

中外製薬R&Dコール

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将来見通し

すべての革新は患者さんのために



Roche ロシュ グループ

本プレゼンテーションには、中外製薬の事業及び展望に関する将来見通しが含まれていますが、いずれも、既存の情報や様々な動向についての中外製薬による現時点での分析を反映しています。

実際の業績は、事業に及ぼすリスクや不確定な事柄により現在の見通しと異なることもあります。

本プレゼンテーションには、医薬品(開発品を含む)に関する情報が含まれていますが、それらは宣伝・広告や医学的なアドバイスを目的とするものではありません。

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

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

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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)]

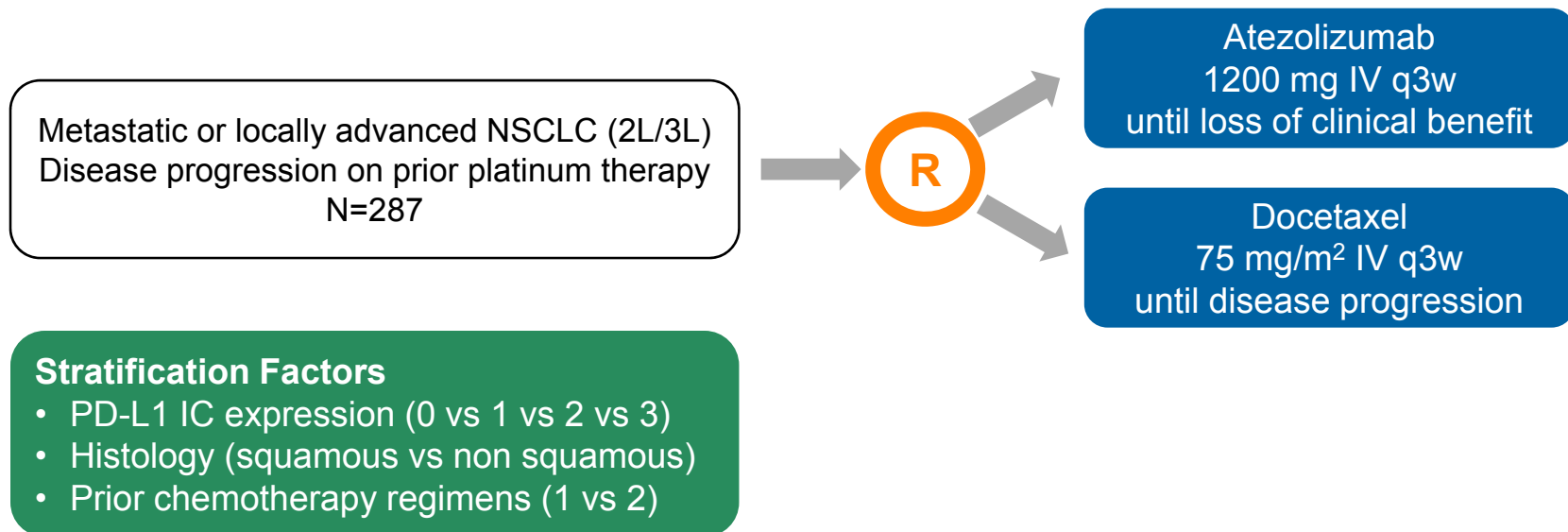
3. Breast Cancer

- 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

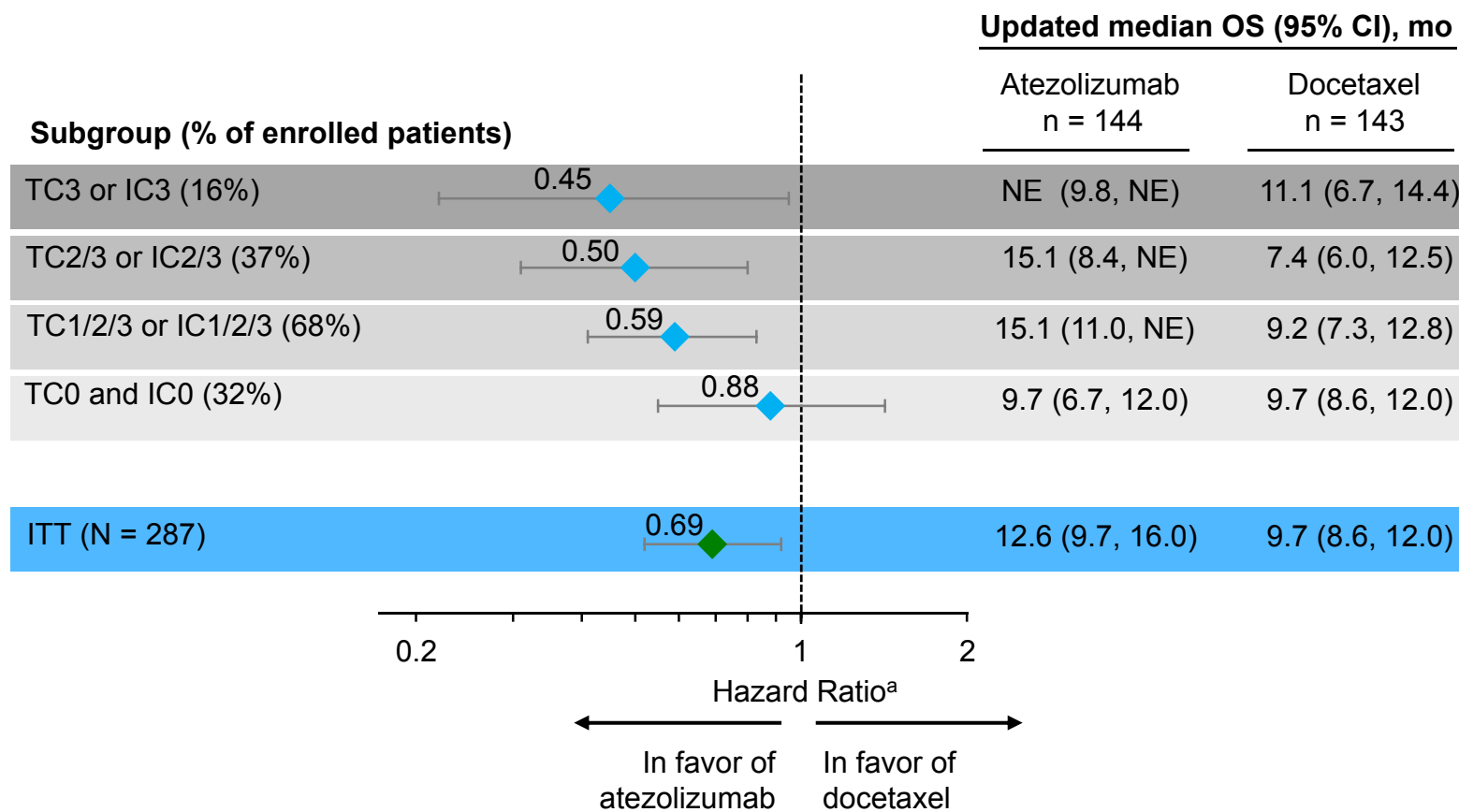




POPLAR: Updated mOS in PD-L1 subgroups

Efficacy increasing with higher PD-L1 expression

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



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

POPLAR:

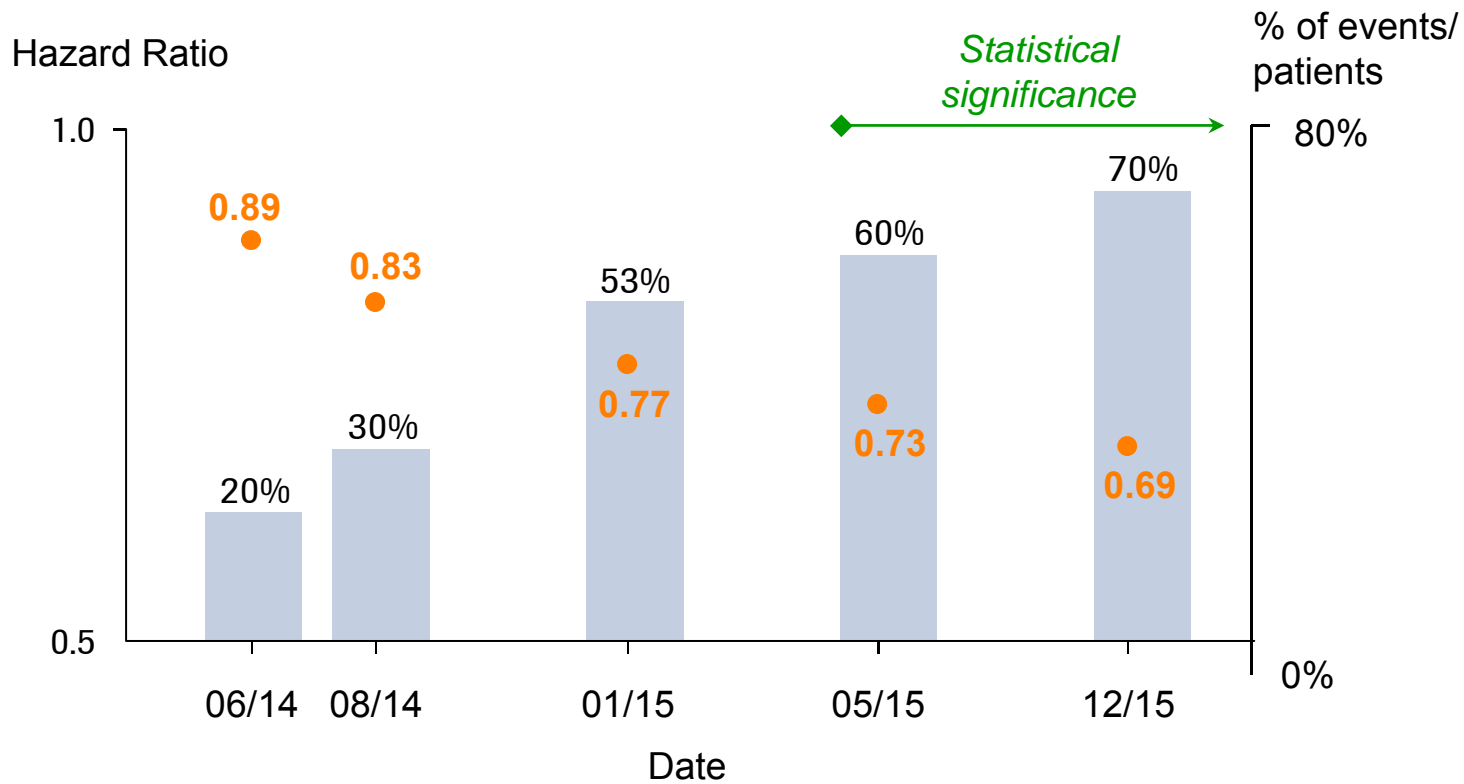
Time shows true size of the treatment effect

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Example: Atezolizumab overall survival in lung cancer

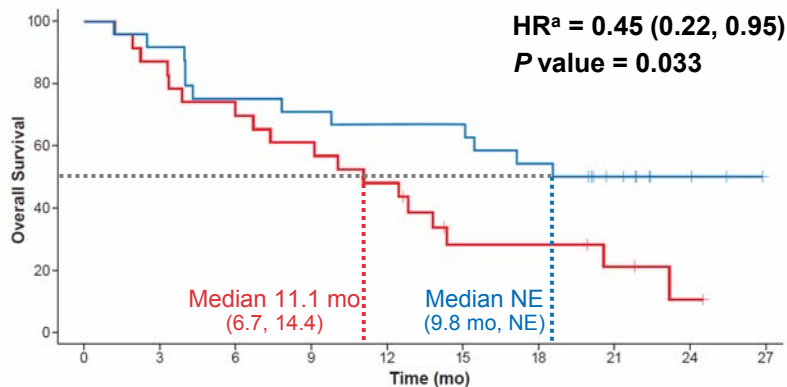




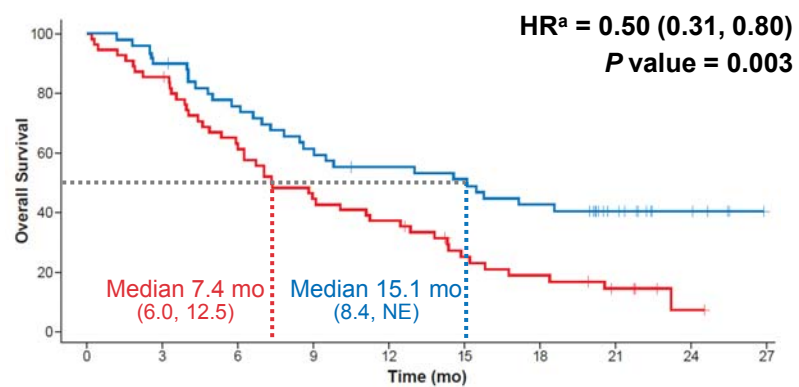
POPLAR: Updated mOS in PD-L1 subgroups

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

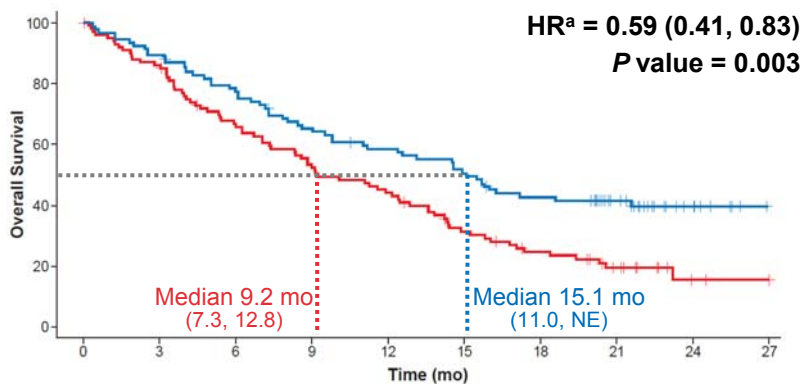
TC3 or IC3 (n = 47)



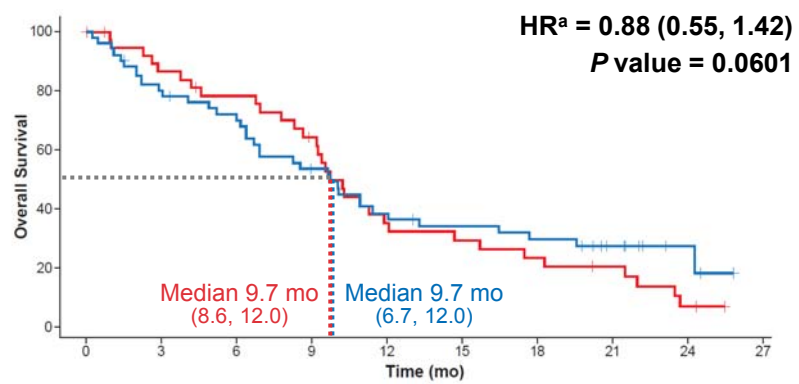
TC2/3 or IC2/3 (n = 105)



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



TC0 and IC0 (n = 92)

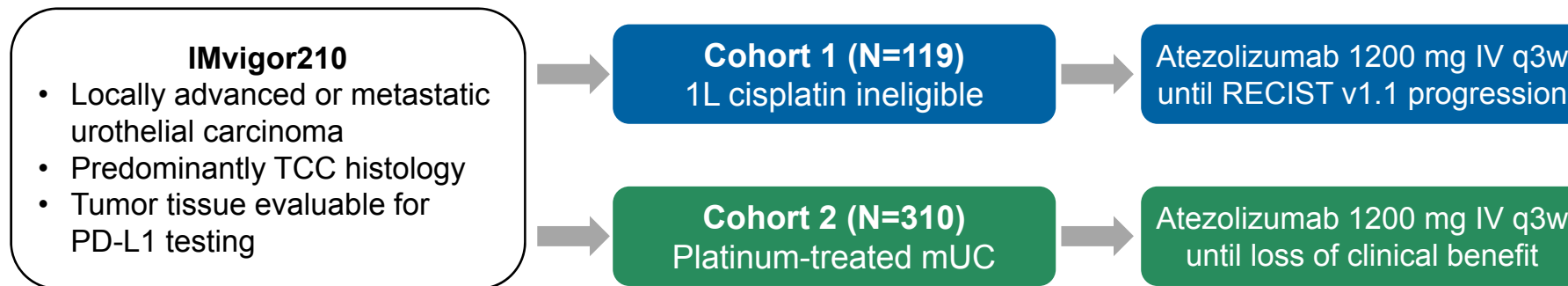


^a Unstratified HR; Data cut-off: December 1, 2015



2. Atezolizumab in Bladder Cancer

Study Design – Phase II IMvigor210



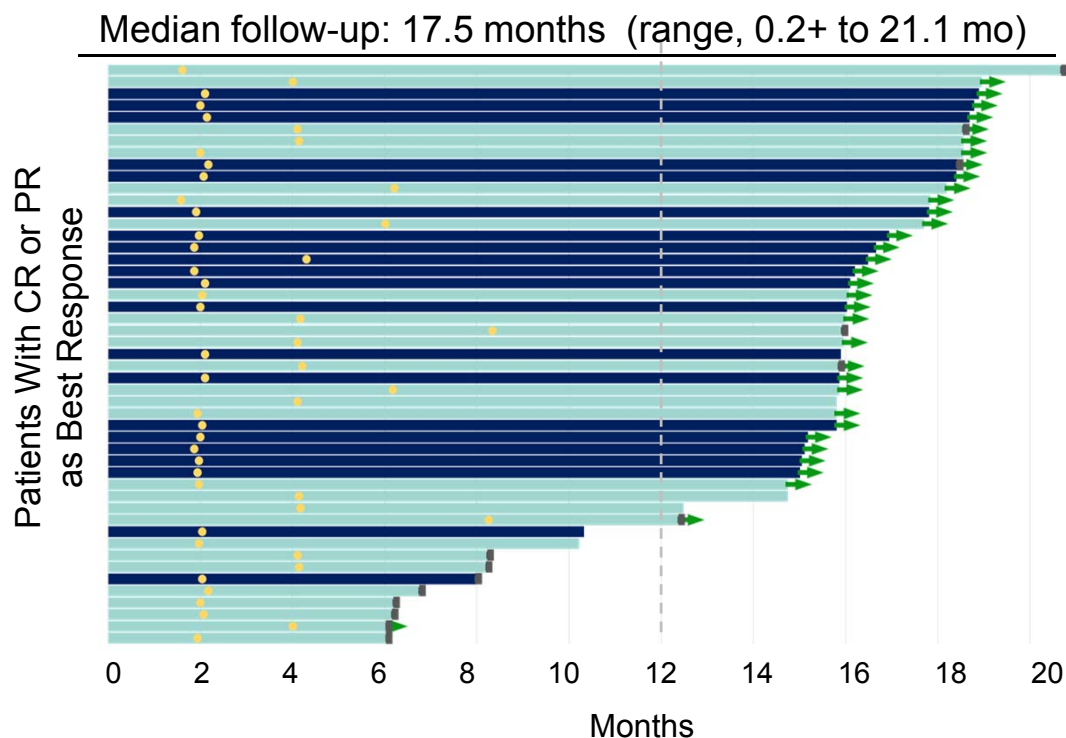
Approved in the US under the brand name Tecentriq® for a specific type of advanced bladder cancer. The US FDA accelerated approval is based on the phase II IMvigor210 study.



Imvigor210: Cohort 2 update

Ongoing & durable responses across all subgroups

	IC2/3 (n = 100)	IC1/2/3 (n = 207)	All ^a (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)^a

- CR as best response
- PR as best response
- First CR/PR
- Treatment discontinuation^b
- ➔ Ongoing response^c

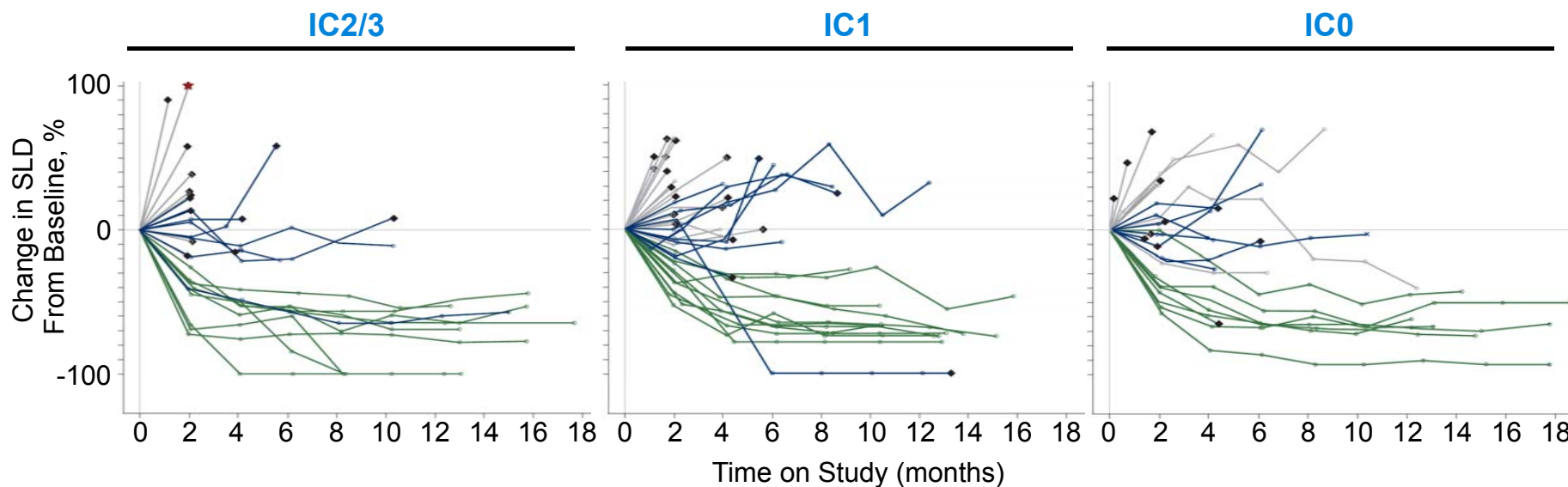
^a Per IRF RECIST v1.1 ^b Discontinuation symbol does not indicating timing. ^c No PD or death only. Data cutoff: Mar. 14, 2016.



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 ^a (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%

^a 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

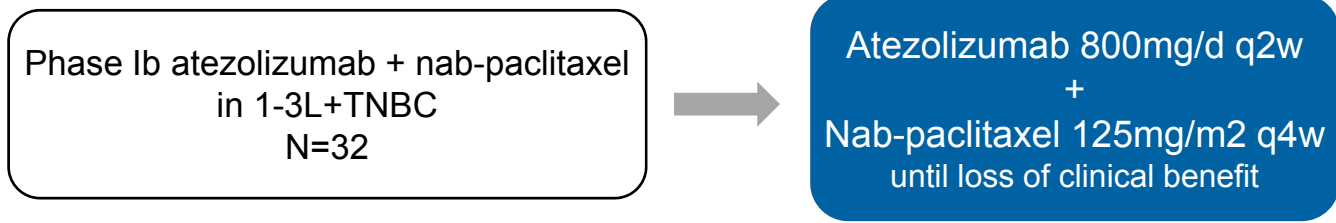
3. Atezolizumab in Triple Negative Breast Cancer (TNBC)

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



Atezolizumab + Abraxane in TNBC

Response rate and duration of response

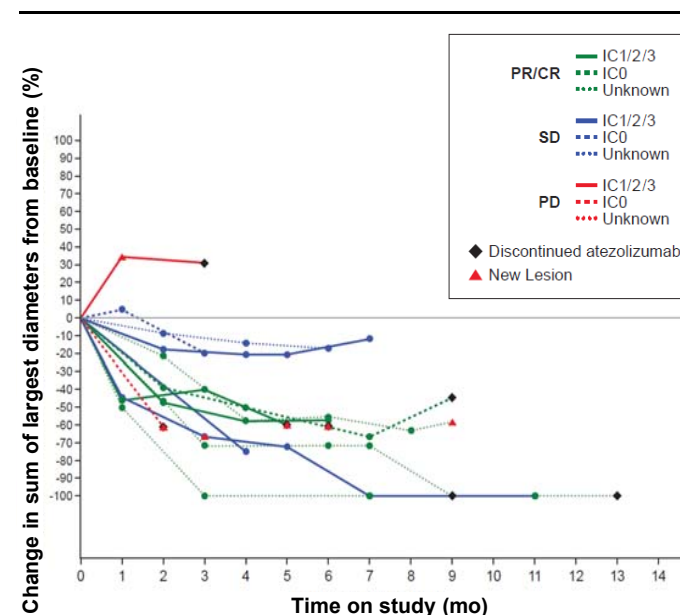
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Best Overall Response	1L (n = 13)	2L (n = 9 ^b)	3L+ (n = 10)	All Patients (N=32)
Confirmed ORR (95% CI) ^a	46% (19, 75)	22% (3, 60)	40% (12, 74)	38% (21-56)
CR	8%	0%	0%	3%
PR	38%	22%	40%	34%
SD	38%	67%	30%	44%
PD	15%	0	30%	16%
Missing or NE	0%	11%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

1L Patients



Phase 3 IMpassion 130 in 1L TNBC patients ongoing

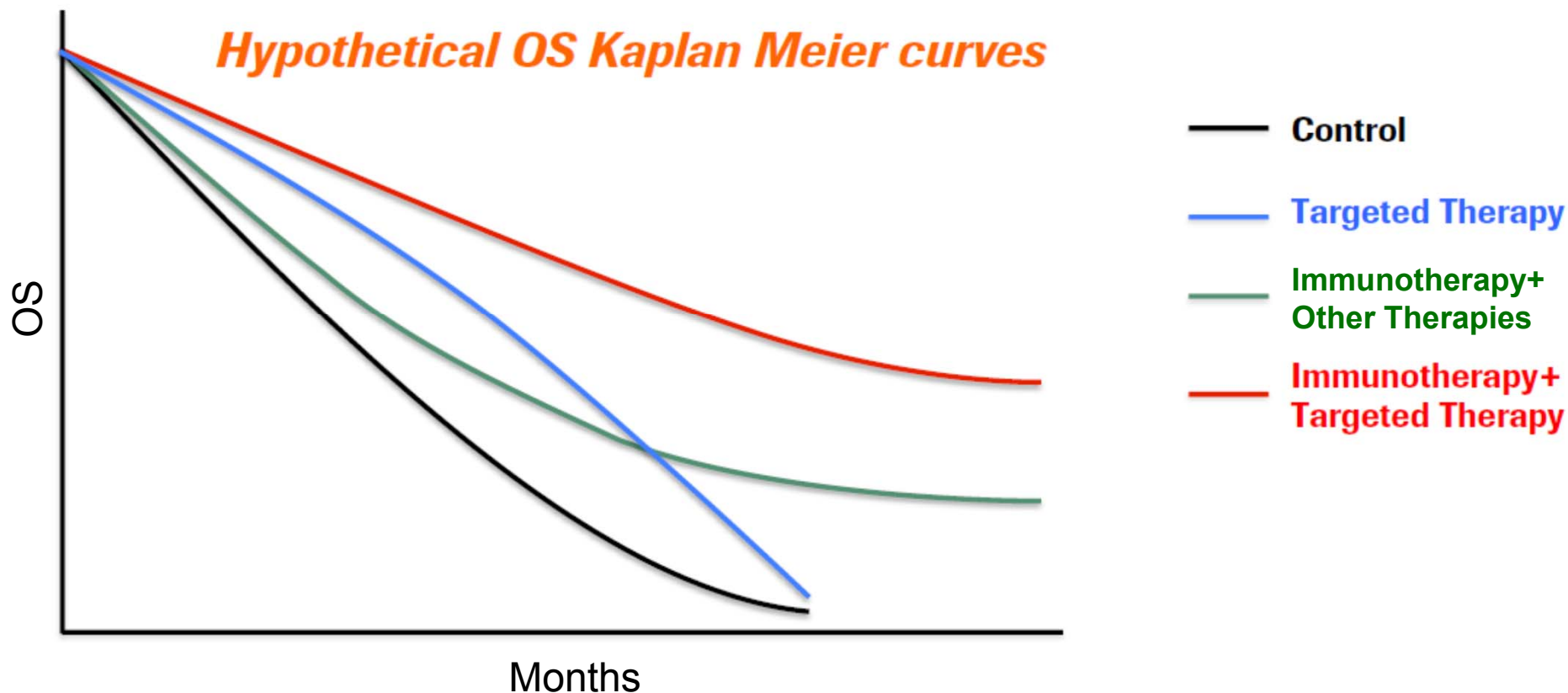
^a Confirmed ORR defined as ≥ 2 consecutive assessments of CR or PR; ^b One patient discontinued with clinical progression before first on-treatment tumor assessment. Data cutoff date: Jan 14, 2016

PD-L1: Expectation to Cancer Immunotherapy

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Conceptual illustration

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