Meet AZN management: ASCO 2019
Opening session

Pascal Soriot, Chief Executive Officer
José Baselga, Executive Vice President, Oncology R&D

3 June 2019
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 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 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.
Presenters

Pascal Soriot
Executive Director and Chief Executive Officer

Dave Fredrickson
Executive Vice President, Oncology Business Unit

Greg Rossi
Vice President, **Lynparza** franchise and Market Access, Oncology Business Unit

Klaus Edvardsen
Senior Vice President, Oncology R&D, late stage

Susan Galbraith
Senior Vice President, Oncology R&D, early stage

Jean-Charles Soria
Senior Vice President, Oncology R&D, early stage

José Baselga
Executive Vice President, Oncology R&D
Agenda

Strategy and business

ASCO 2019 highlights

- *Lynparza* pancreatic cancer (POLO trial)

- *Lynparza* 3rd-line ovarian cancer (SOLO3 trial)

- Other highlights

Breakout sessions followed by drinks and canapés
Cancer is still a growing burden

2018
- 18.1 million new patients
- 9.6 million deaths
- 43 million patients living with cancer

2030 estimate
- 26.4 million new patients
- 17 million deaths
- 82 million patients living with cancer

Source: International Agency for Research on Cancer.
## Oncology: strategy
A leading, diversified oncology business

<table>
<thead>
<tr>
<th>Lung cancer</th>
<th>Multiple cancers</th>
<th>Multiple cancers</th>
<th>Haematology</th>
</tr>
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<tbody>
<tr>
<td><img src="image" alt="TAGRISSO® osimertinib" /></td>
<td><img src="image" alt="IMFINZI™ durvalumab" /></td>
<td><img src="image" alt="Lynparza™ olaparib" /></td>
<td><img src="image" alt="trastuzumab deruxtecan" /></td>
</tr>
<tr>
<td><img src="image" alt="CALQUENCE" /></td>
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</tr>
</tbody>
</table>

- **Stage IV NSCLC**¹
  - T790Mm² / EGFRm³
  - Next: adjuvant, Stage III

- **Unresectable, Stage III NSCLC**
  - Next: early / advanced stages in several cancers

- **Ovarian, breast cancers**
  - MRK collaboration
  - Next: pancreatic, prostate cancers

- **DS⁴ collaboration**
  - Next: HER2⁺⁵ breast, gastric cancers; HER2-low cancers

- **First medicine in haematology**
  - MCL⁶ launched
  - CLL⁷ data started
  - Next: combos

### ‘What’s next’: rich early to mid-stage pipeline, including combinations

1. Non-small cell lung cancer  
2. Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation  
3. Epidermal growth factor receptor mutation  
4. Daiichi Sankyo  
5. Human epidermal growth factor receptor 2 positive  
6. Mantle cell lymphoma  
7. Chronic lymphocytic leukaemia.
Lung cancer: *Tagrisso*
Realising global opportunity in patients with 1st-line EGFRm disease

**1st-line opportunity is moving global**

- Phase III FLAURA trial almost doubled progression-free survival

**Final overall survival data anticipated in H2 2019**

- Source: European Society for Medical Oncology meeting 2017.

**Lifecycle plans include early stage and combinations**

**Phase IIIs in early-stage disease**
- Adjuvant (ADAURA trial)
- Locally-advanced (LAURA trial)

**Phase IIs in post-*Tagrisso* progression**
- Savolitinib/MET combination (SAVANNAH trial)
- EGFR, PD-L1, MET, A2aR, CD73, dual EGFR (ORCHARD trial)

**Strong performance in all markets: +92% in Q1 2019**

**US, Europe, Established rest of world (RoW), Emerging markets**

Absolute values at actual exchange rates; changes at constant exchange rates (CER) and for Q1 2019, unless otherwise stated.

**Source:** AstraZeneca data on file.
**Lung cancer: ****Imfinzi**
Global adoption underway; lifecycle trials will expand to more patients

Ex-US now 22% of total, up from 18% in Q4 2018

Major ongoing Phase III trials with **Imfinzi** used as backbone

- **Stage I-III**
  - POTOMAC (2020+)
  - PACIFIC-2 (2020+)
  - PACIFIC-4 (2020+)
  - EMERALD-1 (2020+)
  - CALLA (2020+)

- **Stage IV**
  - NILE (2020+)
  - PEARL (2020)
  - CASPIAN (H2 2019)
  - DANUBE (H2 2019)
  - POSEIDON (H2 2019)
  - NEPTUNE (H2 2019)
  - HIMALAYA (2020+)
  - KESTREL (H2 2019)
  - TOPAZ-1 (-)

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>Bladder</th>
<th>Lung</th>
<th>Liver</th>
<th>H&amp;N</th>
<th>Cervical</th>
<th>Biliary</th>
</tr>
</thead>
</table>

( ) denote anticipated timeline for data readout. The staging above does not apply to small-cell lung cancer (CASPIAN and ADRIATIC trials)

Source: AstraZeneca Q1 2019 results announcement. Excludes combination trials where Lynparza is considered the backbone medicine.
Lynparza
Strong performance; industry-leading development programme

Seven quarters of strong growth: +105% in Q1 2019
Ex-US now 50% of total

Extensive, strategic development programme underway

Earlier lines of treatment

1st-line ovarian SOLO-1
2nd-line ovarian SOLO-2
3rd-line ovarian SOLO-3
Ovarian with cediranib
Ovarian with bevacizumab
Ovarian with Imfinzi

Adjuvant breast Olympia
Prostate with abiraterone
Ovarian with Imfinzi
Ovarian with abiraterone
Ovarian with Imfinzi

Prostate PROfound
Lung with Imfinzi
Bladder with Imfinzi
DDR combinations

New cancer types

In collaboration with Merck.
Source: AstraZeneca data on file.

Absolute values at actual exchange rates; changes at CER and for Q1 2019, unless otherwise stated.
Trastuzumab deruxtecan and Calquence
Important future platforms with significant growth

Trastuzumab deruxtecan: unprecedented efficacy in heavily-pretreated HER2+ metastatic breast cancer

59.5% confirmed objective response rate

20.7 months median duration of response\(^1\)

Seven median lines of prior treatment

Haematology taking shape: Calquence on track to benefit patients globally

CLL
- Study ‘309’ in relapsed/refractory (r/r) patients met primary endpoint; presentation at meeting in June 2019
- Study ‘007’ in front-line patients on track for H2 2019 data readout

MCL
- Launched in US and a few global markets
- Sales of $94m since launch

US regulatory submission in H2 2019
Regulatory decision anticipated in 2020

\(^1\) Not estimable.
Source: based on Phase I data, The Lancet Oncology, April 2019. Phase II DESTINY-Breast01 data have not been presented yet; trial met primary endpoint in May 2019 and will form the basis for the US regulatory submission.

Absolute values at actual exchange rates.
Source: AstraZeneca data on file.
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Breakout sessions followed by drinks and canapés
ASCO 2019 highlights

Solid AstraZeneca presence at ASCO 2019

- 93 abstracts accepted, including **12 orals** and **11 poster discussions**
- Externally-sponsored ~45% of total

Data highlights from select mid-to-late stage trials

- **Lynparza**
  - Phase III POLO - BRCAm pancreatic cancer
  - Phase III SOLO3 - BRCAm ovarian cancer
  - Phase II TOPARP-B - prostate cancer HRRm

- **Imfinzi**
  - Phase III PACIFIC - unresectable, Stage III NSCLC
    (three-year landmark OS data)

- **Calquence**
  - Phase II ACE-CL-208/ACE-CL-003 - CLL

- **capivasertib (AKT inhibitor)**
  - Phase II FAKTION - ER+ breast cancer

Source: AstraZeneca data on file based on submitted and accepted ASCO 2019 Annual Meeting abstracts.

1. Homologous recombination repair.
2. Estrogen-receptor positive.
   Source: ASCO 2019.
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**Lynparza**
Pancreatic cancer - POLO trial
**Lynparza**
Pancreatic cancer - POLO trial

**Study design**

- **First-line chemotherapy**
- **Randomization**
- **Maintenance treatment**
- **Discontinuation**
- **Follow-up**

**Key eligibility criteria**
Metastatic pancreatic cancer
Deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation
≥16 weeks first-line platinum-based chemotherapy with no limit to duration, without progression (CR, PR or SD)*

**Randomized 3:2**
No stratification factors

- **Olaparib tablets 300 mg bid**
- **Placebo**

**Until investigator-assessed disease progression or unacceptable toxicity**

38% of gBRCAm patients had disease progression, were ineligible, or declined randomization

*There was no maximum limit to the duration of first-line chemotherapy. bid, twice daily; CR, complete response; PR, partial response; SD, stable disease
Lynparza
Pancreatic cancer - POLO trial

**Primary endpoint: PFS by blinded independent central review**

<table>
<thead>
<tr>
<th></th>
<th>Olaparib (N=92)</th>
<th>Placebo (N=62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median PFS, months</td>
<td>7.4</td>
<td>3.8</td>
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<tr>
<td>HR</td>
<td>0.53</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>0.35, 0.82</td>
<td></td>
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<tr>
<td>P</td>
<td>0.0038</td>
<td></td>
</tr>
</tbody>
</table>

Progression-free at data cut-off:
- 30 olaparib patients (32.6%)
- 12 placebo patients (19.4%)

*Dots indicate censorship. †January 15, 2019. CI, confidence interval.
**Lynparza**
Pancreatic cancer - POLO trial

**OS: interim analysis, 46% maturity**

<table>
<thead>
<tr>
<th></th>
<th>Olaparib (N=92)</th>
<th>Placebo (N=62)</th>
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</thead>
<tbody>
<tr>
<td>Median OS, months</td>
<td>18.9</td>
<td>18.1</td>
</tr>
<tr>
<td>HR</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>0.56, 1.46</td>
<td>P=0.68</td>
</tr>
</tbody>
</table>

Final OS analysis planned at 106 events

Subsequent treatment with a PARP inhibitor:†
- 1 olaparib patient (1.1%)
- 9 placebo patients (14.5%)

*Notes: Dots indicate censoring. Crossover to olaparib was not permitted during this study; subsequent therapies were given at the investigators' discretion.*
Lynparza
Pancreatic cancer - POLO trial

Objective response* in patients with measurable disease by blinded independent central review

Two olaparib arm patients had a complete response. Both complete responses were ongoing at the data cut-off.

- Olaparib: 23.1% (n=18), Median time to onset of response: 5.4 months
- Placebo: 11.5% (n=6), Median time to onset of response: 3.6 months

- Olaparib: Median duration of response: 24.9 months
- Placebo: Median duration of response: 3.7 months

*By modified RECIST v1.1. †January 15, 2019
**Lynparza**
Pancreatic cancer - POLO trial

### Safety summary: AEs and exposure

<table>
<thead>
<tr>
<th></th>
<th>Olaparib (N=91)</th>
<th>Placebo (N=60)</th>
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<tbody>
<tr>
<td>Any grade, n (%)</td>
<td>87 (95.6)</td>
<td>56 (93.3)</td>
</tr>
<tr>
<td>Grade ≥3, n (%)</td>
<td>36 (39.6)</td>
<td>14 (23.3)</td>
</tr>
<tr>
<td>AEs leading to dose interruption, n (%)</td>
<td>32 (35.2)</td>
<td>3 (5.0)</td>
</tr>
<tr>
<td>AEs leading to dose reduction, n (%)</td>
<td>15 (16.5)</td>
<td>2 (3.3)</td>
</tr>
<tr>
<td>AEs leading to treatment discontinuation, n (%)</td>
<td>5 (5.5)</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Median duration of treatment, months (range)</td>
<td>6.0 (0.8–45.3)</td>
<td>3.7 (0.1–30.1)</td>
</tr>
</tbody>
</table>

AE, adverse event
Lynparza
Pancreatic cancer - POLO trial

Conclusions

• Maintenance olaparib provided a statistically significant and clinically meaningful improvement in PFS to patients with a gBRCAm and metastatic pancreatic cancer whose disease had not progressed during platinum-based chemotherapy

• Interim OS data (at 46% maturity) showed no difference between arms. Final OS results will be evaluated at 69% data maturity

• Maintenance olaparib was well tolerated, with an AE profile similar to that seen in other tumor types

• HRQoL was preserved with olaparib treatment and showed no difference between arms

• Our results are the first from a Phase III trial to validate a targeted treatment in a biomarker-selected population of pancreatic cancer patients, highlighting the importance of gBRCAm testing in this setting
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Breakout sessions followed by drinks and canapés
Lynparza
Ovarian cancer - SOLO3 trial

Study Design

- Relapsed, high-grade serous or endometrioid ovarian, primary peritoneal, and/or fallopian tube cancer
- Germline BRCAm
- ECOG performance status 0–2
- ≥2 previous lines of platinum-based chemotherapy*
- Platinum sensitive†

Study treatment administered until disease progression

2:1 randomization

Stratified by:
- Selected chemotherapy†
- Number of prior lines of chemotherapy
- Time to progression after previous platinum-based chemotherapy

Olaparib tablets 300 mg bid (n=178)

Non-platinum chemotherapy (n=88)
- PLD (n=47)
- Paclitaxel (n=20)
- Gemcitabine (n=13)
- Topotecan (n=8)

Primary endpoint
- ORR by BICR (RECIST v1.1)

Secondary endpoints
- PFS
- PFS2
- OS
- TFST
- TSST
- HRQoL
- Safety
**Lynparza**

Ovarian cancer - SOLO3 trial

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**Primary Endpoint: ORR by BICR**

<table>
<thead>
<tr>
<th>Group</th>
<th>ORR 72%</th>
<th>ORR 51%</th>
<th>ORR 59%</th>
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<tbody>
<tr>
<td>Olaparib n=151</td>
<td>9%</td>
<td>63%</td>
<td>52%</td>
</tr>
<tr>
<td>Chemotherapy n=72</td>
<td>9%</td>
<td>49%</td>
<td>39%</td>
</tr>
</tbody>
</table>

- **Complete response**
  - Olaparib n=78: 12%
  - Chemotherapy n=39: 5%

- **Partial response**
  - Olaparib n=78: 73%
  - Chemotherapy n=39: 56%

---

**All patients**

OR 2.53 (1.40, 4.58) P=0.002

**Patients with 2 prior lines of chemotherapy**

OR 3.44 (1.42, 8.54)

**Patients with ≥3 prior lines of chemotherapy**

OR 2.21 (0.96, 5.20)

*Patients with measurable disease at baseline*
Lynparza
Ovarian cancer - SOLO3 trial

Investigator-Assessed Best Response for Target Lesions by Patient

Chemotherapy (n=78)*

Olaparib (n=160)†

*19 patients were not evaluable for investigator-assessed best response; †11 patients were not evaluable for investigator-assessed best response
Lynparza
Ovarian cancer - SOLO3 trial

PFS (Intention-To-Treat Population)

- BICR
- Investigator-Assessed

<table>
<thead>
<tr>
<th>No. at risk</th>
<th>Olaparib (n=178)</th>
<th>Chemotherapy (n=88)</th>
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<tr>
<td>Olaparib</td>
<td>178</td>
<td>88</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>156</td>
<td>63</td>
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<tr>
<td>126</td>
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</tbody>
</table>

- PFS events, n (%)
- Median PFS, months
- HR (95% CI), P value

\[ PFS \text{ events, n (%)} \]
\[ \text{Median PFS, months} \]
\[ \text{HR (95\% CI), } P \text{ value} \]

- Olaparib: 110 (62), 13.4 (0.62 (0.43, 0.91); P=0.013)
- Chemotherapy: 49 (56), 9.2

- Olaparib: 123 (69), 13.2
- Chemotherapy: 63 (72), 8.5

- Olaparib: 0.49 (0.35, 0.70); P<0.001
- Chemotherapy: 0.001
**Lynparza**  
Ovarian cancer - SOLO3 trial

### Safety Overview

<table>
<thead>
<tr>
<th>Event</th>
<th>Olaparib (n=178)</th>
<th>Chemotherapy (n=76)</th>
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<tbody>
<tr>
<td><strong>All-grade AEs, n (%)</strong></td>
<td>174 (98)</td>
<td>73 (96)</td>
</tr>
<tr>
<td><strong>Grade ≥3 AEs, n (%)</strong></td>
<td>89 (50)</td>
<td>36 (47)</td>
</tr>
<tr>
<td><strong>Serious AEs, n (%)</strong></td>
<td>42 (24)</td>
<td>14 (18)</td>
</tr>
<tr>
<td><strong>AEs leading to dose interruption, n (%)</strong></td>
<td>85 (48)</td>
<td>32 (42)</td>
</tr>
<tr>
<td><strong>AEs leading to dose reduction, n (%)</strong></td>
<td>48 (27)</td>
<td>25 (33)</td>
</tr>
<tr>
<td><strong>AEs leading to treatment discontinuation, n (%)†</strong></td>
<td>13 (7)</td>
<td>15 (20)</td>
</tr>
</tbody>
</table>

**Median total treatment duration (range), months**

<table>
<thead>
<tr>
<th></th>
<th>Olaparib</th>
<th>Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olaparib</td>
<td>11.3 (0.1–39.5)</td>
<td>–</td>
</tr>
<tr>
<td>PLD</td>
<td>–</td>
<td>6.0 (0.9–15.4)</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>–</td>
<td>5.1 (1.8–18.2)</td>
</tr>
<tr>
<td>Gemcitabine</td>
<td>–</td>
<td>3.3 (0.7–14.3)</td>
</tr>
<tr>
<td>Topotecan</td>
<td>–</td>
<td>6.2 (2.3–9.7)</td>
</tr>
</tbody>
</table>

*Most common serious AE in the olaparib arm was anemia (3%) and in the chemotherapy arm was vomiting (4%);  
†Most common AEs leading to treatment discontinuation in the olaparib arm were vomiting, anemia, and thrombocytopenia (all 1%), and in the chemotherapy arm were PPE (9%), mucosal inflammation, peripheral neuropathy, and neutropenia (all 3%)  
PPE, palmar-planter erythrodysesthesia
Lynparza
Ovarian cancer - SOLO3 trial

Conclusions

• SOLO3 is the first Phase III randomized trial of a PARP inhibitor versus non-platinum-based chemotherapy in women with PSR gBRCA-mutated ovarian cancer

• A statistically significant and clinically relevant improvement in ORR and PFS was observed with olaparib versus non-platinum-based chemotherapy

• The tolerability profiles of olaparib and chemotherapy were consistent with previous data
  • Patients in the chemotherapy arm were more than twice as likely to discontinue study treatment because of an AE

• SOLO3 provides important prospective data on the efficacy of these treatment options for women with heavily pre-treated PSR gBRCA-mutated ovarian cancer
Agenda

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**ASCO 2019 highlights**

- *Lynparza* pancreatic cancer (POLO trial)
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- Other highlights

Breakout sessions followed by drinks and canapés
Other highlights
AstraZeneca continues to redefine cancer treatment

<table>
<thead>
<tr>
<th>Breaking treatment boundaries</th>
<th>Treating patients earlier in their disease</th>
<th>Raising the bar for better outcomes</th>
<th>Advancing presence in haematology</th>
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</thead>
<tbody>
<tr>
<td><strong>Lynparza</strong> prostate cancer Phase II TOPARP-B</td>
<td><strong>Imfinzi</strong> NSCLC Phase III PACIFIC three-year OS</td>
<td><strong>Tagrisso</strong> NSCLC Phase III FLAURA Additional data</td>
<td><strong>Calquence</strong> CLL Phase I/II ACE-CL-003</td>
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<tr>
<td><strong>Lynparza</strong> neo-adjuvant breast cancer Phase II GeparOLA</td>
<td></td>
<td><strong>adavosertib</strong> ovarian cancer Phase II</td>
<td><strong>Calquence</strong> CLL r/r Phase II ACE-CL-208</td>
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<td><strong>capivasertib</strong> breast cancer Phase II FAKTION</td>
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Breakout sessions followed by drinks and canapés
Breakout sessions

Four topics
- sales and marketing
- late-stage pipeline
- early-stage pipeline
- trastuzumab deruxtecan

One time each

Focus on Q&A
Few slides; time for questions

<table>
<thead>
<tr>
<th>Room</th>
<th>E</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Early-stage pipeline</td>
<td>Sales and marketing</td>
</tr>
<tr>
<td>Hosts</td>
<td>Susan Galbraith, Jean-Charles Soria</td>
<td>Dave Fredrickson, Greg Rossi</td>
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18:30

<table>
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<th>Topic</th>
<th>Late-stage pipeline</th>
<th>Trastuzumab deruxtecan</th>
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<tbody>
<tr>
<td>Hosts</td>
<td>Klaus Edvardsen</td>
<td>José Baselga</td>
</tr>
</tbody>
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19:00
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