

# 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 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 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



**José Baselga**  
Executive Vice President,  
Oncology R&D

Additional presenters  
for breakout sessions

**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

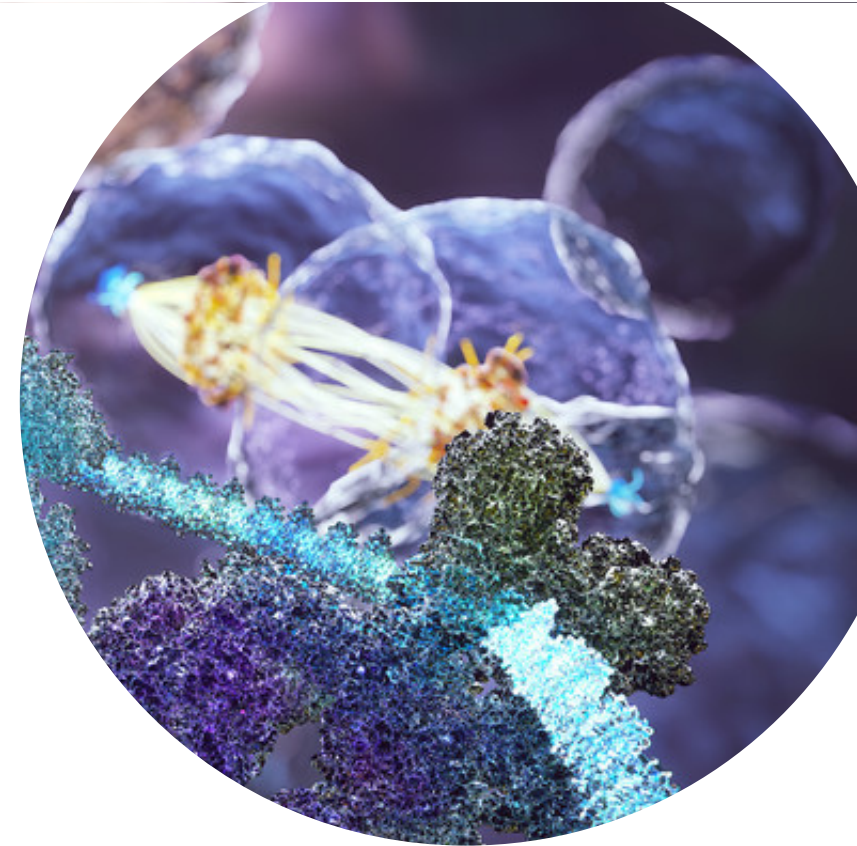
# Agenda

## 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



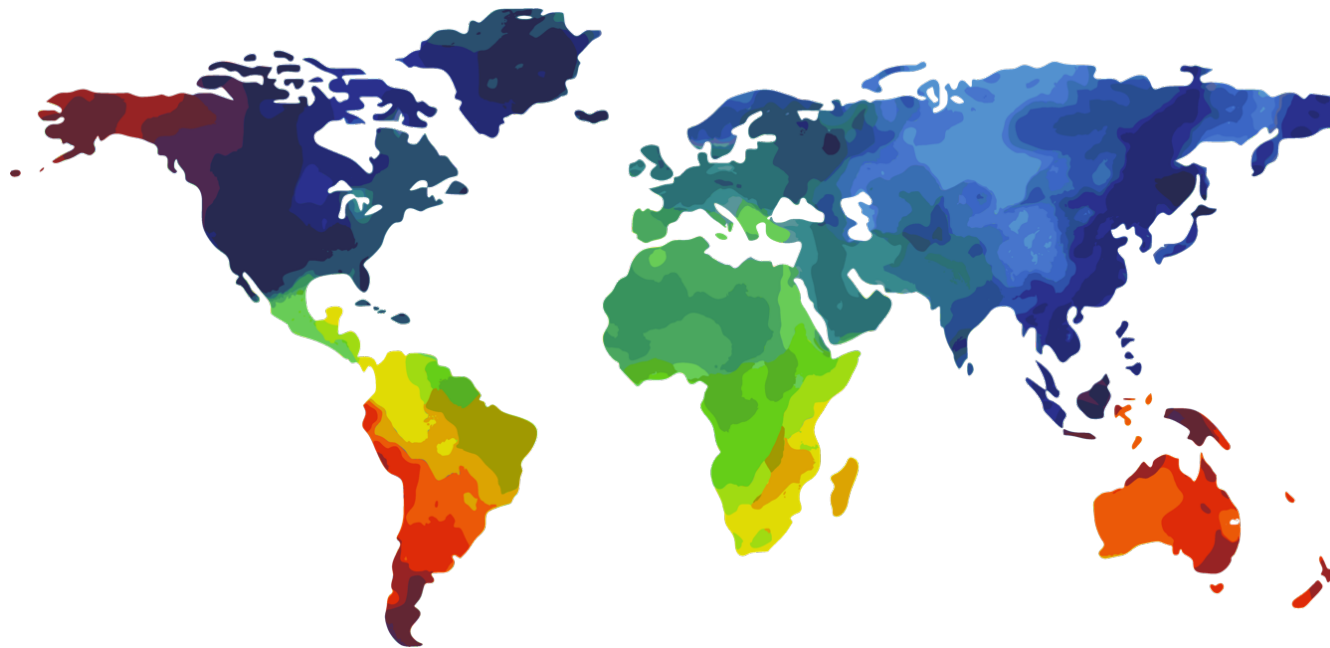
# Cancer is still a growing burden

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

| Lung cancer  | Multiple cancers  | Multiple cancers  | Haematology  |
|--|---|---|--|
|  <ul style="list-style-type: none"> <li>• Stage IV NSCLC<sup>1</sup> T790Mm<sup>2</sup> / EGFRm<sup>3</sup></li> <li>• Next: adjuvant, Stage III</li> </ul> |  <ul style="list-style-type: none"> <li>• Unresectable, Stage III NSCLC</li> <li>• Next: early / advanced stages in several cancers</li> </ul> |  <ul style="list-style-type: none"> <li>• Ovarian, breast cancers</li> <li>• MRK collaboration</li> <li>• Next: pancreatic, prostate cancers</li> </ul> |  <ul style="list-style-type: none"> <li>• DS<sup>4</sup> collaboration</li> <li>• Next: HER2+<sup>5</sup> breast, gastric cancers; HER2-low cancers</li> <li>• First medicine in haematology</li> <li>• MCL<sup>6</sup> launched</li> <li>• CLL<sup>7</sup> data started</li> <li>• Next: combos</li> </ul> |

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

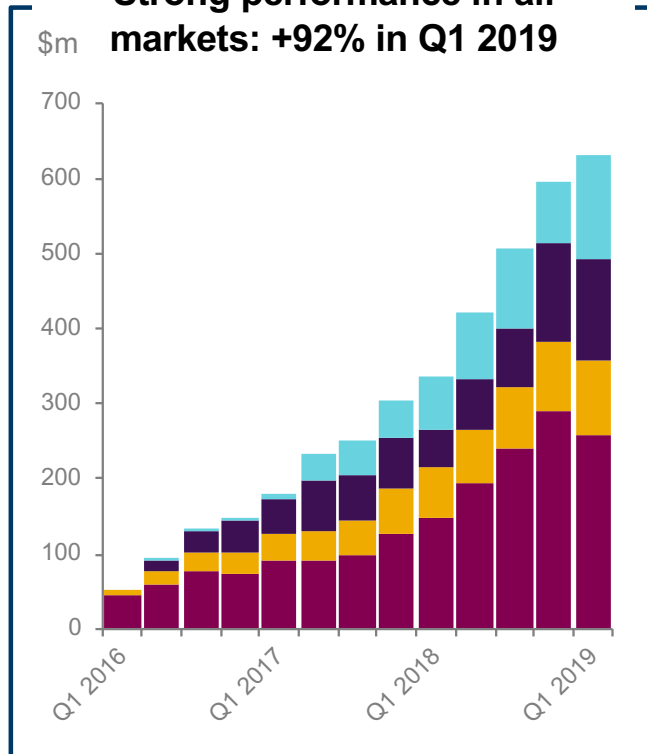
1. Non-small cell lung cancer 2. Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation 3. Epidermal growth factor receptor mutation 4. Daiichi Sankyo 5. Human epidermal growth factor receptor 2 positive 6. Mantle cell lymphoma 7. Chronic lymphocytic leukaemia.



# Lung cancer: *Tagrisso*

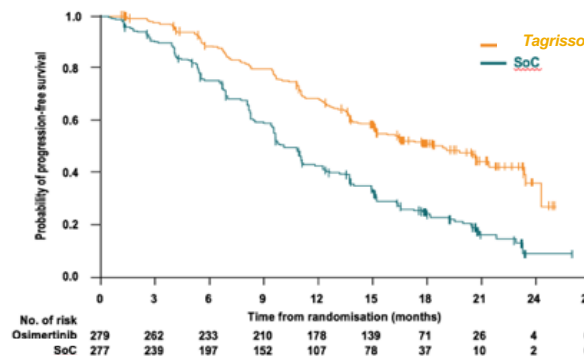
## Realising global opportunity in patients with 1st-line EGFRm disease

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



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

Phase III FLAURA trial almost doubled progression-free survival



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

**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)

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.

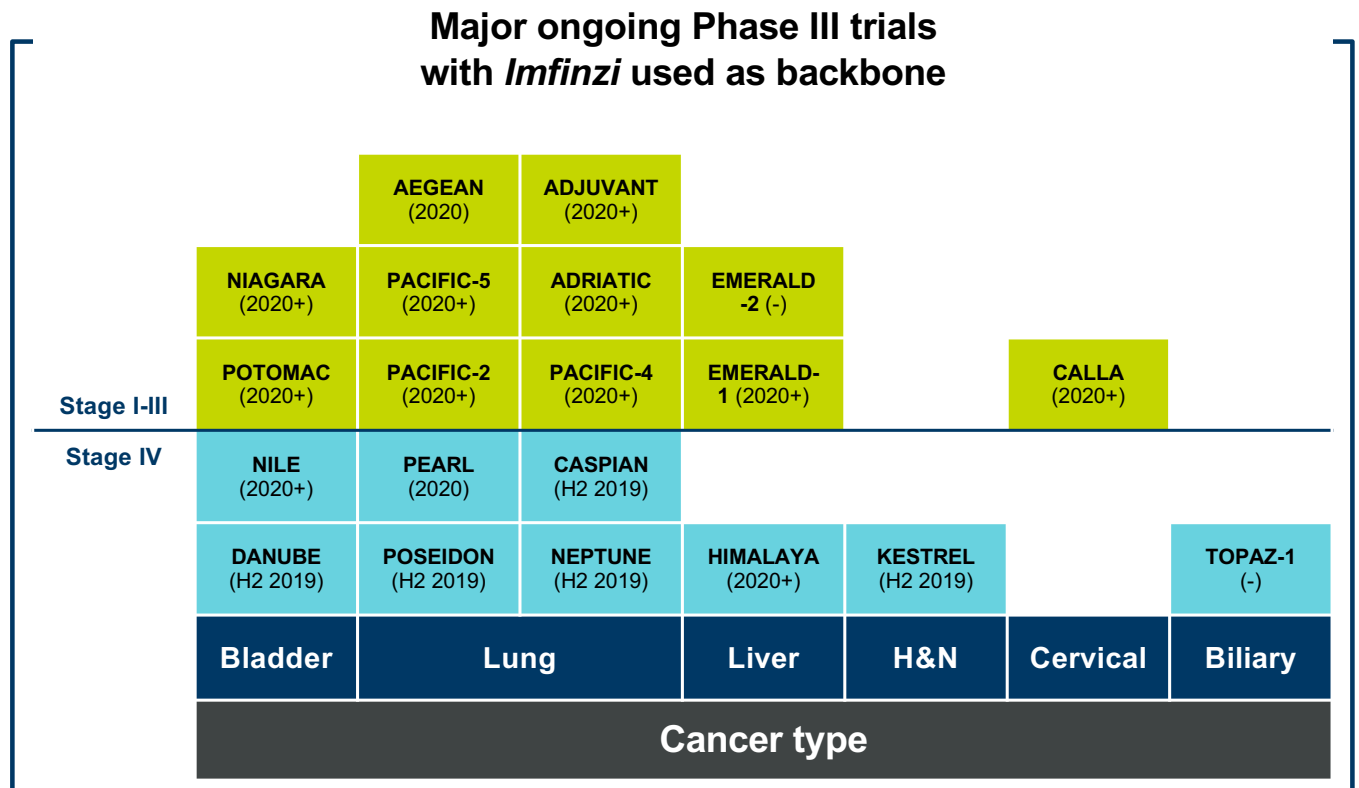
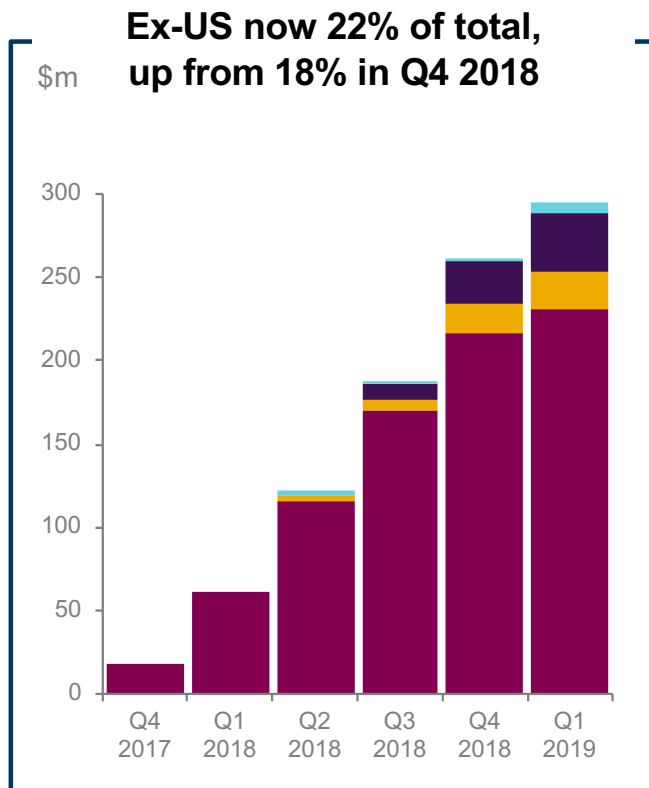
Source: European Society for Medical Oncology meeting 2017.

Source: AstraZeneca data on file.



# Lung cancer: *Imfinzi*

Global adoption underway; lifecycle trials will expand to more patients



US Europe Established RoW Emerging markets

Absolute values at actual exchange rates.

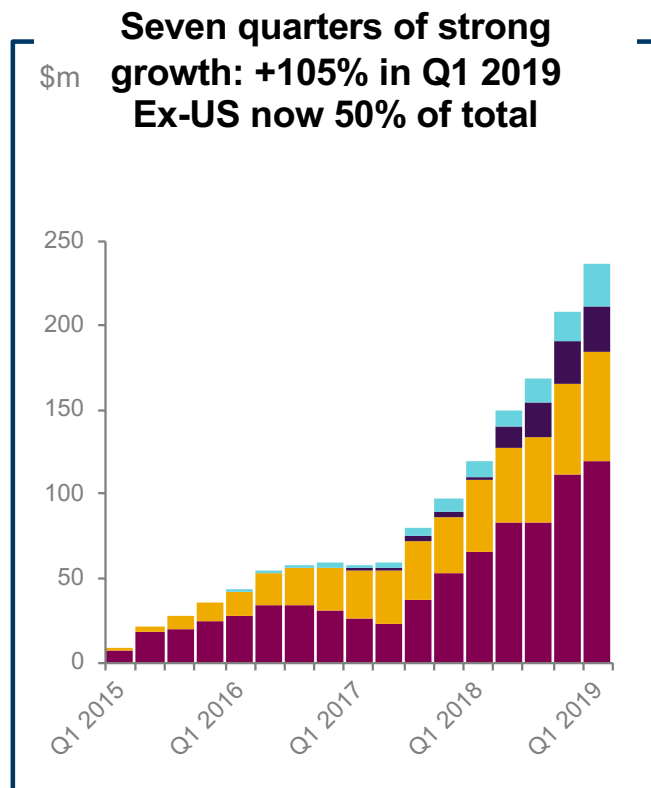
(-) denote anticipated timeline for data readout. The staging above does not apply to small-cell lung cancer (CASPIAN and ADRIATIC trials)  
 Source: AstraZeneca Q1 2019 results announcement. Excludes combination trials where *Lynparza* is considered the backbone medicine.



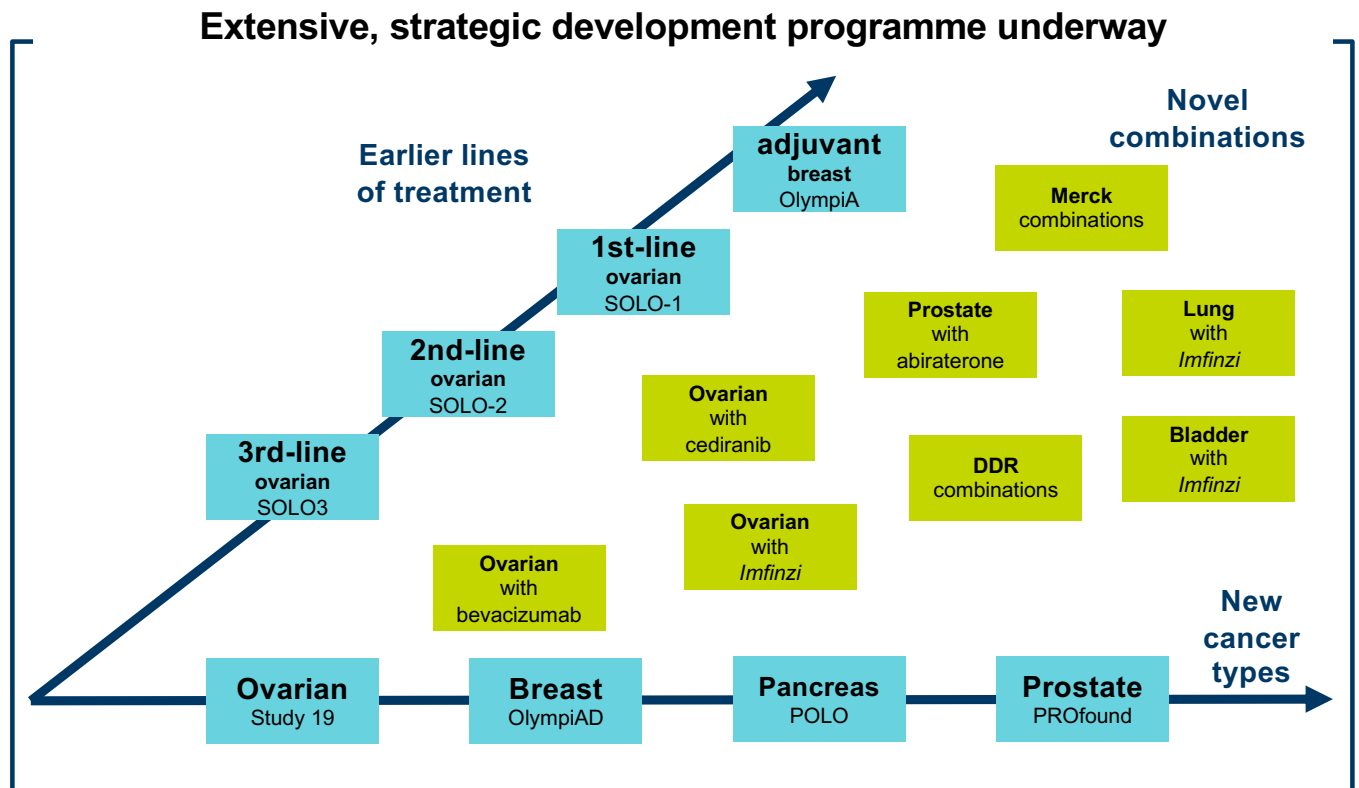


# Lynparza

## Strong performance; industry-leading development programme



US Europe Established RoW Emerging markets  
 Absolute values at actual exchange rates; changes at CER and for Q1 2019, unless otherwise stated.



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



# 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<sup>1</sup>

**Seven**

median lines of prior treatment

**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.

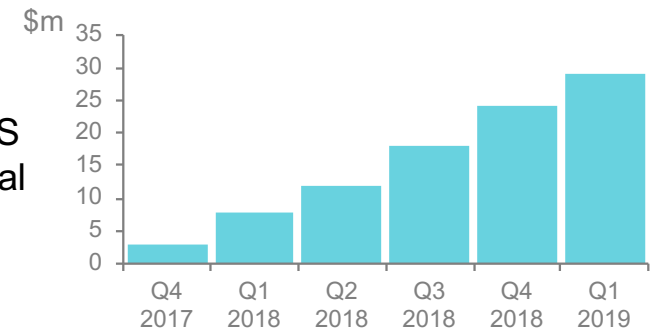
**Haematology taking shape: *Calquence* on track to benefit patients globally**

### 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



Absolute values at actual exchange rates.  
 Source: AstraZeneca data on file.



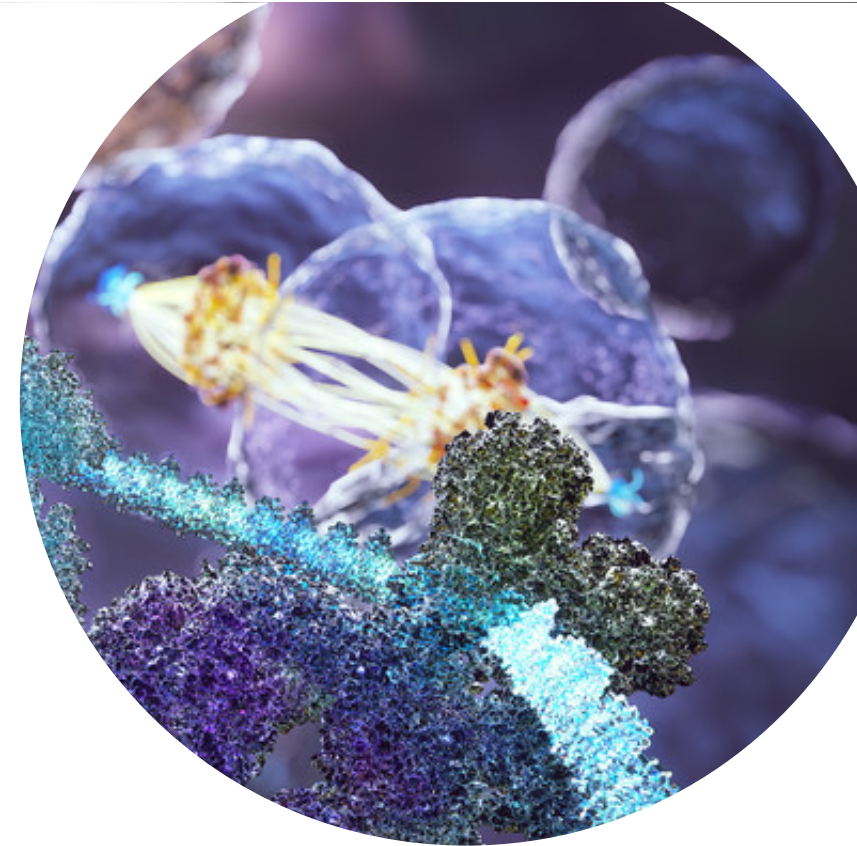
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- *Lynparza* 3rd-line ovarian cancer (SOLO3 trial)
- Other highlights

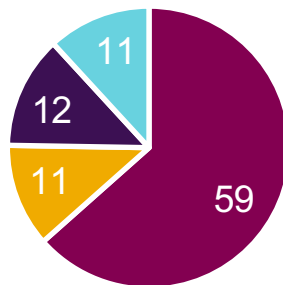
Breakout sessions followed by drinks and canapés



# ASCO 2019 highlights

## Solid AstraZeneca presence at ASCO 2019

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



■ Posters ■ Poster discussions ■ Oral presentations ■ Published only

## 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<sup>1</sup>
- **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+<sup>2</sup> breast cancer

1. Homologous recombination repair.

2. Estrogen-receptor positive.

Source: ASCO 2019.



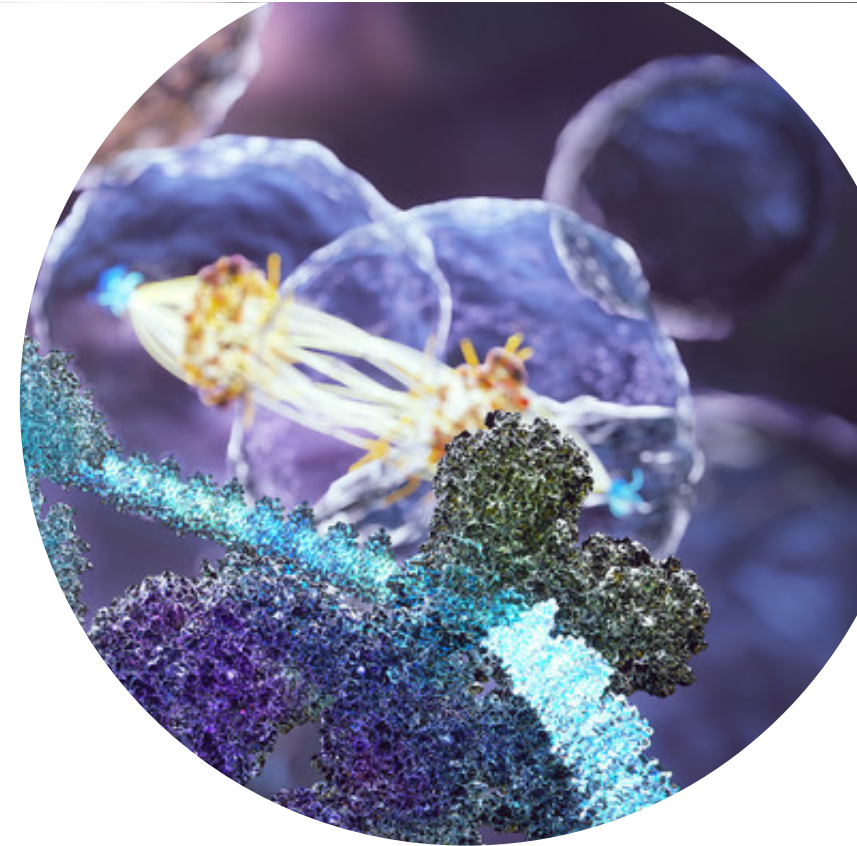
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## ASCO 2019 highlights

- **Lynparza pancreatic cancer (POLO trial)**
- *Lynparza 3rd-line ovarian cancer (SOLO3 trial)*
- Other highlights

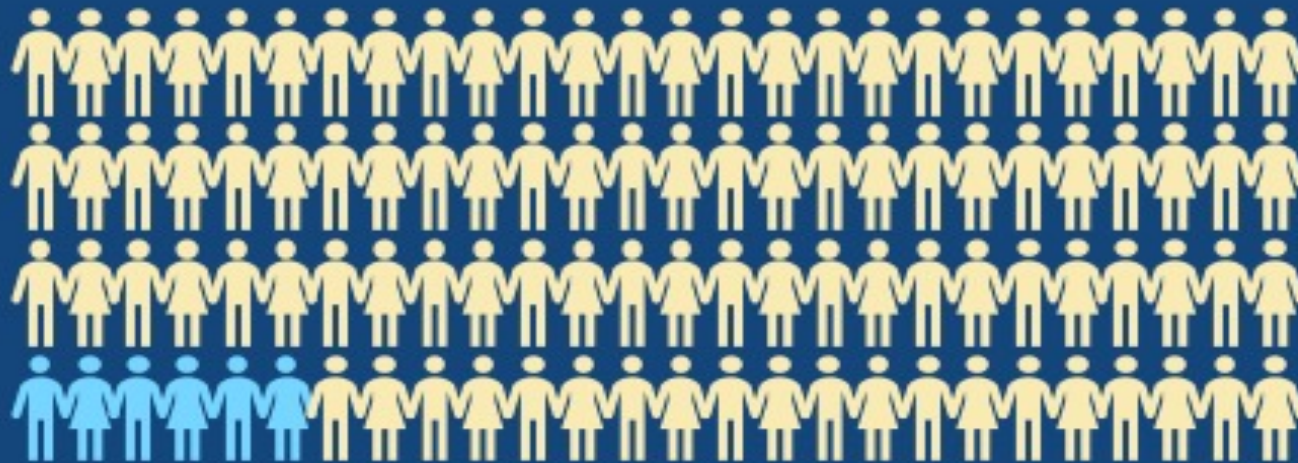
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# Lynparza

## Pancreatic cancer - POLO trial

### Metastatic pancreatic cancer



4–7% harbor a germline *BRCA1* and/or *BRCA2* mutation (gBRCAm)<sup>4,5</sup>

Increased benefit from platinum-based chemotherapy<sup>6,7</sup>

Maintenance treatments aim to delay disease progression following chemotherapy without compromising HRQoL

FOLFIRINOX, leucovorin, fluorouracil, irinotecan and oxaliplatin; HRQoL, health-related quality of life; OS, overall survival; PFS, progression-free survival

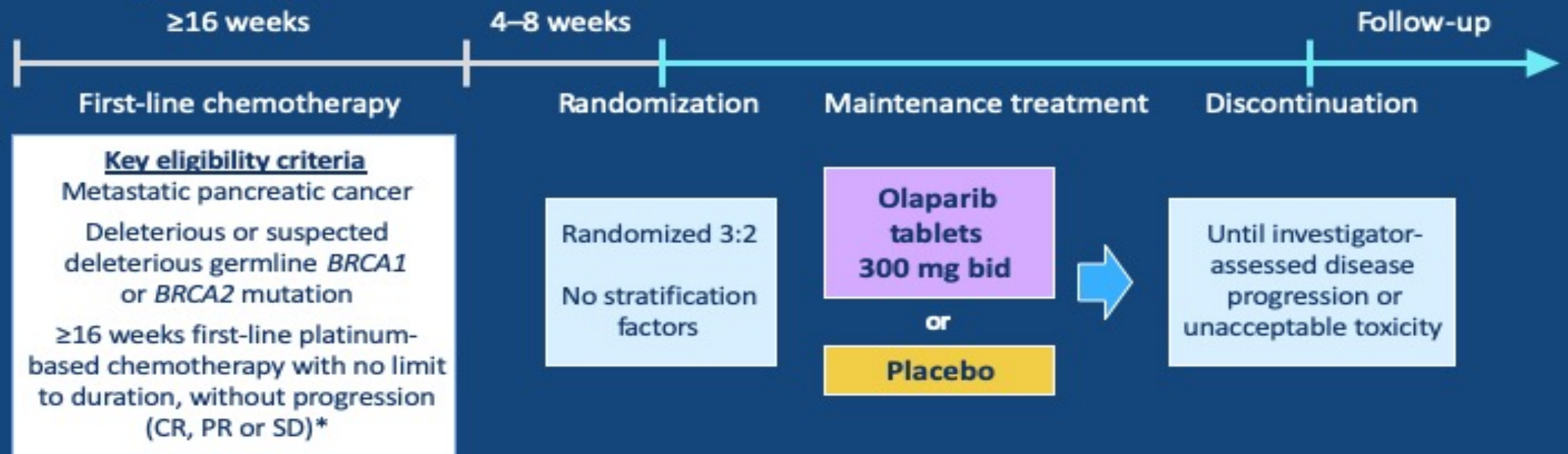
1. Conroy T et al. *N Engl J Med* 2011;364:1817–1825; 2. Von Hoff DD et al. *N Engl J Med* 2013;369:1691–1703; 3. Hidalgo M et al. *Pancreatology* 2015;15:8–18;

4. Friedenson B et al. *MedGenMed* 2005;7:60; 5. Golan T et al. *J Clin Oncol* 2018;36:4115; 6. Waddell N et al. *Nature* 2015;518:495–501; 7. Golan T et al. *Br J Cancer* 2014;111:1132–1138

# Lynparza

## Pancreatic cancer - POLO trial

### Study design



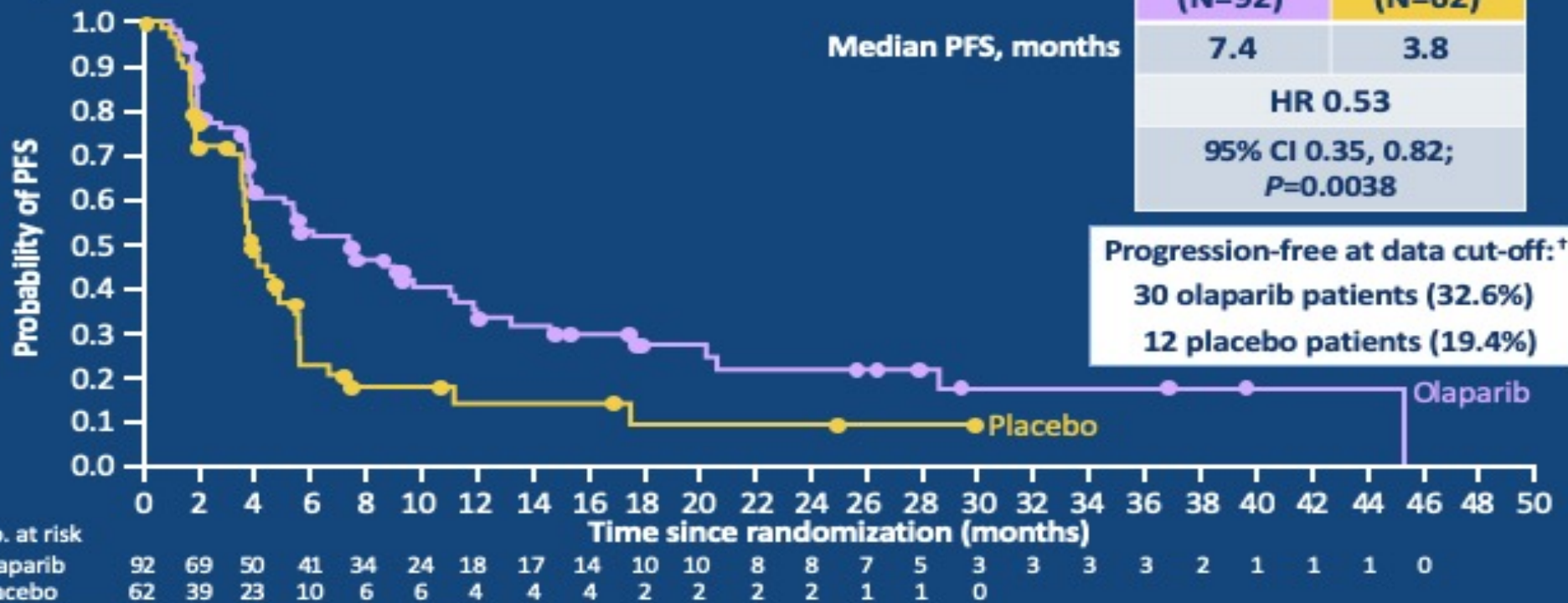
38% of gBRCAm patients had disease progression, were ineligible, or declined randomization

\*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\*

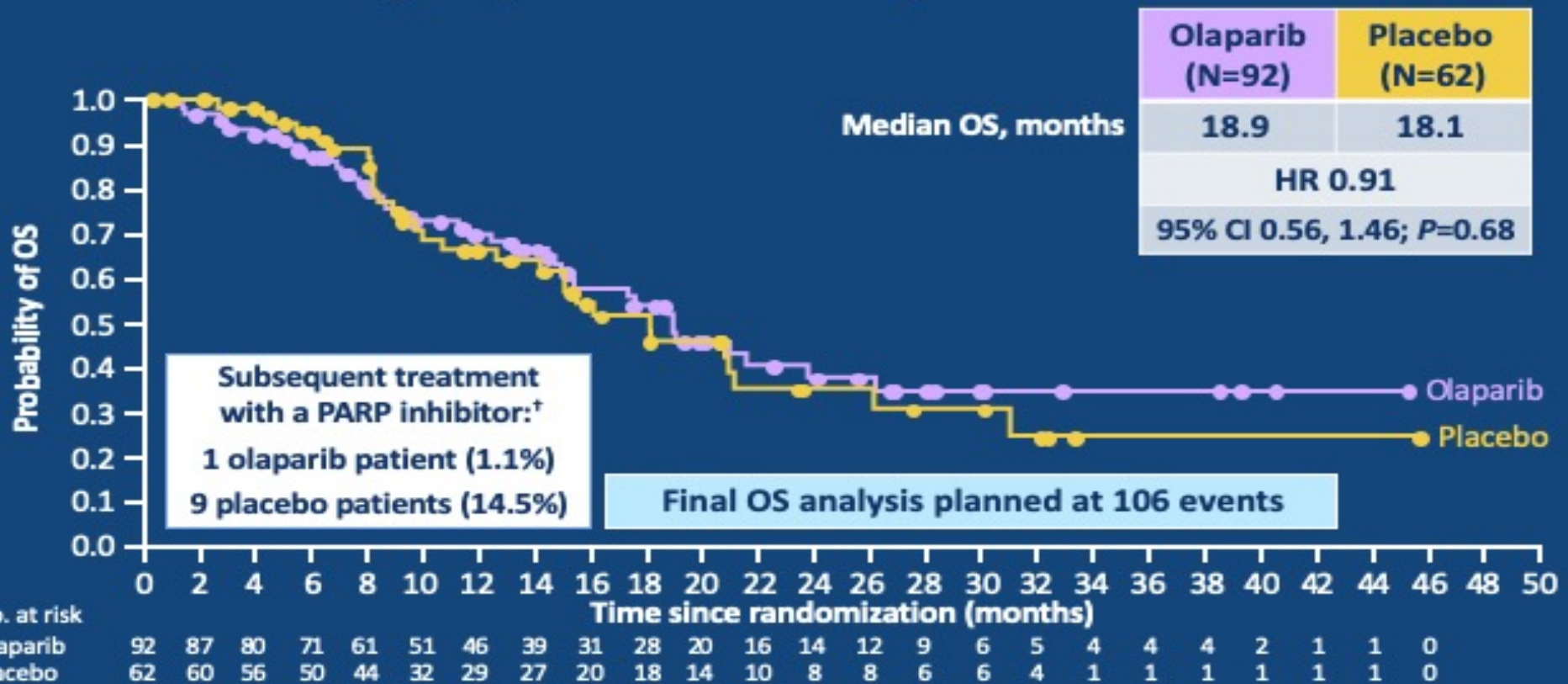




# Lynparza

## Pancreatic cancer - POLO trial

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

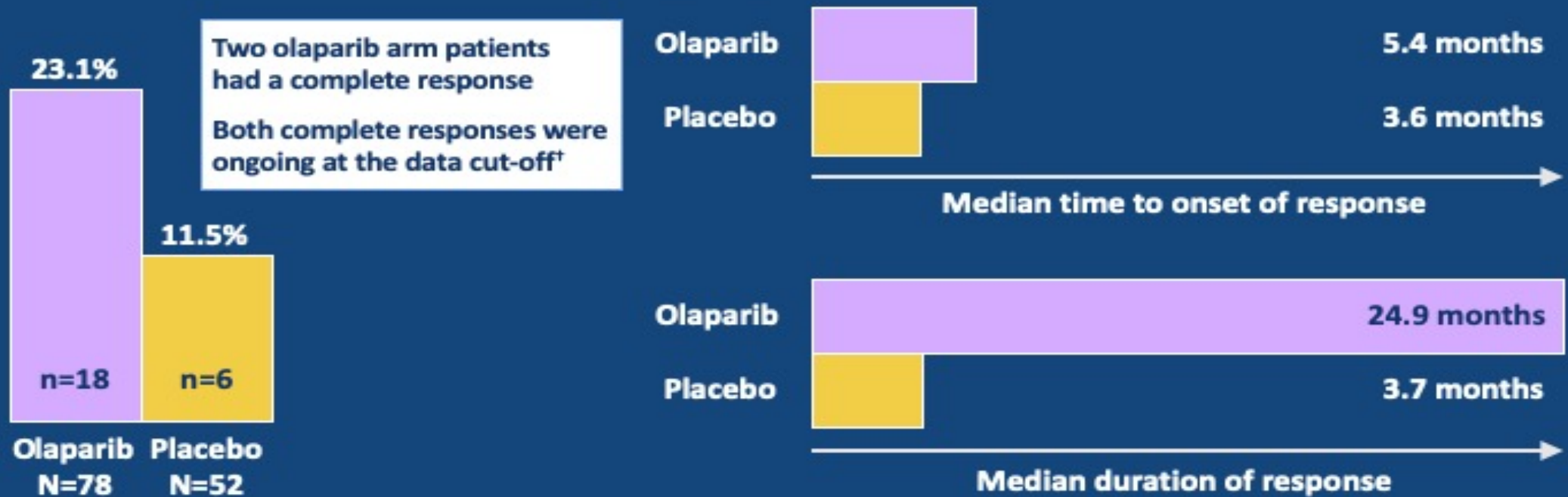


\*Dots indicate censorship. †Crossover to olaparib was not permitted during this study; subsequent therapies were given at the investigators' discretion

# Lynparza

## Pancreatic cancer - POLO trial

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



# Lynparza

## Pancreatic cancer - POLO trial

### Safety summary: AEs and exposure

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

# ***Lynparza***

## Pancreatic cancer - POLO trial

Simultaneous  
publication in *The New  
England Journal of  
Medicine*

### **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

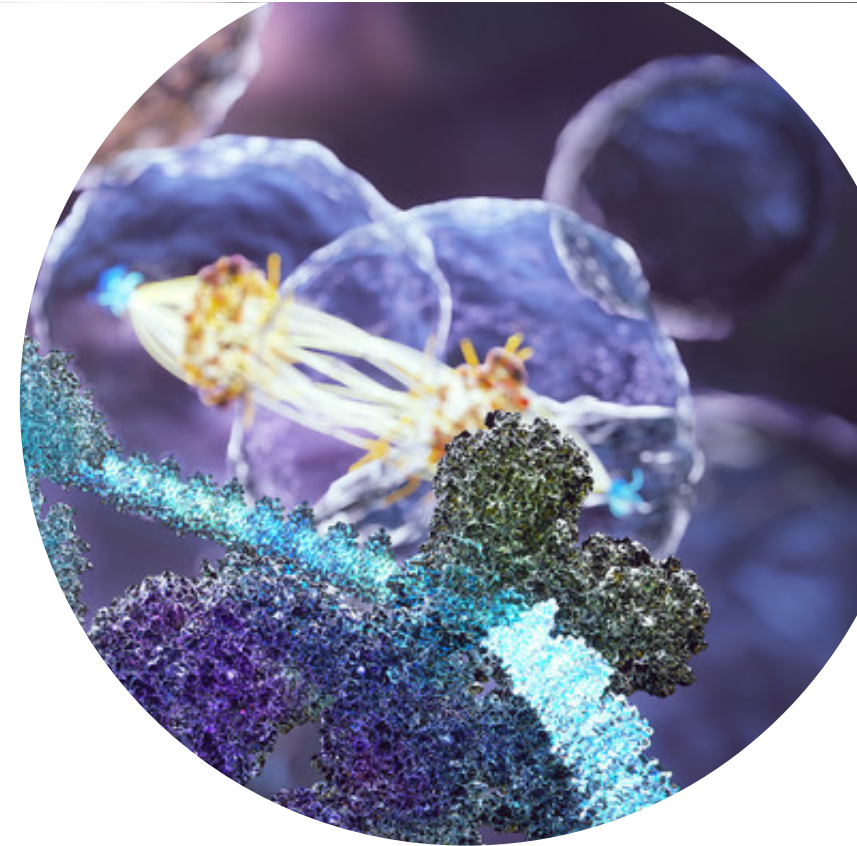
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- ***Lynparza* 3rd-line ovarian cancer (SOLO3 trial)**
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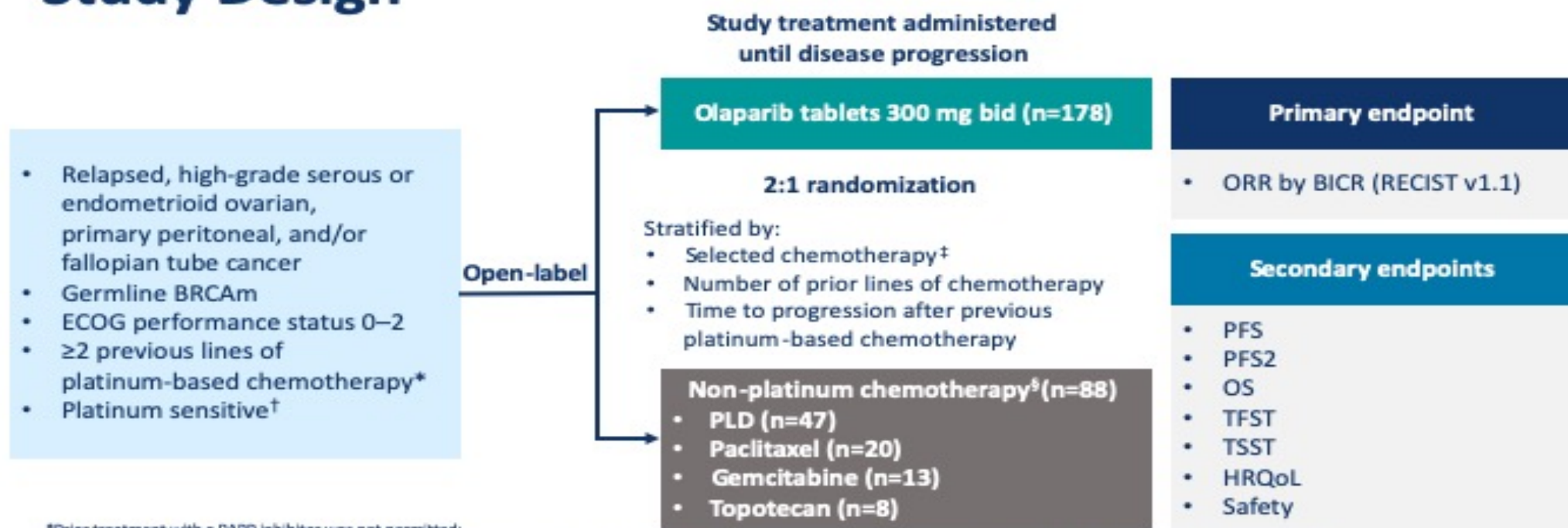
Breakout sessions followed by drinks and canapés



# Lynparza

## Ovarian cancer - SOLO3 trial

### Study Design



\*Prior treatment with a PARP inhibitor was not permitted;

<sup>†</sup>Fully platinum sensitive: progression >12 months after platinum-based chemotherapy; partially platinum sensitive: progression 6–12 months after platinum-based chemotherapy;

<sup>‡</sup>For each patient, the investigator declared their choice of non-platinum chemotherapy before randomization;

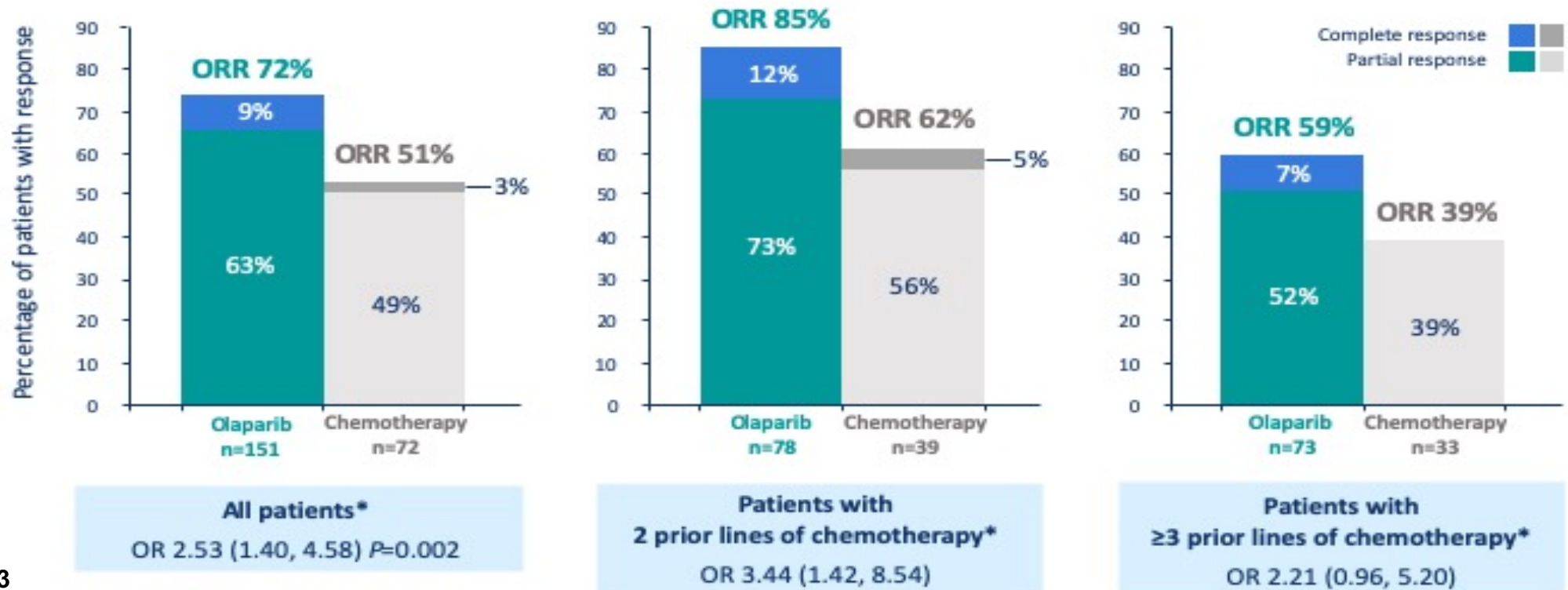
<sup>§</sup>PLD, 50 mg/m<sup>2</sup> on day 1 q4w; paclitaxel, 80 mg/m<sup>2</sup> on days 1, 8, 15, and 22 q4w; gemcitabine, 1000 mg/m<sup>2</sup> on days 1, 8, and 15 q4w; topotecan, 4 mg/m<sup>2</sup> on days 1, 8, and 15 q4w

BICR, blinded independent central review; BRCAm, BRCA1 or BRCA2 mutation; ECOG, Eastern Cooperative Oncology Group; HRQoL, health-related quality of life; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PFS2, second progression-free survival; PLD, pegylated liposomal doxorubicin; q4w, every 4 weeks; RECIST, response evaluation criteria in solid tumors; TFST, time to first subsequent therapy or death; TSST, time to second subsequent therapy or death

# Lynparza

## Ovarian cancer - SOLO3 trial

### Primary Endpoint: ORR by BICR

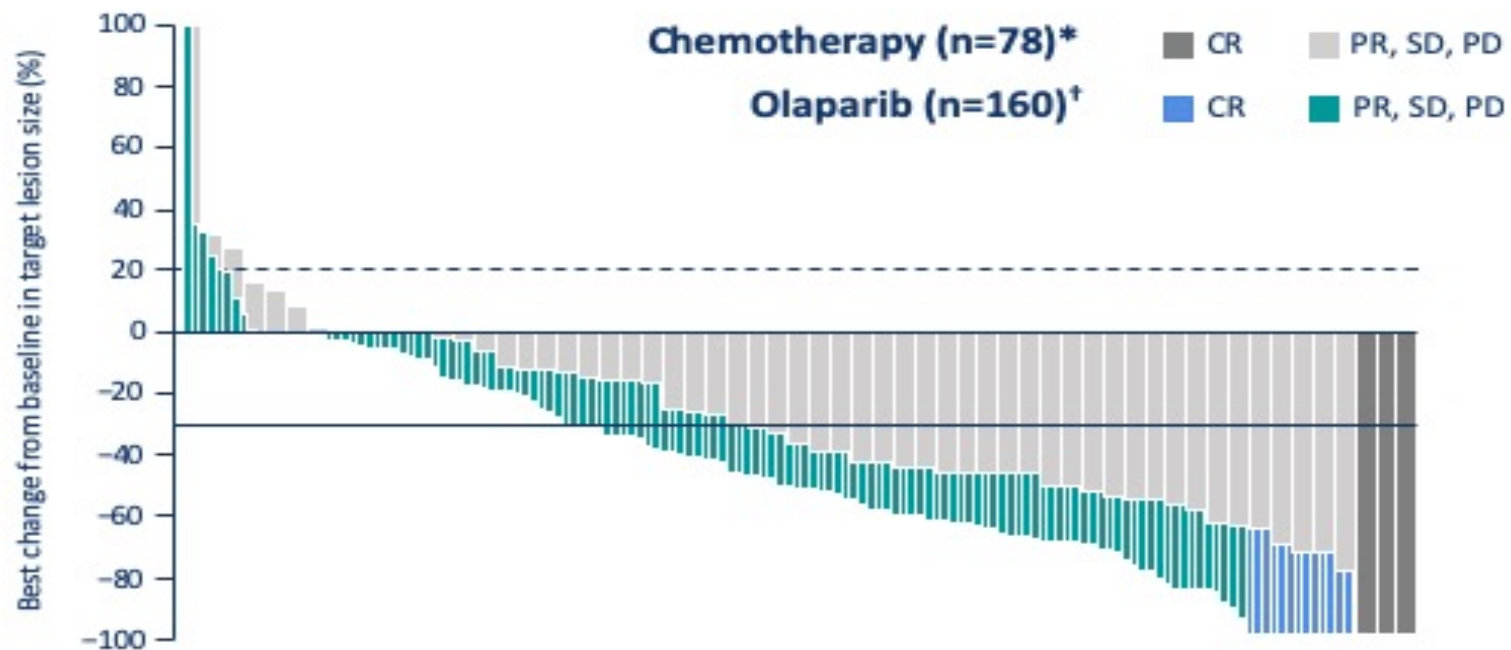


\*Patients with measurable disease at baseline

# Lynparza

Ovarian cancer - SOLO3 trial

## Investigator-Assessed Best Response for Target Lesions by Patient



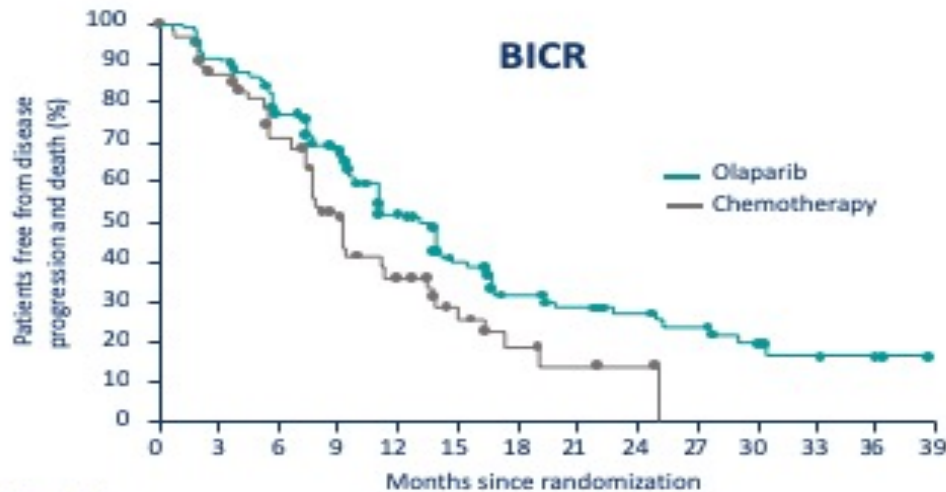
\*19 patients were not evaluable for investigator-assessed best response; †11 patients were not evaluable for investigator-assessed best response



# Lynparza

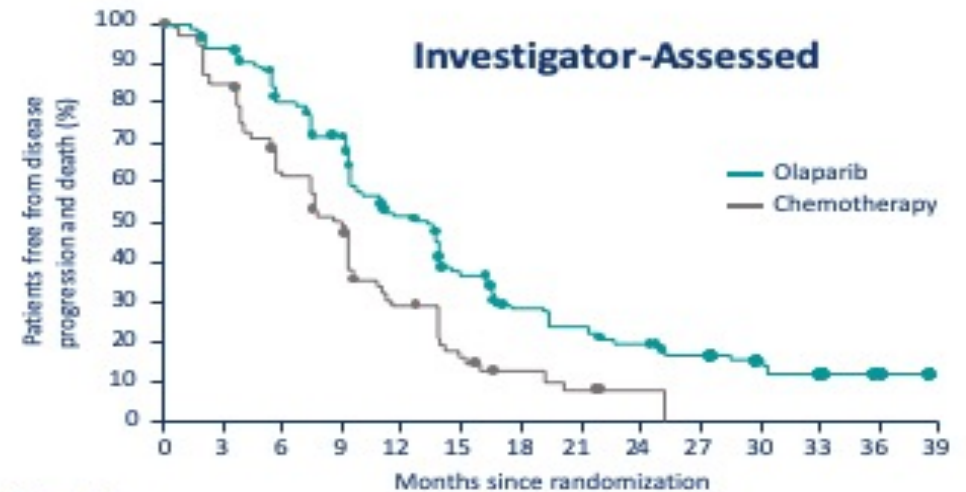
## Ovarian cancer - SOLO3 trial

### PFS (Intention-To-Treat Population)



| No. at risk  |     |     |     |     |    |    |    |    |    |    |   |   |   |   |
|--------------|-----|-----|-----|-----|----|----|----|----|----|----|---|---|---|---|
| Olaparib     | 178 | 156 | 126 | 108 | 71 | 47 | 30 | 25 | 18 | 14 | 8 | 5 | 2 | 0 |
| Chemotherapy | 88  | 63  | 47  | 31  | 18 | 9  | 5  | 3  | 2  | 0  | 0 | 0 | 0 | 0 |

|                      | Olaparib (n=178)           | Chemotherapy (n=88) |
|----------------------|----------------------------|---------------------|
| PFS events, n (%)    | 110 (62)                   | 49 (56)             |
| Median PFS, months   | 13.4                       | 9.2                 |
| HR (95% CI), P value | 0.62 (0.43, 0.91); P=0.013 |                     |



| No. at risk  |     |     |     |     |    |    |    |    |    |    |   |   |   |   |
|--------------|-----|-----|-----|-----|----|----|----|----|----|----|---|---|---|---|
| Olaparib     | 178 | 155 | 126 | 110 | 72 | 48 | 31 | 26 | 19 | 12 | 8 | 6 | 2 | 0 |
| Chemotherapy | 88  | 62  | 43  | 34  | 18 | 9  | 5  | 3  | 1  | 0  | 0 | 0 | 0 | 0 |

|                      | Olaparib (n=178)           | Chemotherapy (n=88) |
|----------------------|----------------------------|---------------------|
| PFS events, n (%)    | 123 (69)                   | 63 (72)             |
| Median PFS, months   | 13.2                       | 8.5                 |
| HR (95% CI), P value | 0.49 (0.35, 0.70); P<0.001 |                     |

# Lynparza

## Ovarian cancer - SOLO3 trial

### Safety Overview

|  | Olaparib (n=178) | Chemotherapy (n=76) |
|--|------------------|---------------------|
| All-grade AEs, n (%)   | 174 (98)         | 73 (96)             |
| Grade ≥3 AEs, n (%)  | 89 (50)          | 36 (47)             |
| Serious AEs, n (%)*  | 42 (24)          | 14 (18)             |
| AEs leading to dose interruption, n (%)                      | 85 (48)          | 32 (42)             |
| AEs leading to dose reduction, n (%)                         | 48 (27)          | 25 (33)             |
| AEs leading to treatment discontinuation, n (%) <sup>†</sup> | 13 (7)           | 15 (20)             |
| Median total treatment duration (range), months              |                  |                     |
| Olaparib   | 11.3 (0.1–39.5)  | –                   |
| PLD  | –                | 6.0 (0.9–15.4)      |
| Paclitaxel   | –                | 5.1 (1.8–18.2)      |
| Gemcitabine  | –                | 3.3 (0.7–14.3)      |
| Topotecan  | –                | 6.2 (2.3–9.7)       |

\*Most common serious AE in the olaparib arm was anemia (3%) and in the chemotherapy arm was vomiting (4%);

<sup>†</sup>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-plantar 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

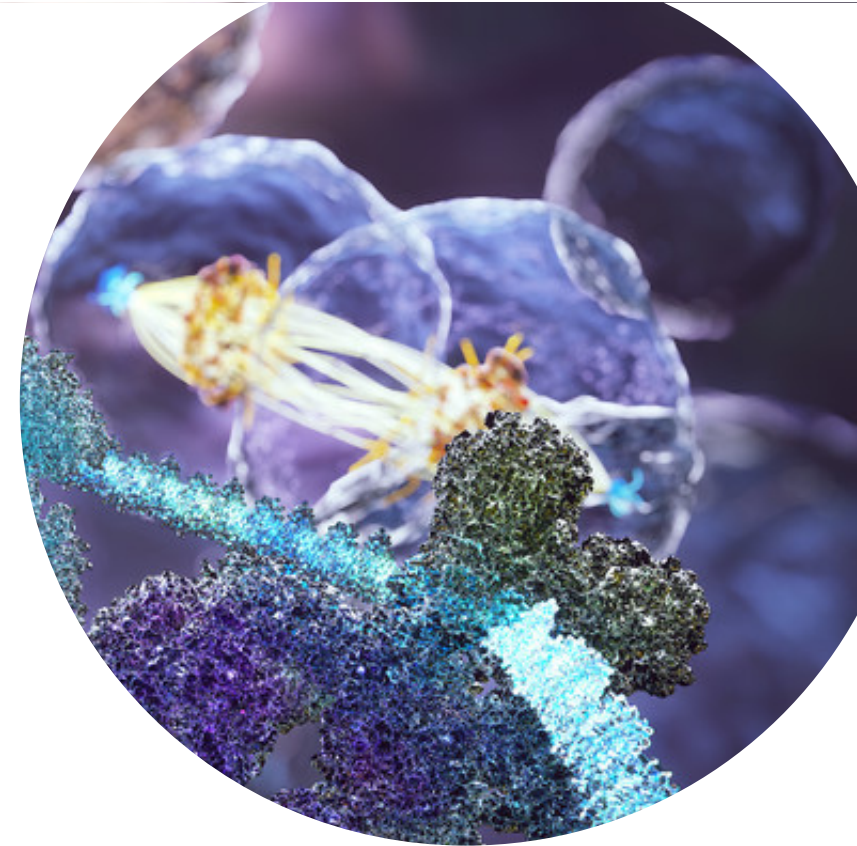
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- **Other highlights**

Breakout sessions followed by drinks and canapés



# Other highlights

AstraZeneca continues to redefine cancer treatment

**Breaking  
treatment  
boundaries**

***Lynparza***  
prostate cancer  
Phase II TOPARP-B

***Lynparza***  
neo-adjuvant  
breast cancer  
Phase II GeparOLA

**capivasertib**  
breast cancer  
Phase II FAKTION

**Treating patients  
earlier in their  
disease**

***Imfinzi***  
NSCLC  
Phase III PACIFIC  
three-year OS

**Raising the bar for  
better outcomes**

***Tagrisso***  
NSCLC  
Phase III FLAURA  
Additional data

**adavosertib**  
ovarian cancer  
Phase II

**Advancing  
presence in  
haematology**

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

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



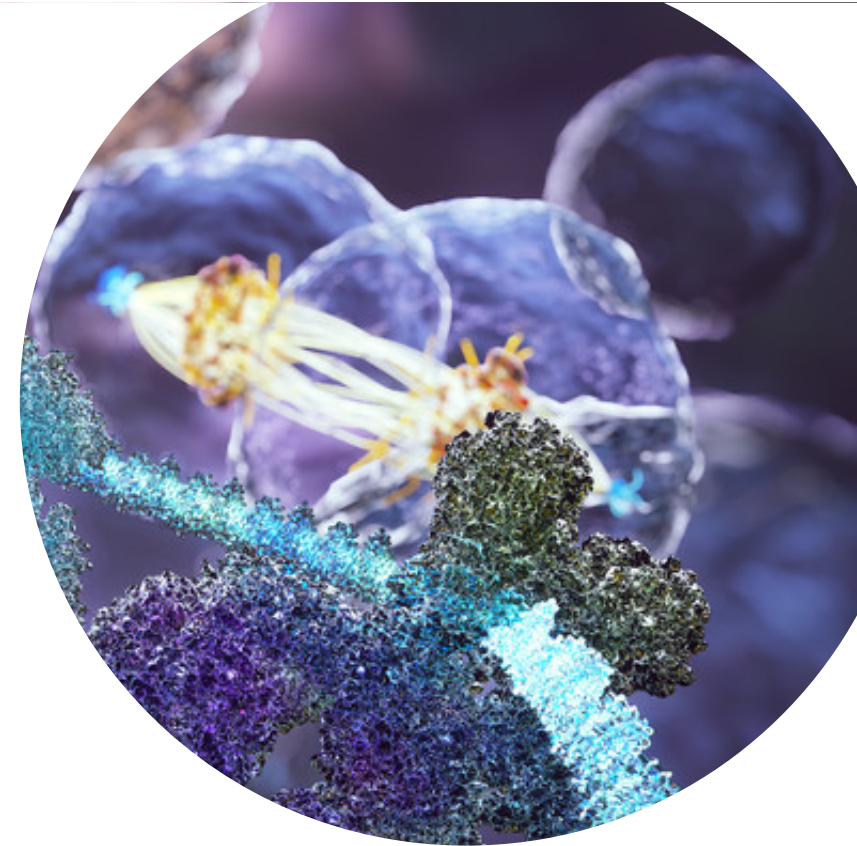
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# Breakout sessions

## 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

| Breakout sessions |                                       |                                |
|-------------------|---------------------------------------|--------------------------------|
| Room              | E                                     | F                              |
|                   | Same as opening session               |                                |
|                   | 18:30                                 |                                |
| Topic             | Early-stage pipeline                  | Sales and marketing            |
| Hosts             | Susan Galbraith<br>Jean-Charles Soria | Dave Fredrickson<br>Greg Rossi |
|                   | 19:00                                 |                                |
| Topic             | Late-stage pipeline                   | Trastuzumab deruxtecan         |
| Hosts             | Klaus Edvardsen                       | José Baselga                   |



# Investor Relations



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