type 1 IFN (IFN-α) receptor</td>
<td>MEDI6012</td>
<td>anifrolumab TL1A</td>
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<td>RORγt agonist</td>
<td>Type 1 IFN receptor</td>
<td>LCA10™</td>
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<td>MEDI7352 NGF/TNFαα OA pain</td>
<td>MEDI1341#</td>
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### Key Points
- Highlighted in breakout sessions
- Other pipeline medicines

### Abbreviations
Agenda

BioPharmaceuticals Business Unit

BioPharmaceuticals R&D

COVID-19

Q&A
### COVID-19 treatment and prevention approaches

Advancing vaccine, antibody, other options

<table>
<thead>
<tr>
<th><strong>COVID-19 Vaccine</strong></th>
<th><strong>AZD7442 long-acting antibody (LAAB) combo</strong></th>
<th><strong>Other COVID efforts continue</strong></th>
</tr>
</thead>
</table>
| **AstraZeneca (C19VAZ)** | • Potential to offer immediate protection  
• Late-stage trials in both prophylaxis and treatment  
• US Government agreements for potential supply of 700,000 doses in 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 |
| **UK emergency use authorisation; EU conditional marketing authorisation** | • UK emergency use authorisation; EU conditional marketing authorisation | • **UK emergency use authorisation; EU conditional marketing authorisation**  
• Real world data from UK rollout showing >80% protection against hospitalisation  
• US Phase III met the primary endpoint |  
| **Granted conditional approval or emergency use in >70 countries** | **First data in H1 2021** | **First data in H1 2021** |
Vaccine development typically takes a decade or longer

**C19VAZ**: an unprecedented acceleration

Interim analysis

Source: adapted from Plotkin’s Vaccines (7th edition).
**COVID-19 Vaccine AstraZeneca**

Shown to be safe and effective in clinical trials and real-world data

**US Phase III trial primary analysis**

- Protection from hospitalisation and severe disease
  - 100% efficacy against severe disease, hospitalisation and death

- First dose protection
  - 76% efficacy from day ≥15 after second dose in all adult age groups

- Increased efficacy with a longer dosing interval
  - 85% efficacy from day 15 after first dose in adults 65 years and over

**Real world effectiveness**

- 94% effective against hospitalisation in enriched elderly population

- 80% effective against hospitalisation in ≥80 years with extensive comorbid disease

- 73% effective from day 35 after first dose in older adults (≥70 years)

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Clinical priorities

Establishing optimal dosing regimen

Different populations

Heterologous boosting

New variants

• Older adults ✓
• Paediatrics - started
• Pregnant women
AZD7442 long-acting antibody (LAAB) combination
COVID-19 unmet needs persist even during a successful vaccine rollout

AZD7442

- Extended half-life using YTE\(^1\)
- Intra-muscular administration
- Potent and synergistic combination
- >2% of population immune suppressed\(^2\)

2021 capacity of 1-2m doses

Neutralisation profiles of therapeutic mAbs\(^3,4\)

Phase III trials

- PROVENT and STORMCHASER Phase III trial in pre- and post-exposure prophylaxis; 300mg IM\(^5\) dose; potential for 12 months protection
- TACKLE Phase III trial of 600mg IM in outpatient setting and collaborator trials

First data H1 2021


5. Intra-muscular.
Agenda

BioPharmaceuticals Business Unit

BioPharmaceuticals R&D

COVID-19

Q&A
Questions & Answers

To ask a question

Webinar
Click ‘Raise Hand’ (preferred):

or type your question into the Q&A box (alternative)

Phone
*6 - Toggle mute/unmute
*9 - Raise hand
Meet AZN management: BioPharmaceuticals
Four Q&A-focused, virtual breakout sessions

Opening session and Q&A
14:30-15:20 GMT

Mene Pangalos, Ruud Dobber

https://astrazeneca.zoom.us/webinar/register/WN_bGgqh6nRS120V4JAbnFLvQ
Webinar ID: 96770774469 | IR moderator: nick.stone@astrazeneca.com

New CVRM: emerging pipeline
Session 1: 15:30 GMT
Session 2: 16:15 GMT

Regina Fritsche Danielson,
Tomas Andersson,
Lori Kreamer

https://astrazeneca.zoom.us/webinar/register/WN_geSO9qdvR1GP_vsnR79e8A
Webinar ID: 92950815561
IR moderator: christer.gruvris@astrazeneca.com

New CVRM: near-term opportunities
Session 1: 15:30 GMT
Session 2: 16:15 GMT

Elisabeth Björk,
John Houghton,
Joris Silon

https://astrazeneca.zoom.us/webinar/register/WN__3rpTdMKRnCkrh72_ksHYA
Webinar ID: 95741428905
IR moderator: nick.stone@astrazeneca.com

Respiratory & Immunology: emerging pipeline
Session 1: 15:30 GMT
Session 2: 16:15 GMT

Maria Belvisi,
Ben Fenby,
Iain Chessell

https://astrazeneca.zoom.us/webinar/register/WN_mahGlEaxaRVIgh?xsI6zlow
Webinar ID: 95277051413
IR moderator: tom.waldron@astrazeneca.com

Respiratory & Immunology: near-term opportunities
Session 1: 15:30 GMT
Session 2: 16:15 GMT

Richard Marshall, Pablo Panella, Gerard O’Malley, Micki Hultquist

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