



## R&D Conference Call

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July 4, 2016



## Forward-Looking Statements

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Although this presentation includes information regarding pharmaceuticals (including products under development), the information is not intended as any advertisement and/or medical advice.

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# Oncology Field Projects under Development (as of 4 July, 2016)

	Phase I	Phase II	Phase III	Filed
Oncology	<p><b>CKI27 / RG7304</b> (Japan / overseas) - solid tumors</p> <p><b>RG7596 / polatuzumab vedotin</b> - NHL</p> <p><b>RG7604 / taselisib</b> - solid tumors</p> <p><b>RG7440 / ipatasertib</b> - solid tumors</p>	<p><b>GC33 (RG7686)</b> / <b>codrituzumab</b> - hepatocellular carcinoma</p>	<p><b>AF802 (RG7853)</b> / <b>Alecensa (overseas)</b> - NSCLC [1L]</p> <p><b>RG1273 / Perjeta</b> - breast cancer (adjuvant) - gastric cancer</p> <p><b>RG3502 / Kadcyca</b> -breast cancer (adjuvant)</p> <p><b>GA101 (RG7159)</b> / <b>obinutuzumab</b> - aggressive NHL - indolent NHL</p> <p><b>RG7446 / atezolizumab</b> - NSCLC - NSCLC (adjuvant) - bladder cancer - MIBC (adjuvant) - renal cell carcinoma</p> <p><b>RG435 / Avastin</b> - renal cell carcinoma</p>	<p><b>AF802 (RG7853)</b> / <b>Alecensa (EU)</b> - NSCLC [post-crizotinib]</p>

In principle, completion of first dose is regarded as the start of clinical studies in each phase.  
 NHL: non-Hodgkin's Lymphoma  
 NSCLC: non-small cell lung cancer  
 MIBC: muscle invasive bladder cancer

**Letters in orange: in-house projects**  
**★: Projects with advances in stages since 22 April, 2016**

# ASCO 2016: Key Presentations Featuring Chugai Medicines



## ALECTINIB

- Alectinib (ALC) versus crizotinib (CRZ) in ALK-inhibitor naive ALK-positive non-small cell lung cancer (ALK+ NSCLC): Primary results from the J-ALEX study [Abstract #9008 (oral)]

## CKI27

- Updated efficacy and safety results from the Phase I study of intermittent dosing of the dual MEK/RAF inhibitor, RO5126766 in patients (pts) with RAS/RAF mutated advanced solid tumors [Abstract #2582 (poster)]

# ASCO 2016: Key Presentations Featuring Chugai Medicines



## ATEZOLIZUMAB

### 1. Non Small Cell Lung Cancer (NSCLC)

- Updated survival and biomarker analysis of a randomized phase II study of atezolizumab vs docetaxel in 2L/3L NSCLC (POPLAR) [Abstract #9028 (poster)]

### 2. Bladder Cancer

- Updated efficacy and >1-y follow up from IMvigor210 Atezolizumab (atezo) in platinum (plat) treated locally advanced/metastatic urothelial carcinoma (mUC) [Abstract #4515 (oral)]
- Atezolizumab (atezo) as first-line (1L) therapy in cisplatin-ineligible locally advanced/metastatic urothelial carcinoma (mUC): Primary analysis of IMvigor210 cohort [Abstract LBA4500 (oral)]

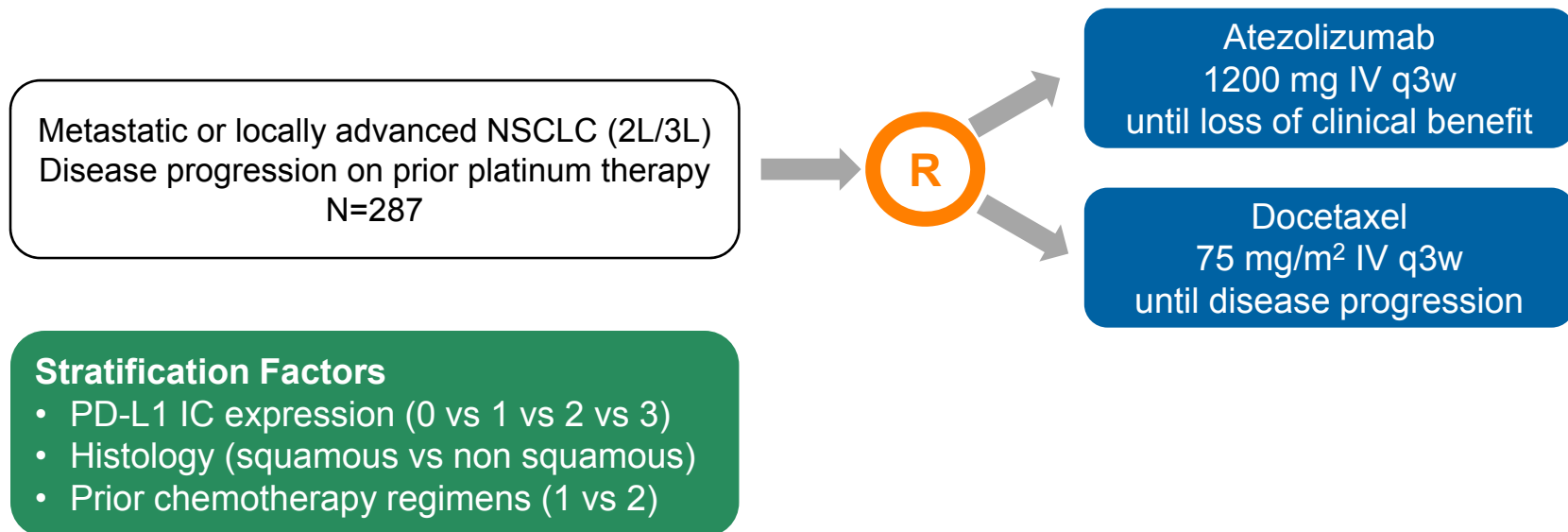
### 3. Breast Cancer

- Phase Ib trial of atezolizumab in combination with nab-paclitaxel in patients with metastatic triple negative breast cancer (mTNBC) [Abstract #1009 (poster discussion)]



# 1. Atezolizumab in NSCLC

Study Design – POPLAR randomized phase II in all-comer population

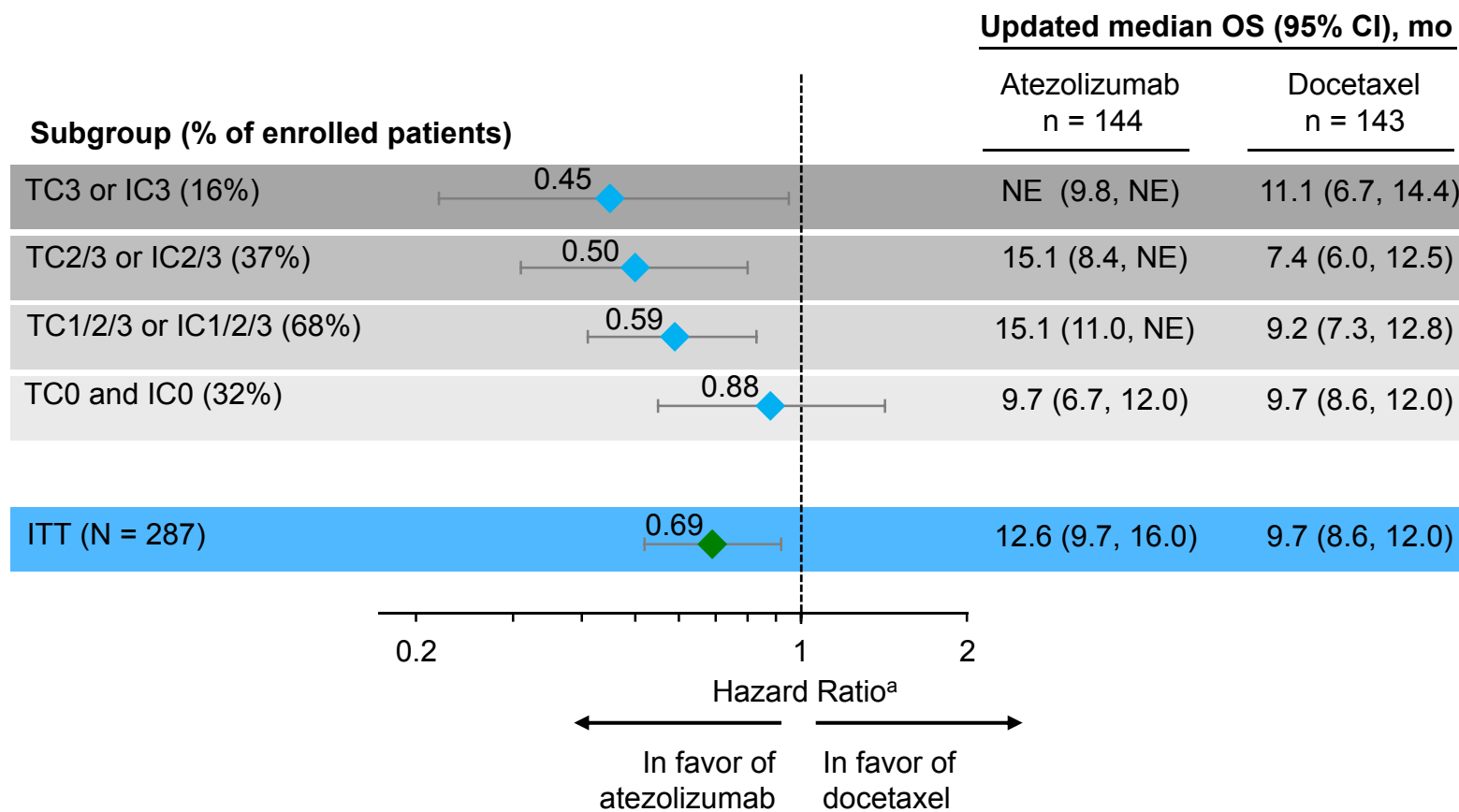




# POPLAR: Updated mOS in PD-L1 subgroups

*Efficacy increasing with higher PD-L1 expression*

**Updated analysis (Event / N=70%): Minimum follow-up 20 months**



<sup>a</sup> Stratified HR for ITT and unstratified HRs for PD-L1 subgroups; NE, not estimable; Data cut-off: December 1, 2015

# POPLAR:

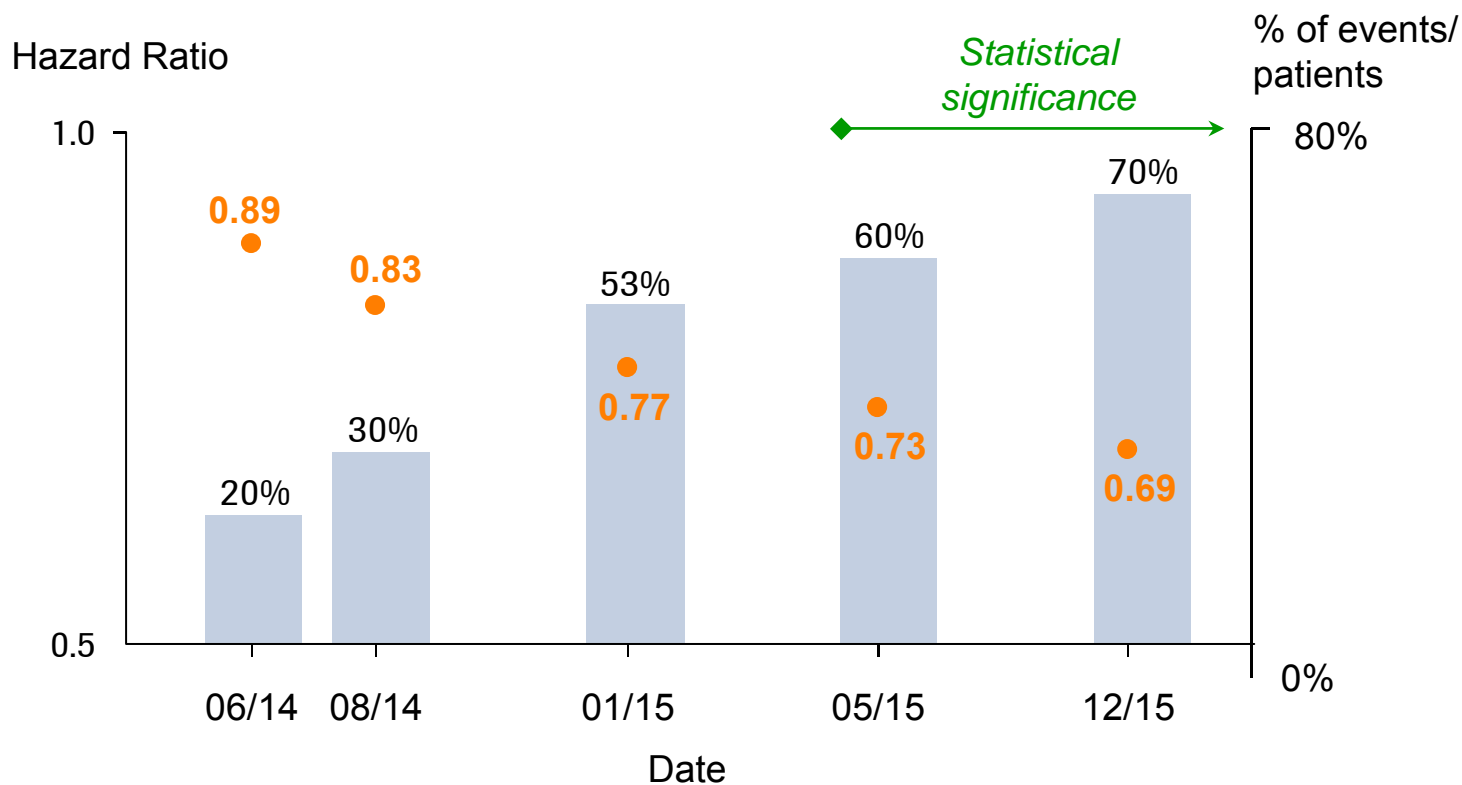
*Time shows true size of the treatment effect*

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## Example: Atezolizumab overall survival in lung cancer



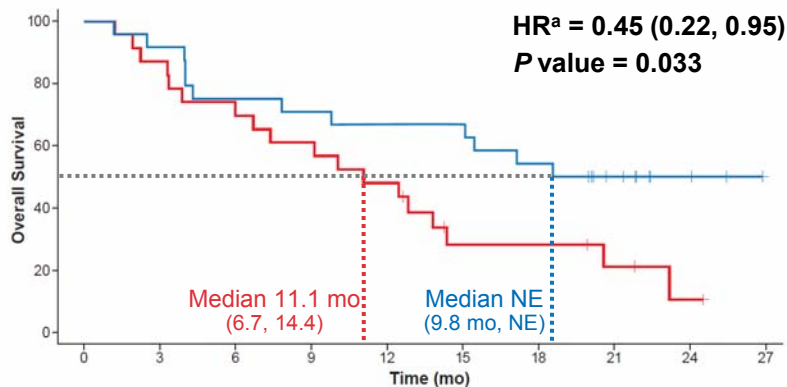




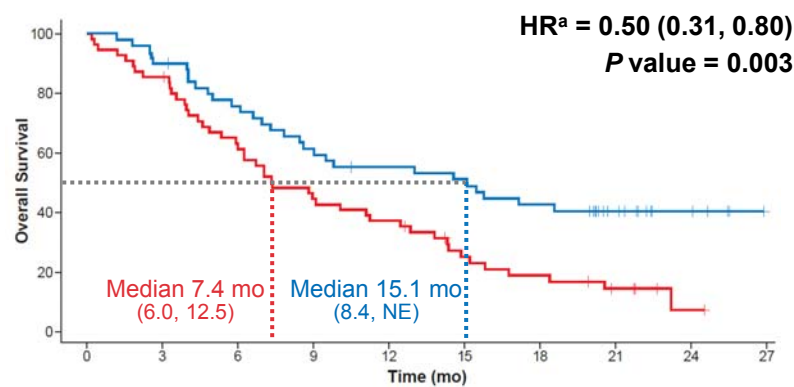
# POPLAR: Updated mOS in PD-L1 subgroups

*OS curves separate in all subgroups incl. TC0/IC0 over time*

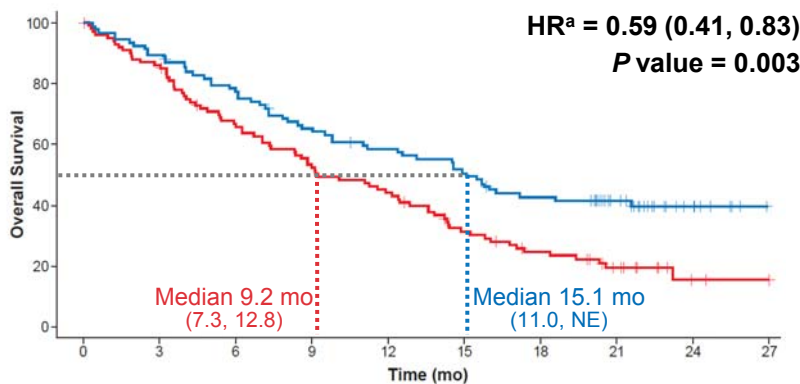
**TC3 or IC3 (n = 47)**



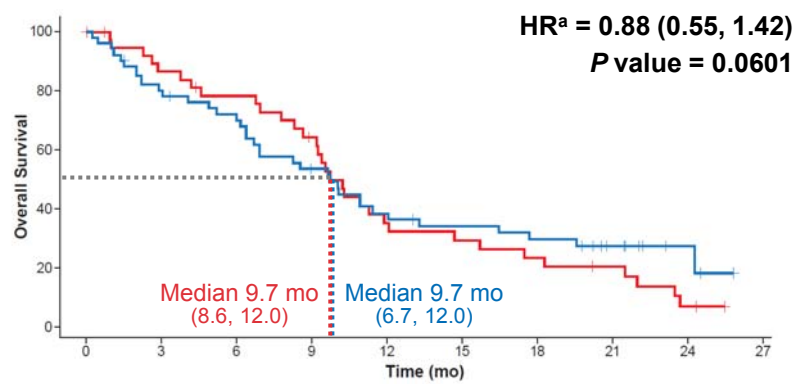
**TC2/3 or IC2/3 (n = 105)**



**TC1/2/3 or IC1/2/3 (n = 195)**



**TC0 and IC0 (n = 92)**

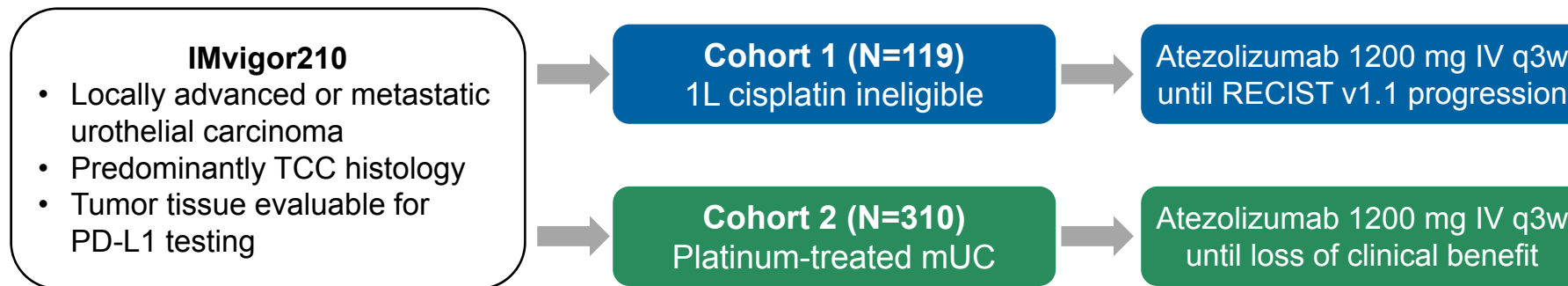


<sup>a</sup> Unstratified HR; Data cut-off: December 1, 2015



# 2. Atezolizumab in Bladder Cancer

## Study Design – Phase II IMvigor210



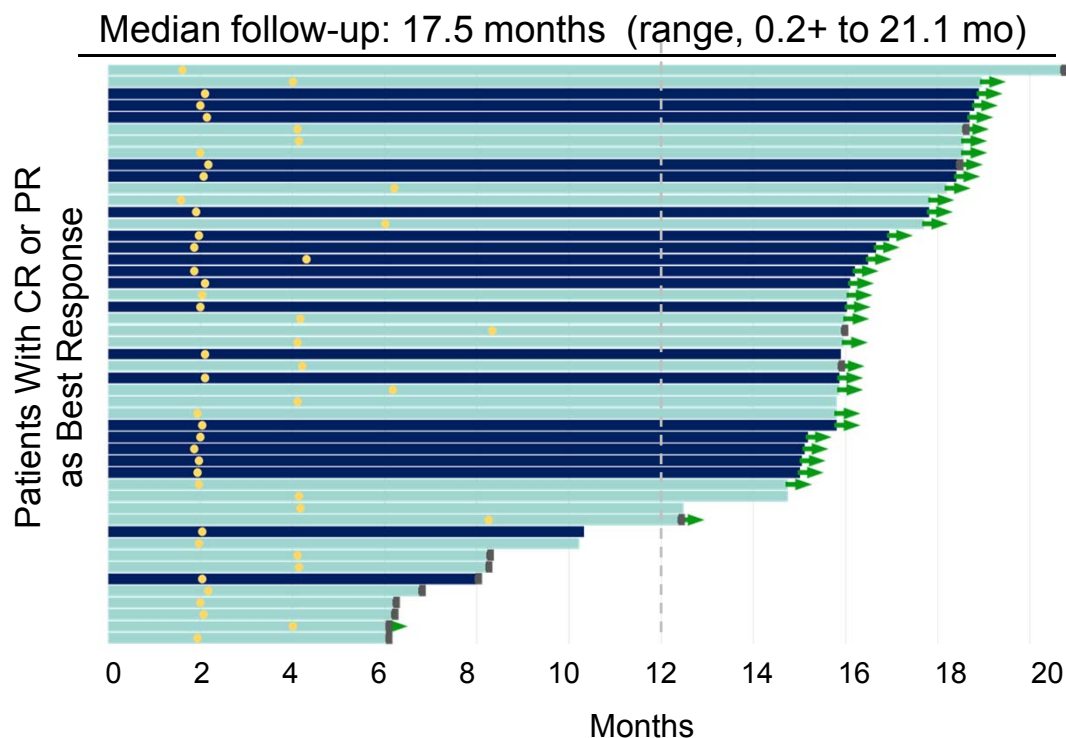
Approved in the US under the brand name Tecentriq® for a specific type of advanced bladder cancer. The US FDA accelerated approval is based on the phase II IMvigor210 study.



# Imvigor210: Cohort 2 update

*Ongoing & durable responses across all subgroups*

	IC2/3 (n = 100)	IC1/2/3 (n = 207)	All <sup>a</sup> (N = 310)	IC1 (n = 107)	IC0 (n = 103)
ORR: confirmed IRF RECIST v1.1 (95% CI)	28% (19, 38)	19% (14, 25)	16% (12, 20)	11% (6, 19)	9% (4, 16)
CR rate: confirmed IRF RECIST v1.1 (95% CI)	15% (9, 24)	9% (6, 14)	7% (4, 10)	4% (1, 9)	2% (0, 7)



- 71% of responses (35/49) were ongoing
  - 86% of CRs ongoing
- mDOR was not yet reached in any PD-L1 IC subgroup (range, 2.1+ to 19.2+ mo)<sup>a</sup>

- CR as best response
- PR as best response
- First CR/PR
- Treatment discontinuation<sup>b</sup>
- ➔ Ongoing response<sup>c</sup>

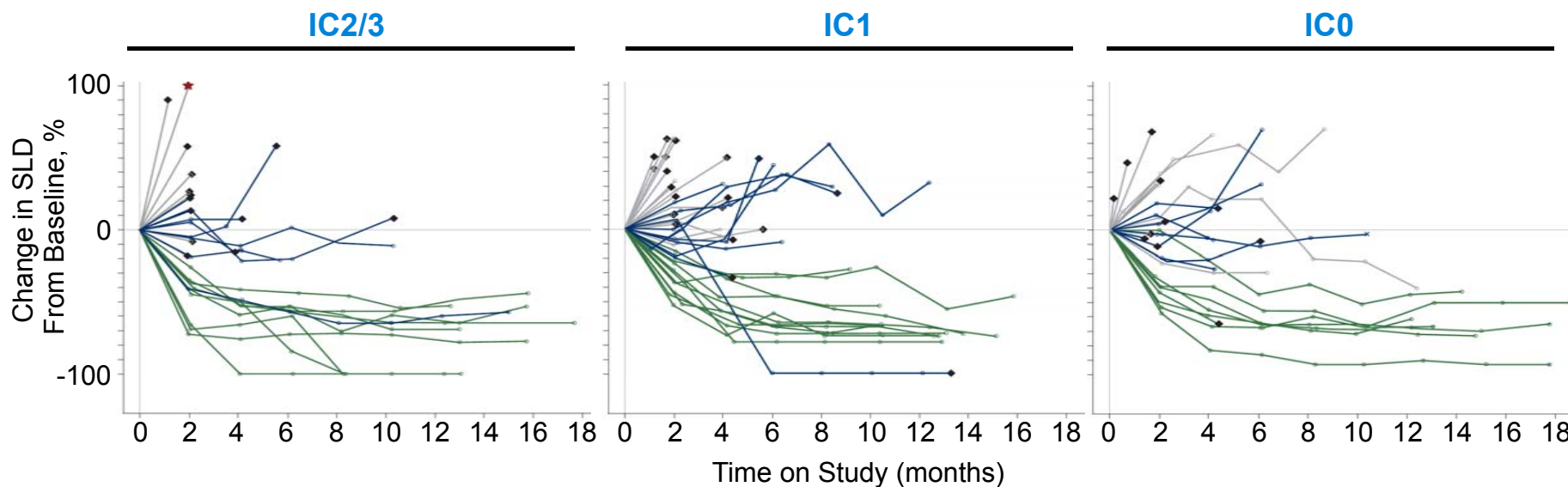
<sup>a</sup> Per IRF RECIST v1.1 <sup>b</sup> Discontinuation symbol does not indicating timing. <sup>c</sup> No PD or death only. Data cutoff: Mar. 14, 2016.



# IMvigor210: Cohort 1 response rate & durability

*Confirmed responses, incl. CRs observed in all subgroups*

	IC2/3 (n = 32)	IC1/2/3 (n = 80)	All Patients (N = 119)	IC1 (n = 48)	IC0 (n = 39)
ORR <sup>a</sup> (95% CI)	28% (14, 47)	25% (16, 36)	24% (16, 32)	23% (12, 37)	21% (9, 36)
CR	6%	6%	7%	6%	8%
PR	22%	19%	17%	17%	13%



- mOS in all patients was 14.8 mo with a median follow-up of 14.4 mo

■ PD  
■ SD  
■ PR/CR  
◆ Discontinued  
★ > 100%

<sup>a</sup> Includes 19 patients with missing/unevaluable responses. All treated patients had measurable disease at baseline per investigator-assessed RECIST v1.1. PD-L1 IC status: IC2/3 (≥ 5%), IC1 (≥ 1 but < 5%), IC0 (< 1%). Data cut-off: March 14, 2016

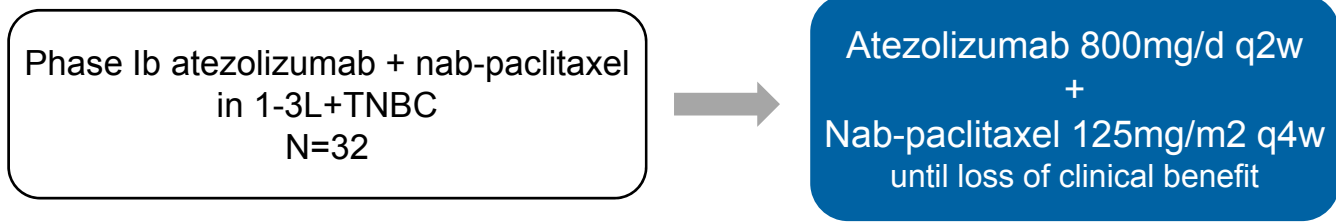
### 3. Atezolizumab in Triple Negative Breast Cancer (TNBC)

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Study Design – atezolizumab + nab-paclitaxel Phase Ib (Arm F)



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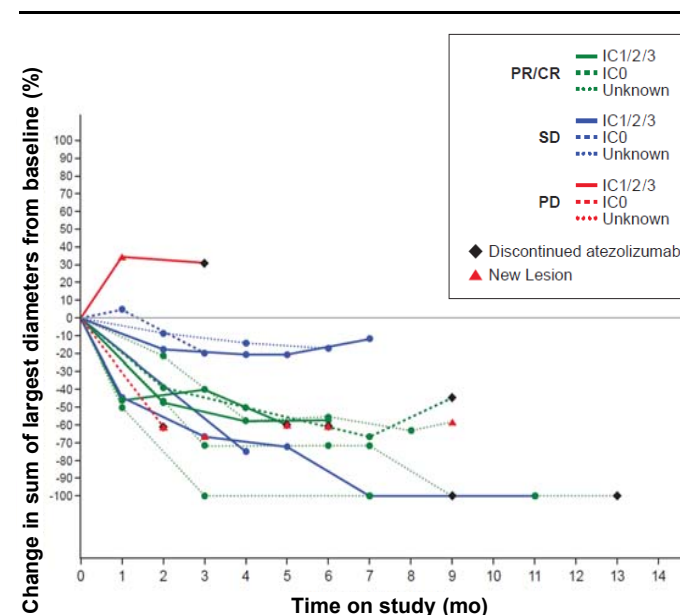
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# Atezolizumab + Abraxane in TNBC

## *Response rate and duration of response*

Best Overall Response	1L (n = 13)	2L (n = 9 <sup>b</sup> )	3L+ (n = 10)	All Patients (N=32)
Confirmed ORR (95% CI) <sup>a</sup>	46% (19, 75)	22% (3, 60)	40% (12, 74)	38% (21-56)
CR	8%	0%	0%	3%
PR	38%	22%	40%	34%
SD	38%	67%	30%	44%
PD	15%	0	30%	16%
Missing or NE	0%	11%	0%	3%

### 1L Patients



**Phase 3 IMpassion 130 in 1L TNBC patients ongoing**

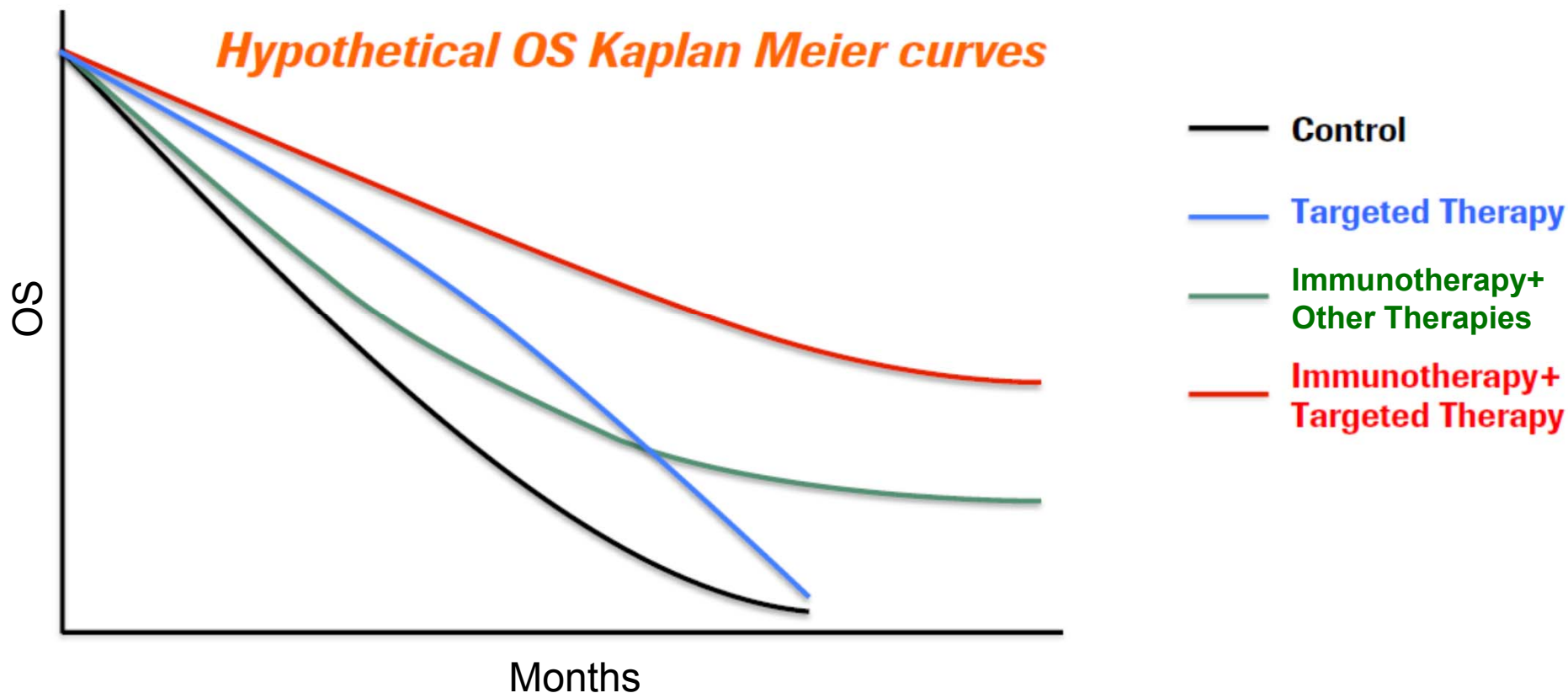
<sup>a</sup> Confirmed ORR defined as ≥ 2 consecutive assessments of CR or PR; <sup>b</sup> One patient discontinued with clinical progression before first on-treatment tumor assessment. Data cutoff date: Jan 14, 2016

# PD-L1: Expectation to Cancer Immunotherapy

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Conceptual illustration

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