55th ASCO Annual Meeting, Chicago

Roche Analyst Event
Monday, 3 June 2019
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ASCO 2019

Karl Mahler | Head of Investor Relations
Welcome
Karl Mahler, Head of Investor Relations

ASCO 2019 Key readouts across tumor types
Hematology
Nancy Valente, M.D., Global Head of Product Development - Hematology

Breast cancer, lung cancer & tumor agnostic
Alan Sandler, M.D., Global Head of Product Development - Solid Tumors

Roche Oncology strategy update
Bill Anderson, CEO Roche Pharmaceuticals

Q&A
Roche transforming BC over 2 decades and continuing the journey

1L HER2+ mBC (1998-2019)

Adjuvant HER2+ BC (2003-2019)

Adjuvant HER2+ BC without pCR (2013-2018)

1L TNBC PD-L1+ (2015-2018/19)
Hematology franchise

Nancy Valente, M.D. | Global Head of Product Development - Hematology
Uniquely positioned to improve SOC in hematology

Largest late stage portfolio allows to develop new combinations

- Rituxan
- Gazyva
- Venclexta
- polatuzumab vedotin
- mosunetuzumab CD20 x CD3 TCB
- idasanutlin

- Anti-CD20
- Bcl2 inhibitor
- Anti-CD79b
- Anti-CD20 x Anti-CD3
- MDM2 antagonist

- Abs
- Small molecule
- Ab-drug conjugate
- T cell bispecifics
- Small molecule

7 molecules approved / late stage
5 different MOAs
4 different platform technologies
Redefining the SOC in CLL, aNHL and iNHL

**Hematology market**

- **Incidence rates**
  - ALL: 3%
  - CLL: 13%
  - aNHL (DLBCL): 14%
  - MM: 7%
  - AML: 9%
  - iNHL: 26%

**SOC chemo**
- R+chemo
  - benda
  - clb
- G+chemo
  - G+benda
  - G+clb

**Future SOC**
- R+Venclexta
- G+Venclexta

**CLL**
- Venclexta combinations induce deep responses, and long treatment-free remissions
  - R/R
  - clb
  - R+benda
  - R+clb
  - R+Venclexta
  - G+clb
  - G+Venclexta

**aNHL (DLBCL)**
- Polatuzumab vedotin drives high CR rates with durable responses
  - R/R
  - CHOP
  - R+benda
  - R-CHOP
  - Pola+R+benda / CD20 x CD3
  - Pola+R-CHP/ CD20 x CD3

**iNHL**
- Gazyva established as SOC in 1L iNHL with estimated 3 yrs longer mPFS than Rituxan
  - R/R
  - chemo
  - benda
  - G+benda
  - G+chemo
  - CD20 x CD3
  - CD20 x CD3

**Total CLL, NHL (DLBCL/iNHL) market growing to 9bn & 15bn, respectively by 2024**

SOC=standard of care; CLL=chronic lymphocytic leukemia; aNHL=aggressive non-hodgkin’s lymphoma; iNHL=indolent non-hodgkin’s lymphoma; R/R=relapsed refractory; DLBCL=diffuse large B-cell lymphoma; R=Rituxan; G=Gazyva; clb=chlorambucil; benda=bendamustine; 1 Datamonitor: incidence rates includes the 7 major markets (US, Japan, France, Germany, Italy, Spain, UK); 2 Evaluate Pharma; Venclexta in collaboration with AbbVie
Expanding into AML and MM

Hematology market

Incidence rates

- CD20 backbone
- Historical SOC
- Future SOC
- Total MM & AML market growing to USD 25bn & 7bn, respectively by 2024

AML

- Advancing the SOC in a market which has been historically difficult to treat
- R/R
  - LDAC
  - idasanutlin + LDAC
  - Ph III (MIRROS) results upcoming
  - Confirmatory Ph III (Viale-C) on-going

- 1L unfit (50% of 1L patients)
  - LDAC
  - Venclexta + LDAC
  - Confirmatory Ph III (Viale-A) on-going

- HMAs
  - azacitidine/decitabine
  - Venclexta + HMA

MM

- Multiple combinations in development to address 2/3L market; focus on t(11;14) patients
- R/R t(11;14)
  - bortezomib + dexamethasone
  - Venclexta + dexamethasone

- Ph III (BELLINI) data at EHA 2019
- Ph III (CANOVA) in t(11;14) R/R MM initiated

AML=Acute Myeloid Leukemia; MM=Multiple Myeloma; R/R=relapsed refractory; LDAC=low dose aracytarabine; HMA=hypomethylating agent; Datamonitor: incidence rates includes the 7 major markets (US, Japan, France, Germany, Italy, Spain, UK); 2 Evaluate Pharma; Venclexta in collaboration with AbbVie

= approved
Deep MRD responses predictive of long term outcomes
Association with prolonged PFS and OS in various indications

MRD-negativity associated with prolonged PFS

Potential to develop fixed treatment courses instead of chronic treatments

1 Kater A., et al, ASH 2018; 2 Pott C., et al, ASH 2018; 3. Strickland, et al, EHA 2018; MRD=minimal residual disease; AML=acute myeloid leukemia; R/R=relapsed refractory; FL=follicular lymphoma; CLL=chronic lymphocytic leukemia; HMA=hypomethylating agent; PFS=progression free survival; OS=overall survival; Venclexta in collaboration with AbbVie
Venclexta + Gazyva in 1L unfit CLL
Fast track approval following outstanding PFS data

Fischer K. et al., ASCO 2019; PFS=progression free survival; HR=hazard ratio; V=Venclexta; G=Gazyva; clb=chlorambucil; R=Rituxan; dex=dexamethasone; bor=bortezomib; T=Tecentriq; aza=azacitidine; LDAC=low dose cytarabine; RTOR=real-time oncology review; Venclexta in collaboration with AbbVie; Gazyva in collaboration with Biogen; Cotellic in collaboration with Exelixis

Venclexta progam

Bcl-2 inhibitor

<table>
<thead>
<tr>
<th>Combination</th>
<th>Indication</th>
<th>Ph1</th>
<th>Ph2</th>
<th>Ph3</th>
</tr>
</thead>
<tbody>
<tr>
<td>V+r/g+cHOP</td>
<td>1L DLBCL (AMNL)</td>
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<tr>
<td>V+r</td>
<td>DLBCL</td>
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<tr>
<td>V+pola+g/r</td>
<td>R/R DLBCL/FL</td>
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<tr>
<td>V+g</td>
<td>1L CLL</td>
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<tr>
<td>V+r</td>
<td>R/R CLL</td>
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<tr>
<td>V</td>
<td>R/R CLL 17p</td>
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<tr>
<td>V</td>
<td>R/R CLL after bisulfid</td>
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<tr>
<td>V+g</td>
<td>1L and R/R CLL</td>
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<tr>
<td>V+dex</td>
<td>i(1;14) R/R MM</td>
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<tr>
<td>V+bor+dex</td>
<td>R/R MM</td>
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<tr>
<td>V+Cotellic+i-T</td>
<td>R/R MM</td>
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<tr>
<td>V+aza</td>
<td>1L AML</td>
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<tr>
<td>V+LDAC</td>
<td>1L AML</td>
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<tr>
<td>V+daCucumil</td>
<td>R/R AML unfit</td>
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<td>V+Cotellic</td>
<td>R/R AML unfit</td>
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<tr>
<td>V+gilbertinb</td>
<td>R/R AML unfit</td>
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<tr>
<td>V+aza</td>
<td>1L MDS</td>
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<tr>
<td>V+/-aza</td>
<td>R/R MDS</td>
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Ph III (CLL14) results:

Minimal residual disease

<table>
<thead>
<tr>
<th></th>
<th>V+G</th>
<th>G+Clb</th>
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</thead>
<tbody>
<tr>
<td>MRD-negative, %, bone marrow (95%CI)</td>
<td>57  (50-64)</td>
<td>17  (12-23)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>MRD-negative, %, peripheral blood (95%CI)</td>
<td>76  (69-81)</td>
<td>35  (29-42)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
</tbody>
</table>

- PFS HR of 0.33 versus Gazyva + chlorambucil; mPFS not reached
- First fixed 12-month treatment, chemotherapy-free option
- Approval following 10 weeks after submission via the RTOR pilot program

IRC assessed PFS

HR (95% CI) 0.33 (0.22-0.51) p<0.0001
Polatuzumab vedotin + Gazyva + lenalidomide in R/R FL

Broad program with first approval to come

Polatuzumab program

anti-CD79b ADC

Ph I/II results in R/R FL:

<table>
<thead>
<tr>
<th>Combination</th>
<th>Indication</th>
<th>Ph1</th>
<th>Ph2</th>
<th>Ph3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pola+R+CHP</td>
<td>1L DLBCL</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pola+R+Gemox</td>
<td>R/R DLBCL</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pola+G/R+V</td>
<td>R/R DLBCL/FL</td>
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<td></td>
<td></td>
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<tr>
<td>Pola+G/R</td>
<td>R/R DLBCL/FL</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pola+G/R+benda</td>
<td>R/R DLBCL/FL</td>
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<tr>
<td>Pola+G/R+lon</td>
<td>R/R DLBCL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pola+mosun+CHP</td>
<td>1L DLBCL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pola+mosun+benda</td>
<td>R/R DLBCL/FL</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pola+mosun+CHP</td>
<td>R/R NHL</td>
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<td></td>
<td></td>
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<tr>
<td>Pola+mosun</td>
<td>R/R DLBCL/FL</td>
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<table>
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<th>Response</th>
<th>Modified Lugano 2014 (PET/CT)</th>
<th>Lugano 2014 (PET)</th>
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<tbody>
<tr>
<td>N=18, n (%)</td>
<td>INV</td>
<td>IRC</td>
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<tr>
<td>Objective response</td>
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<tr>
<td>CR*</td>
<td>16 (89)</td>
<td>16 (89)</td>
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<tr>
<td>PR</td>
<td>11 (61)</td>
<td>12 (67)</td>
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<tr>
<td>Stable disease</td>
<td>5 (28)</td>
<td>4 (22)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Missing/NE</td>
<td>1 (6)</td>
<td>1 (6)</td>
</tr>
</tbody>
</table>

- Triplet combination (Pola+G+len) showed an OR rate of 89% and a CR rate of 78%
- Safety profile consistent with the individual drugs and manageable
- PDUFA date for Pola+R+benda in R/R DLBCL set for August 19
- Ph III (POLARIX) in 1L DLBCL on-going

Diefenbach C. et al., ASCO 2019; ADC=antibody drug conjugate; pola=polatuzumab; R=Rituxan; CHOP=cyclophosphamide, doxorubicin, vincristine, prednisone; Gemox=gemcitabine+oxaliplatin; G=Gazyva; V=venclexta; benda=bednamustin; len=lenalidomide; mosun=mosunetuzumab; CR=complete response; PR=partial response; NE=not available; PET=positron emission tomography; CT=computed tomography; INV=investigator assessed; IRC=independent review committee assessed; * Primary endpoint; 1 Modified Lugano: designation of a CR requires normal bone marrow by morphology for patients with bone marrow involvement at baseline; Polatuzumab in collaboration with Seattle Genetics
**CD20 x CD3 in NHL**

*Strong efficacy and tolerable safety*

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**CD20 x CD3 program**

- **Mosunetuzumab (Ph1 dosing)**
  - Durable CRs as single agent in 2L+ iNHL/aNHL; CRs in patients refractory to R-CHOP and CAR-T
  - Dose escalation and combination trials with Tecentriq, polatuzumab and CHOP ongoing
  - Efficacy update planned for H2 2019

- **CD20 x CD3 (Ph1 dosing)**
  - **aNHL/DLBCL 10mg cohort**
    - ORR 34/98 (35.1%); CR 20/98 (20.6%)
  - **R/R iNHL**
    - ORR 37/55 (67.3%); CR 20/55 (36.4%)

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Bartlett N. L. et al, ASCO 2019; Hutchings, M., et al, ASH 2018; NHL=non-Hodgkin’s lymphoma; mosun=mosunetuzumab; CHOP=cyclophosphamide, doxorubicin, vincristine, prednisone; pola=polatuzumab; T=Tecentriq; G=Gazyva; R=Rituxan; CR=complete response; SPD=sum of the product diameters; R/R=relapsed/refractory; CAR T cells=chimeric antigen receptor; AE=adverse event; *aNHL includes FL Grade 3B, DLBCL, trFL, PMBCL, MCL, trMZL, RS and DLBCL/MCL.
Idasanutlin in AML
Promising activity in combination

Ph III (MIRROS) trial design

- Ph I in heavily pretreated AML patients: idasanutlin+cytarabine showed a 42% cCR rate in patients dosed with Ph III dose with a mDoR >8m
- Ph II combination: Venclexta+idasanutlin showed clinical activity (38% cCR with 600mg Venclexta and 200mg idasanutlin) in heavily pre-treated elderly unfit R/R AML
- Possible NME filing based on MIRROS in 2020

Responding patients may receive optional consolidation with up to 2 additional cycles
### Hematology franchise with 7 BTDs

*Brodest portfolio with 12 assets in combination trials*

<table>
<thead>
<tr>
<th></th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approved</th>
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<tbody>
<tr>
<td><strong>Rituxan / Rituxan SC</strong></td>
<td>eNHL, iNHL, CLL</td>
<td>CLL</td>
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<td>✓</td>
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<tr>
<td><strong>Gazyva</strong></td>
<td>CLL, FL (NHL)</td>
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<td><strong>Venclexta</strong></td>
<td>CLL</td>
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<td></td>
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<td><strong>Polatuzumab vedotin</strong></td>
<td>DLBCL (eNHL)</td>
<td>FL (NHL)</td>
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<td><strong>Idasanutlin</strong></td>
<td>AML, PV</td>
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<tr>
<td><strong>Mosunetuzumab</strong></td>
<td>FL, DLBCL, MCL</td>
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<td><strong>CD20xCD3</strong></td>
<td>FL, DLBCL</td>
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<tr>
<td><strong>Tecentriq</strong></td>
<td>NHL, MM</td>
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<tr>
<td><strong>Cotellic</strong></td>
<td>AML, MM</td>
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<td><strong>RG6160</strong></td>
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<tr>
<td><strong>BETi</strong></td>
<td>AML, DLBCL</td>
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<tr>
<td><strong>RG6109</strong></td>
<td>AML</td>
<td></td>
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*Venclexta in collaboration with AbbVie; polatuzumab vedotin in collaboration with Seattle Genetics; Cotellic in collaboration with Exelixis; NHL = non-hodgkin’s lymphoma; FL = follicular lymphoma; CLL = chronic lymphoid leukemia; MM = multiple myeloma; MDS = myelodysplastic syndrome; AML = acute myeloid leukemia; MCL = mantle cell lymphoma; DLBCL = diffuse large B cell lymphoma*

*PDUFA Aug 19*
ASCO 2019 Key readouts across tumor types
Breast cancer, lung cancer & tumor agnostic

Alan Sandler, M.D. | Global Head of Product Development - Solid Tumors
Breast cancer

• IMpassion130: Tecentriq + nab-paclitaxel in 1L TNBC
• CLEOPATRA: Perjeta + Herceptin + chemo in 1L HER2+ mBC

Lung cancer

Tumor agnostic indications
Roche continuing to define SoC in HER2+ BC, launching in TNBC, pipeline targeting major subsets in breast cancer

**Standard of care in HER2+ BC**

**2L mBC**
- Xeloda + lapatinib
- Kadcyla (EMILIA)

**1L mBC**
- Herceptin + chemo (CLEOPATRA)
- H + P + chemo

**Adjuvant**
- Herceptin + chemo
- Herceptin SC + chemo
- H + P + chemo (APHINITY)

**Neo-adjuvant**
- Herceptin + chemo
- H + P + chemo (NEOSPHERE, TRYPHAENA)
- H + P + chemo (FEDERICA)*

**Expanding into areas with high unmet need**

| TNBC | ipatasertib | IPATunity130 (Ph III 1L Dx+)
| IMpassion130 (Ph III 1L) |
| Tecentriq | IMpassion132 (Ph III 1L) |
| IMpassion031 (Ph III neoadj) |
| IMpassion030 (Ph III adj) |

| HER2-HR+ | ipatasertib | IPATunity130 (Ph III Dx+ HR+ mBC)
| Venclexta | IMpassion131 (Ph III 1L) |
| SERDi | IMpassion132 (Ph III 1L) |
| PI3Ki | IMpassion031 (Ph III neoadj) |
| RG6171 (Ph I) |
| RG6114 (Ph I) |

| HER2+ | Kadcyla |
| KATHERINE (Ph III adj) |
| Tecentriq +H+P |
| IMpassion050 (Ph III neoadj) |
| HER2xCD3 |
| RG6194 (Ph I) |
| ADC |
| RG6148 (Ph I) |

H+P=Herceptin+Perjeta; SC=subcutaneous; FEDERICA=fixed dose combination; SoC=standard of care; BC=breast cancer; TNBC=triple negative breast cancer
IMpassion130: First phase III cancer immunotherapy in mTNBC study to demonstrate clinical benefit in PD-L1+ patients

Study design

Key eligibility criteria:
- No prior therapy for advanced TNBC
- ECOG PS 0-1

Stratification factors:
- Prior taxane use (yes vs no)
- Liver metastases (yes vs no)
- PD-L1 status on IC (pos [≥ 1%] vs neg [< 1%])

Treatment arms:
- **Atezolizumab**
  - 840 mg IV q2w
  - + nab-paclitaxel
  - 100 mg/m2 IV on d1, d8, d15b

- **Placebo**
  - q2w IV
  - + nab-paclitaxel
  - 100 mg/m2 IV on d1, d8, d15b

Double blind; no crossover permitted

RECIST v1.1 PD or toxicity

Survival follow-up

- Co-primary endpoints: PFS and OS in the ITT and PD-L1+ populations
- Prevalence of patients with PD-L1+ status: 41% in both treatment arms
- First OS IA: median follow-up: 12.9 months, 43% of death events had occurred (clinical cutoff April 17 2018)
- Second OS IA: median follow-up 18.0 months, 59% of death events (clinical cutoff Jan 2 2019)
**IMpassion130: Primary PFS in ITT and PD-L1+ population**

Co-primary endpoint of PFS met for Tecentriq + nab-paclitaxel

**ITT**

- Arm A: Atezo + nab-P
- Arm B: Plac + nab-P

Stratified HR = 0.80
(95% CI: 0.69, 0.92)

\( P = 0.002 \)

Progression-free survival (%)

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<th>Time (months)</th>
<th>ITT</th>
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<tbody>
<tr>
<td>0</td>
<td>100</td>
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<tr>
<td>3</td>
<td>80</td>
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<tr>
<td>6</td>
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<td>9</td>
<td>40</td>
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<tr>
<td>12</td>
<td>20</td>
</tr>
<tr>
<td>15</td>
<td>0</td>
</tr>
</tbody>
</table>

- 5.5 mo (5.3, 5.6)
- 7.2 mo (5.6, 7.5)

**PD-L1-positive**

- Arm A: Atezo + nab-P
- Arm B: Plac + nab-P

Stratified HR = 0.62
(95% CI: 0.49, 0.78)

\( P < 0.001 \)

Progression-free survival (%)

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>PD-L1-positive</th>
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<tbody>
<tr>
<td>0</td>
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<td>3</td>
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<td>12</td>
<td>20</td>
</tr>
<tr>
<td>15</td>
<td>0</td>
</tr>
</tbody>
</table>

- 5.0 mo (3.8, 5.6)
- 7.5 mo (6.7, 9.2)

Tecentriq + nab-paclitaxel is approved by the FDA and recommended for the treatment of patients with PD-L1 IC+ mTNBC by the NCCN and AGO guidelines


IMpassion130: 2nd interim OS in ITT and PD-L1+ population

Positive OS trend for Tecentriq + nab-P maintained

**ITT**

<table>
<thead>
<tr>
<th></th>
<th>Arm A: Atezo + nab-P</th>
<th>Arm B: Plac + nab-P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stratified HR</td>
<td>0.86</td>
<td></td>
</tr>
<tr>
<td>(95% CI)</td>
<td>0.72, 1.02</td>
<td></td>
</tr>
<tr>
<td><em>P</em></td>
<td>0.0777</td>
<td></td>
</tr>
</tbody>
</table>

**PD-L1-positive**

<table>
<thead>
<tr>
<th></th>
<th>Arm A: Atezo + nab-P</th>
<th>Arm B: Plac + nab-P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stratified HR</td>
<td>0.71</td>
<td></td>
</tr>
<tr>
<td>(95% CI)</td>
<td>0.54, 0.94</td>
<td></td>
</tr>
</tbody>
</table>

**Atezo + nab-P**

<table>
<thead>
<tr>
<th></th>
<th>OS events, n (N = 451)</th>
<th>2-year OS (95% CI), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>OS events, n</td>
<td>255</td>
<td>42% (37, 47)</td>
</tr>
<tr>
<td>2-year OS (95% CI), %</td>
<td>279</td>
<td>39% (34, 44)</td>
</tr>
</tbody>
</table>

**Plac + nab-P**

<table>
<thead>
<tr>
<th></th>
<th>OS events, n (N = 451)</th>
<th>2-year OS (95% CI), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>OS events, n</td>
<td>279</td>
<td>39% (34, 44)</td>
</tr>
<tr>
<td>2-year OS (95% CI), %</td>
<td>279</td>
<td>39% (34, 44)</td>
</tr>
</tbody>
</table>

**Tecentriq + nab-paclitaxel: First therapy to cross the 2-year landmark OS benefit in PD-L1+ 1L mTNBC**

Data cutoff: January 2, 2019. Median OS durations (and 95% CI) are indicated on the plot. *Not formally tested due to pre-specified hierarchical analysis plan.

Median FU (ITT): 18.0 months. Schmid P, et al. ASCO 2019, abstract #1003; PD-L1 expression on ≥1% of tumor-infiltrating immune cells
IMpassion130 conclusions

• First and only Phase III study to show the clinically meaningful benefit of immunotherapy in 1L mTNBC; the combination of Tecentriq + nab-paclitaxel is approved by the FDA in PD-L1+ patients

• Although not formally testable due to the pre-specified statistical analysis plan, updated median OS improvement from 18 to 25 months was observed in the PD-L1+ population (HR 0.71)

• Tecentriq + nab-paclitaxel was well tolerated, with no cumulative toxicities and no new or late-onset safety signals

• For patients with PD-L1+ tumors Tecentriq + nab-paclitaxel is a new standard of care
**CLEOPATRA: Perjeta+Herceptin and chemo in 1L HER2+ mBC**

**Study design**

- **Primary endpoint:** Independently-assessed PFS
- **Secondary endpoints:** Investigator-assessed PFS, OS, ORR, safety (monitored by an independent DMC and CRC)

---

DMC, data monitoring committee; PD, progressive disease; PFS, progression-free survival; mBC, metastatic breast cancer
ORR, overall response rate; OS, overall survival.
CLEOPATRA: Overall survival 1st interim analysis May 2011

HR 0.64 (95% CI = 0.47, 0.88)  
p=0.005

* Crossover pts were analyzed in the Placebo (HT) arm. OS was compared between arms using the log-rank test, stratified by prior treatment status and geographic region. The Kaplan–Meier approach was used to estimate median OS, and a stratified Cox proportional hazards model was used to estimate the HR and 95% CIs; CI, confidence interval; H, Herceptin; HR, hazard ratio; P, PERJETA; OS, overall survival; PFS, progression-free survival; T, docetaxel.
CLEOPATRA: Overall survival 2nd interim analysis May 2012

HR 0.66 (95% CI = 0.52, 0.84)  
p=0.0008

* Crossover pts were analyzed in the Placebo (HT) arm. OS was compared between arms using the log-rank test, stratified by prior treatment status and geographic region. The Kaplan–Meier approach was used to estimate median OS, and a stratified Cox proportional hazards model was used to estimate the HR and 95% CIs; CI, confidence interval; H, Herceptin; HR, hazard ratio; P, PERJETA; OS, overall survival; PFS, progression-free survival; T, docetaxel.
Patients lived 15.7 months longer, OS almost 5 years, with Perjeta+Herceptin and docetaxel for 1L HER2-positive mBC

* Crossover pts were analyzed in the Placebo (HT) arm. OS was compared between arms using the log-rank test, stratified by prior treatment status and geographic region. The Kaplan–Meier approach was used to estimate median OS, and a stratified Cox proportional hazards model was used to estimate the HR and 95% CIs; CI, confidence interval; H, Herceptin; HR, hazard ratio; P, PERJETA; OS, overall survival; PFS, progression-free survival; T, docetaxel.
CLEOPATRA: Overall survival end-of-study analysis Nov 2018

Unprecedented median OS of >57 months confirms the Perjeta+Herceptin regimen as first-line SoC for patients with HER2-positive mBC

* Crossover pts were analyzed in the Placebo (HT) arm. OS was compared between arms using the log-rank test, stratified by prior treatment status and geographic region. The Kaplan–Meier approach was used to estimate median OS, and a stratified Cox proportional hazards model was used to estimate the HR and 95% CIs; CI, confidence interval; H, Herceptin; HR, hazard ratio; P, PERJETA; OS, overall survival; PFS, progression-free survival; T, docetaxel.
CLEOPATRA conclusions

• The OS and investigator-assessed PFS improvements with Perjeta + Herceptin + chemo vs. placebo + Herceptin + chemo observed in previous analyses were maintained after approximately 8 years of median follow-up.

• This is the longest follow-up of pts for 1L treatment of HER2-positive MBC (max. 120 mo).

• The long-term safety and cardiac safety profiles of Perjeta + Herceptin + chemo in the overall safety population, and within crossover pts, were maintained.

• HER2-targeted therapy has changed the natural history of HER2-positive MBC, with the dual blockade of Perjeta + Herceptin with chemo demonstrating an 8-year landmark OS rate of 37%.
Breast cancer

Lung cancer

- **IMpower150**: Tecentriq + chemo ± Avastin in 1L non-sq NSCLC; analysis of efficacy in patients with liver metastases
- **LCMC3**: Neoadjuvant Tecentriq in resectable NSCLC interim analysis

Tumor agnostic indications
## Broader NSCLC portfolio with the ability to cover all key segments

<table>
<thead>
<tr>
<th>NSCLC (NSq)</th>
<th>NSCLC (Sq)</th>
<th>SCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK</td>
<td>EGFR</td>
<td>ROS</td>
</tr>
<tr>
<td>Neo- / Adj</td>
<td>Alecensa</td>
<td>IMpower010 (adj)</td>
</tr>
<tr>
<td>1L</td>
<td>Alecensa</td>
<td>IMpower110</td>
</tr>
<tr>
<td></td>
<td>Tarceva ± Avastin</td>
<td>Avastin + CP</td>
</tr>
<tr>
<td></td>
<td>Entrectinib</td>
<td>Entrectinib</td>
</tr>
<tr>
<td>2L</td>
<td>IMpower150</td>
<td>IMpower150</td>
</tr>
<tr>
<td></td>
<td>Tarceva</td>
<td>Positive readout</td>
</tr>
</tbody>
</table>

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Roche
IMpower150 study design

**Study design**

Stage IV or recurrent metastatic non-squamous NSCLC chemotherapy-naïve

- any PD-L1 IHC
- N = 1202

**Arm A:**
- TECENTRIQ
- CP (ACP)

**Arm B:**
- TECENTRIQ +
- CP + Avastin (ABCP)

**Arm C:** (control)
- CP + Avastin

**Co-primary endpoints Arm B vs C**
- Investigator-assessed PFS, OS (ITT)
- INV-assessed PFS in Teff-high WT

- Patients with a sensitizing EGFR mutation or ALK translocation must have disease progression or intolerance of treatment with one or more approved targeted therapies.

- Tecentriq: 1200 mg IV q3w.
- CP carboplatin: AUC 6 IV q3w; paclitaxel: 200 mg/m² IV q3w.
- Bevacizumab: 15 mg/kg IV q3w.

- HR refers to patients without EGFR or ALK genetic alterations.

- For descriptive purposes only. Data cutoff: January 22, 2018. Minimum follow-up: 13.5 months; median follow-up: ~20 months

**PFS for Tecentriq+Avastin+chemo**

- Median, 8.3 mo (95% CI: 7.7, 9.8)
- HR¹, 0.59 (95% CI: 0.50, 0.70) P<0.0001²

**OS for Tecentriq+Avastin+chemo**

- Median, 14.7 mo (95% CI: 13.3, 16.9)
- HR¹, 0.78 (95% CI: 0.64, 0.96) P=0.0164

**Statistically significant and clinically meaningful PFS and OS benefit; approved in US and EU**

---

¹Stratified HR. ²For descriptive purposes only. Data cutoff: January 22, 2018. Minimum follow-up: 13.5 months; median follow-up: ~20 months
IMpower150 clinical benefit for patients with liver metastases

Tecentriq + Avastin + CP reduced the risk of death by 48% in patients with baseline liver metastases compared to Avastin + CP

Well tolerated regardless of baseline liver metastases status

An important new treatment option for patients with baseline liver metastases

*HR for ABCP vs BCP; CP carboplatin; paclitaxel
IMpower150 clinical benefit for patients with liver metastases

**Increased ORR and DoR**

<table>
<thead>
<tr>
<th></th>
<th>With liver metastases&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ABCP</td>
</tr>
<tr>
<td><strong>ORR</strong></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>51</td>
</tr>
<tr>
<td><strong>ORR, n (%)</strong></td>
<td>31 (60.8)</td>
</tr>
<tr>
<td><strong>DoR</strong></td>
<td></td>
</tr>
<tr>
<td>Median, months</td>
<td>10.7</td>
</tr>
<tr>
<td>HR (95% CI), ABCP vs BCP</td>
<td></td>
</tr>
<tr>
<td>HR (95% CI), ACP vs BCP</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Patients with measurable disease at baseline. ABCP-atezolizumab+bevacicumab+carboplatin+paclitaxel, ACP-atezolizumab+carboplatin+paclitaxel, BCP-bevacicumab+carboplatin+paclitaxel

DoR: Duration of Response
IMpower150 conclusions

• Improved clinical outcomes with Tecentriq+Avastin and chemo (ABCP) vs Avastin and chemo (BCP) were observed in patients with chemotherapy-naïve, metastatic NSCLC with and without liver metastases
  - Presence of liver metastases represents a poor prognostic factor

• In patients with liver metastases ABCP vs BCP reduced the risk of death by 48% (OS HR 0.52 vs 0.82)

• ABCP was well tolerated regardless of baseline liver metastases status and there were no new safety signals seen in this patient subgroup

• ABCP is an important new treatment option for patients with liver metastases
Encouraging Phase II interim data from LCMC3 study in neoadj. NSCLC Phase III program for early lung cancer ongoing

*MPR at surgical resection, defined as ≤ 10% viable tumor cells; pCR = pathologic complete response; data cutoff Sep 5, 2018. 1 EGFR+ patient had aborted surgery; EGFR+, 7 patients; ALK+, 1 patient; no MPR and no RECIST PD pre-surgery observed. The regression line is shown with shaded region indicating the confidence band for mean.

Kwiatkowski et al, ASCO 2019

---

**Study design**

<table>
<thead>
<tr>
<th>Neoadjuvant treatment</th>
<th>Surgery</th>
<th>Surveillance (2 years)</th>
<th>Survival follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atezolizumab (2 cycles)</td>
<td>SOC chemotherapy</td>
<td>Optional adjuvant astezolizumab (≤ 12 months)</td>
<td></td>
</tr>
</tbody>
</table>

**Primary endpoint: Major pathologic response (MPR)**

Patients in intended surgery population (n=90)

- PR: 6 (7%), SD: 80 (89%), PD: 4 (4%) by RECIST

Primary efficacy population (n=77; excl. 7 EGFR/ALK+ pts)

- MPR: 19% (15/77), pCR: 5% (4/77)
- 49% (38/77) had a ≥50% pathological regression

---

**Pathological regression in intended surgery population (n=90)**

---

**Clinical stage at initial diagnosis, n (%)**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>IB</td>
<td>11</td>
<td>11%</td>
</tr>
<tr>
<td>IIA / IIB</td>
<td>44</td>
<td>44%</td>
</tr>
<tr>
<td>IIIA / IIIB</td>
<td>46</td>
<td>46%</td>
</tr>
</tbody>
</table>

---

**Roche Ph III program in early lung cancer ongoing**

- Adjuvant Tecentriq + chemotherapy - IMpower010
- Neoadjuvant Tecentriq + chemotherapy - IMpower030
- Adjuvant Alecensa - ALINA

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35
Breast cancer

Lung cancer

Tumor agnostic indications

• STARTRK-NG: Entrectinib in pediatric/adolescent solid tumors/CNS
Entrectinib is a CNS active ROS1/NTRK/ALK inhibitor

**Ph1/2 ALKA-372-001, STARTRK-1 & 2 efficacy in adults:**

**ROS1+ NSCLC (n=53)**
- ORR 77.4%; median DoR 24.6 months
- Intracranial ORR in baseline CNS disease: 55%, mDoR 12.9 mo’s

**NTRK + solid tumors (n=54)**
- ORR 57.4%; median DoR 10.4 months
- Intracranial ORR in baseline CNS disease: 54.5%, mDoR NE (5.0-NE)

**Clinically meaningful and durable response in adult patients with and without CNS malignancy**

**Ph1/1b STARTRK-NG : Efficacy analysis of 12 children/adolescents with NTRK1/2/3, ROS1 or ALK fusions:**

- A variety of pediatric cancers harbor mutations and fusions including high grade glioma, sarcoma and melanoma
- STARTRK-NG conducted in children with recurrent refractory solid tumors including primary CNS tumors
STARTRK-NG: Entrectinib activity in children and adolescents in tumors with and without NTRK1/2/3, ROS1 or ALK fusions

Response rate in pediatric solid tumors
ORR 100% in patients with fusions (11/11)¹

PFS for all patients with and without gene fusion-positive tumors (n=29)

All patients with NTRK1/2/3, ROS1 or ALK fusions showed rapid durable responses without relapse (ORR 100%) including
5 patients with primary high-grade CNS tumors
2 patients showed complete responses (CRs in high-grade glioma, sarcoma)

Data cut-off October 31, 2018; MTD, maximum tolerated dose; ORR, overall response rate; PFS, progression-free survival; PK, pharmacokinetics; RP2D, recommended phase II dose; ¹Investigator-assessed: includes only patients with measurable disease at baseline and tumor assessment; *unconfirmed response at time of data cut-off; Median duration of therapy was 85 days (6–592 days) for all patients; 56 days (6–338 days) for non-responders; and 281 days (56–592 days) for responders
STARTRK-NG conclusions

• Entrectinib produced striking, rapid and durable objective responses in all 11 children with refractory CNS and solid tumors harboring NTRK1/2/3, ROS1 or ALK fusions

• Entrectinib was well tolerated; dose-limiting toxicities were elevated creatinine, dysgeusia, fatigue and pulmonary edema; other adverse events included weight gain and sensory impairments (ataxia)

• Entrectinib was submitted to health authorities globally and recently granted Priority Review by the FDA with an expected decision on approval by 18 August, 2019

• Roche is partnering with FMI using the F1CDx platform to develop companion diagnostic to effectively and accurately identify these patients
Roche Oncology: Industry leading portfolio

Through continuously improving standard of care

BREAST
- AVASTIN
- Herceptin
- Perjeta
- FDC SC

GYNECOLOGY
- AVASTIN
- TECENTRIQ
- TECENTRIQ (atezolizumab)
- ALECENSA
- Kadcyla
- TECENTRIQ (atezolizumab)
- ipatatasib

LUNG / DISEASE AGNOSTIC
- AVASTIN
- TECENTRIQ
- TECENTRIQ (atezolizumab)
- ENTRECTINIB

SKIN
- COTELLC
- ZELBORAF
- Erivedge
- TECENTRIQ
- TECENTRIQ (atezolizumab)

GASTRO-INTESTINAL
- Herceptin
- Tarceva
- ZELBORAF
- Erivedge
- TECENTRIQ
- TECENTRIQ (atezolizumab)

GENITO-URINARY
- TECENTRIQ
- ipatatasib

HEMATOLOGY
- MabThera Rituximab
- GAZYVA obinutuzumab
- VENCLEXTA venetoclax
- Idasanutlin
- polatuzumab vedotin
- CD20xCD3 mosunetuzumab

Roche Oncology: Industry leading portfolio

Through continuously improving standard of care
Replace and extend the business
Through continuously improving standard of care

<table>
<thead>
<tr>
<th>Replace/extend existing businesses</th>
<th>Entering new franchises</th>
</tr>
</thead>
<tbody>
<tr>
<td>MabThera/Rituxan</td>
<td>Gazyva, Venclexta, polatuzumab vedotin, mosunetuzumab, CD20 x CD3</td>
</tr>
<tr>
<td>Herceptin</td>
<td>Perjeta, Kadcyla, Herceptin + Perjeta SC</td>
</tr>
<tr>
<td>Avastin</td>
<td>Tecentriq, Alecensa, entrectinib, ipatasertib</td>
</tr>
<tr>
<td>Lucentis</td>
<td>faricimab Port delivery system (PDS)</td>
</tr>
<tr>
<td>Tamiflu</td>
<td>Xofluza</td>
</tr>
</tbody>
</table>

**ASCO 2019 Highlights**

**Lung:**
- NSCLC: IMpower150, benefit in patients with liver metastasis with Tecentriq
- Neoadjuvant lung cancer: Encouraging early data with Tecentriq
- Entrectinib: Efficacy benefit

**Heme:**
- CLL: Venclexta + Gazyva strong benefit in 1L treatment
- R/R FL: Polatuzumab +Gazyva +lenalidomide encouraging efficacy in PhI-IIb

**Breast:**
- TNBC: Tecentriq confirmed OS benefit in PD-L1+
- HER2+ mBC: CLEOPATRA long term survival benefit

**Tumour Agnostic:**
- Pediatric CNS tumors: Entrectinib strong response data

SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder; RMS=relapsing MS; PPMS=primary progressive MS; R/R CLL=relapsed/refractory chronic lymphocytic leukemia; AML=acute myeloid leukemia; BC=breast cancer; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; TNBC=triple-negative BC; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; PDS=Port Delivery Systemc
Extend current franchise in lung cancer
Ongoing trial program with differentiated growth opportunities

**Incidence rates (980’000 pts)\(^1\)**

- **ALK+ NSCLC**: 3–5%
- **ROS1+/NTRK+ NSCLC**: 1%
- **SCLC**: 15%
- **Sq. NSCLC**: 30%
- **NSq. NSCLC PDL1 neg.**: 21%
- **NSq. NSCLC PDL1 low**: 13%
- **NSq. NSCLC PDL1 high**: 9%
- **EGFR+ NSCLC**: 8%

**Ph3 NeoAdj uvant** (IMpower010) + chemo
**Ph3 Adjuvant (IMpower010)** + chemo

**Ph3 Adjuvant (ALINA)**

**NSCLC ALK+**

**NSCLC NTRK+ / ROS1+**

**ENTRECTINIB** Ph2 (STARTRK-NG)

**TECENTRIQ**

**SCLC**

- Ph3 1L (IMpower133) + chemo

**NSCLC Sq.**

- Ph3 1L (IMpower131) + carbo-pac/nab-pac (IMpower110) + carbo/cis+gem

**NSCLC**

- Ph3 1L (IMpower110) + carbo/cis+gem
- (IMpower150) + carbo-pac±Avastin
- (IMpower130) + carbo/nab-pac
- (IMpower132) + carbo/cis+pem

**NSq. NSCLC**

**TECENTRIQ**

1. Decision Resources, Evaluate pharma
NTRK=neurotrophic-tropomyosin receptor kinase; SCLC=small cell lung cancer; NSCLC=non-small cell lung cancer; Sq=squamous; Nsq=non-squamous

ASCO 2019
Extend current franchise in hematology

Ongoing trial program with differentiated growth opportunities

Incidence rates (330’000 patients)

CLL
Ph3 1L (CLL14): Ven + G
Ph3 R/R (MURANO): Ven + R

DLBCL
Ph2 R/R (GO29365): Pola + BR
Ph3 1L (POLARIX): Pola + R-CHP
polatuzumab vedotin

MM
Ph3 R/R (BELLINI): Ven + bortezomib/dex
Ph3 R/R CANOVA): t(11:14) Ven + dex

AML
Ph3 1L (Viale-A & Viale-C): Ven + azacitidine/LDAC

Idasanutlin
Ph3 R/R (MIRROS): Idasa + cytarabine

1. Decision Resources. Evaluate pharma
CLL=chronic lymphoid leukemia; DLBCL (aNHL)=diffuse large B-cell lymphoma; iNHL=indolent non-hodgkin’s lymphoma; AML=acute myeloid leukemia; MM=multiple myeloma; MDS=myelodysplastic syndrome; ALL=acute lymphoblastic leukemia. Venclexta in collaboration with AbbVie; Gazyva in collaboration with Biogen; Polatuzumab vedotin in collaboration with Seattle Genetics
Extend current franchise in breast cancer

Ongoing trial program with differentiated growth opportunities

**Incidence rates (600’000 patients)\(^1\)**

- **HER2+**
  - Ph3 neoadjuvant (IMpassion050)
  - Ph3 Adj (KATHERINE)
  - Ph3 Adj (KATLIN)
  - Ph3 eBC (FeDeriCa)
  - Ph2 eBC (FDC SC cross-over)

- **HER2-/HR+**
  - Ph3 1L Dx+ (IPATunity130)
  - Ph3 1/2L (IPATunity150)

- **TNBC**
  - Ph3 1L (IMpassion130/131/132)
  - Ph3 neoadjuvant (IMpassion031)
  - Ph3 adjuvant (IMpassion030)

**FDC SC**

**ASCO 2019**

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1. Decision Resources, Evaluate pharma

FDC=Fixed dose combination; TNBC=triple negative breast cancer
Our technology platforms in cancer
Roche pipeline includes differentiated therapeutic platforms

<table>
<thead>
<tr>
<th>Bi-specifics</th>
<th>Fusion Protein</th>
<th>Monoclonal antibody</th>
<th>ADC</th>
<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD20 x CD3, CEA x CD3</td>
<td>Her2 x CD3, mosunetuzumab, glypican-3 x CD3</td>
<td>FAP x IL2v</td>
<td>TIGIT (tiragolumab)</td>
<td>polatuzumab vedotin, HER2</td>
</tr>
<tr>
<td>Engage and activate T cells to kill tumour cells</td>
<td>Amplify immune response</td>
<td>Amplify immune response</td>
<td>Targeted tox load</td>
<td>Patient’s neo-antigens for anti-tumour immune response</td>
</tr>
</tbody>
</table>

ADC=antibody-drug conjugate; iNeST=Individualized Neoantigen-Specific Therapy
Transforming the way we work
*Empowered and agile teams to deliver more and faster for patients*

The Lifecycle Triad - Fit for purpose working group

80% of decisions delegated to Life Cycle Teams

Faster-Filing - Portfolio wide efficiency

LCL=Life Cycle Leader; GDL=Global Development Leader; iSL=integrated Strategy Leader
Leveraging Real World Data to accelerate development

Targeting rare tumor agnostic ROS-1 & NTRK fusions in STARTRK-2

Uncovering new biologic insights and developing pan-tumor strategies

External control from Flatiron to generate comparative evidence

Doebele et al, ASCO 2019

NTRK=neurotrophic-tropomyosin receptor kinase
Using genomic profiling to address poorly understood cancers

Matching patients to best known treatment option or clinical trial

CUPISCO\(^1\) phase II trial: Cancer of Unknown Primary (CUP) patients receive treatment based on genomic profiling

Cancer spreads from an unknown site to other parts of the body

Lung metastasis

Liver metastasis

Unknown primary tumour

Investigator choice
MTB advice

Molecularly-guided therapy regimens

Chemotherapy

FOUNDATIONACT\(^\circledR\)

FOUNDATIONONE\(^\circledR\)

Leveraging Foundation Medicine to address high unmet opportunities

1. Clinicaltrials.gov NCT03498521
MTB=Multidisciplinary Tumor Board; CUP=Cancer of Unknown Primary
Doing now what patients need next