UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JUNE 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12 D-55131 Mainz
Germany
+49 6131-9084-0
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On June 23, 2020, BioNTech SE (the "Company"), together with its collaborator Genentech, Inc. ("Genentech"), at the American Association for Cancer Research (AACR), presented data from a Phase 1b study sponsored by Genentech to evaluate RO7198457, an individualized Neoantigen Specific Immunotherapy (iNeST), in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. The presentation is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Financial Officer

Date: June 23, 2020

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	A Phase 1b Study to Evaluate RO7198457, an Individualized Neoantigen-Specific Immunotherapy (iNeST), in Combination With Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors.

A Phase Ib Study to Evaluate RO719845 Individualized Neoantigen-Specific Immun (iNeST), in Combination With Atezolizumab With Locally Advanced or Metastatic Solic

Lopez J,[1] Camidge DR,[2] Iafolla M,[3] Rottey S,[4] Schuler M,[5] Hellmann MD,[6] Balmanoukian A,
Sullivan RJ,[10] Henick BS,[11] Drake C,[11] Wong KM,[12] LoRusso P,[13] Ott PA,[14] Fong L,[15] Schiz
Ottensmeier C,[18] Braiteh F,[19] Bendell J,[20] Leidner R,[21] Fisher G,[22] Jerusalem G,[23] Molenaar-Ku
Laurie S,[26] Aljumaily R,[27] Rittmeyer A,[28] Gort E,[29] Melero I,[30] Mueller L,[31] Sabado RL,[31] Twomey P
Zhang J,[32] Müller F,[33] Derhovanessian E,[33] Türeci Ö,[33] Sahin U,[33] Powles

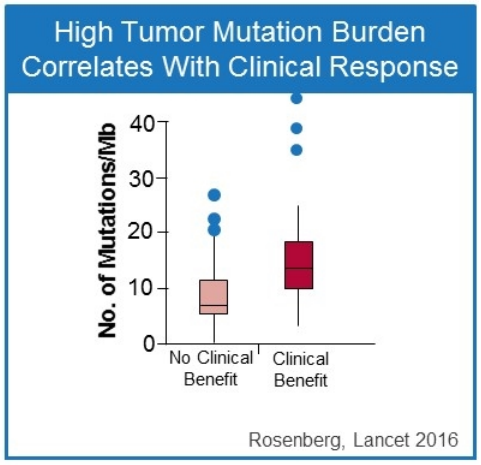
[1]Royal Marsden Hospital, Sutton, UK; [2]Division of Medical Oncology, University of Colorado School of Medicine and Developmental Therape
Cancer Center, Aurora, CO; [3]Princess Margaret Cancer Centre, Toronto, Canada; [4]Cancer Research Institute Ghent (CRIG Ghent), Ghen
Oncology, West German Cancer Center, University Hospital Essen, Essen, Germany; [6]Memorial Sloan Kettering Cancer Center, New Y
Research Institute, Santa Monica, CA; [8]Translational Cancer Research Unit, GZA Hospitals Sint-Augustinus, Antwerp, Belgium; [9]HonorHea
[10]Massachusetts General Hospital, Boston, MA; [11]Herbert Irving Comprehensive Cancer Center, Columbia University, New York, NY; [12]Seat
[13]Smilow Cancer Center, Yale University, New Haven, CT; [14]Dana-Farber Cancer Institute, Boston, MA; [15]UCSF Helen Diller Family Co
Francisco, CA; [16]Uppsala University, Uppsala, Sweden; [17]Karolinska University Hospital, Stockholm, Sweden; [18]University of Southampton,
Cancer Center Nevada, Las Vegas, NV; [20]Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN; [21]Providence Cancer Cer
University School of Medicine, Stanford, CA; [23]CHU Liege and Liege University, Liege, Belgium; [24]Netherlands Cancer Institute, Amsterdam
Universitat Mainz, Mainz, Germany; [26]Ottawa Hospital Cancer Centre, Ontario, Canada; [27]Stephenson Cancer Center, The University o
[28]Lungenfachklinik Immenhausen, Immenhausen, Germany; [29]UMC Utrecht, Utrecht, Netherlands; [30]University Clinic of Navarra, Centre of
Spain; [31]Genentech, Inc, South San Francisco, CA; [32]F. Hoffmann-La Roche, Ltd, Basel, Switzerland; [33]BioNTech SE, Mainz, Germany; [34

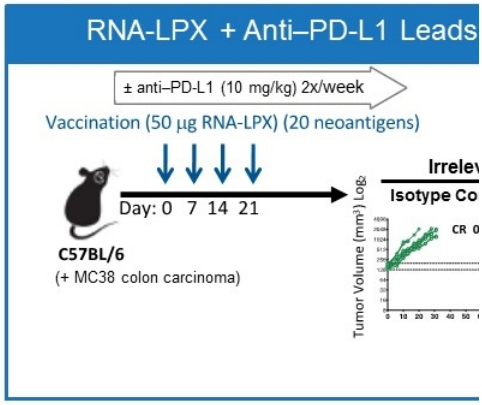
Disclosures

- Dr Lopez has the following relationships to disclose:
  - Research grant funding: Roche/Genentech, Basilea, Genmab
  - Ad board: Basilea

Cancer Mutations Are Drivers of Protective Immunity

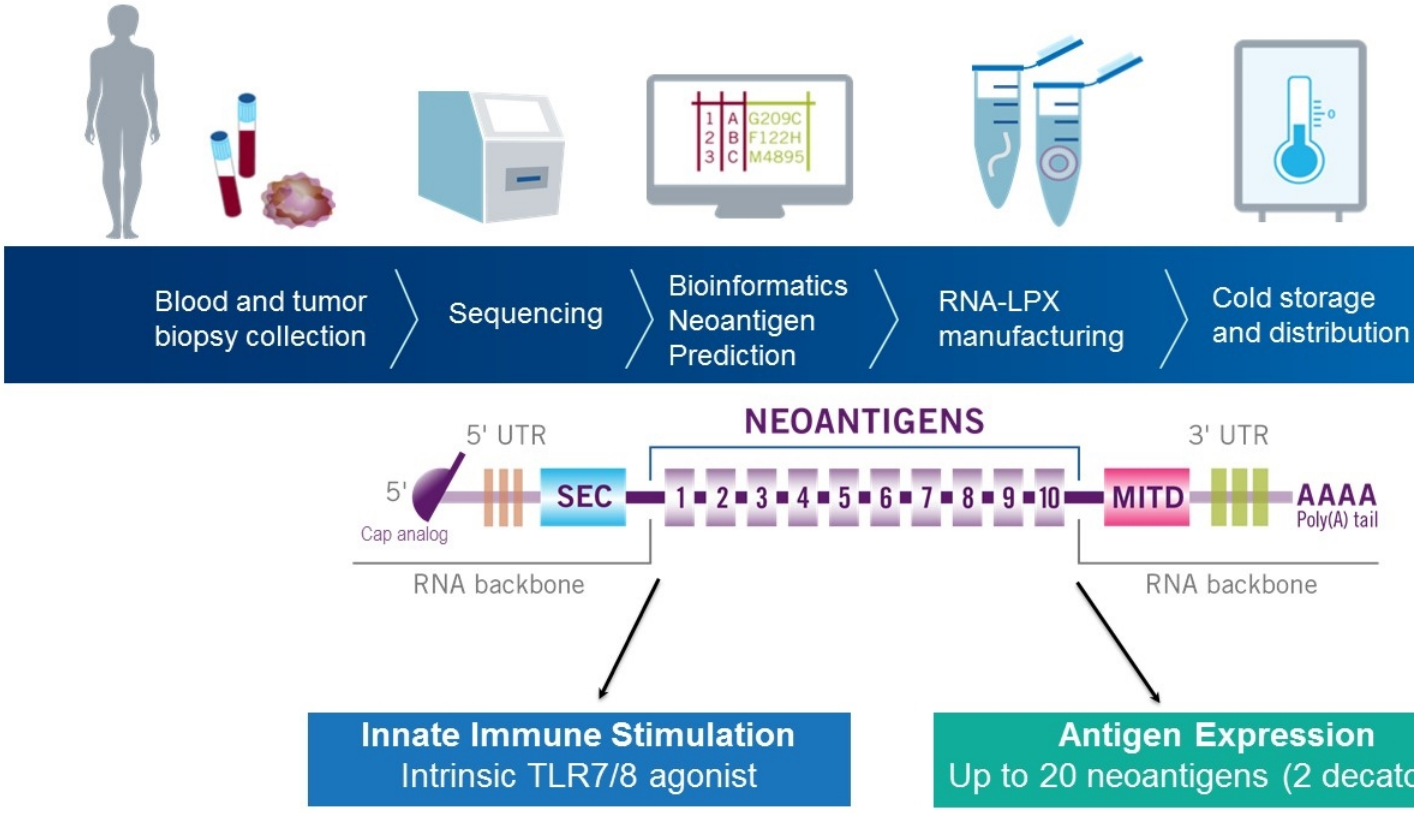
- High tumor mutation burden correlates with clinical response to immune checkpoint blockade
- Mutated neoantigens are recognized as foreign and induce stronger T-cell responses than shared antigens, likely due to the lack of central tolerance
- Most of these mutated neoantigens are not shared between patients; therefore, targeted neoantigen-specific therapy requires an individualized approach
- RO7198457[a] is a systemically administered RNA-Lipoplex Neoantigen Specific immunoTherapy (iNeST), designed to stimulate T-cell responses against neoantigens
- RO7198457 has the potential to increase anti-tumor activity of atezolizumab (anti–PD-L1) by expanding the number of neoantigen-specific T cells





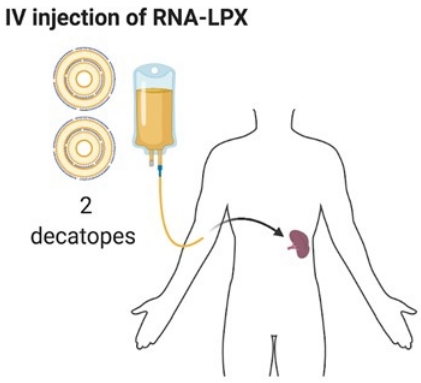
LPX, lipoplex; MHC, major histocompatibility complex.
[a] Also known as RG6180.

Targeting Neoantigens Requires an Individualized A

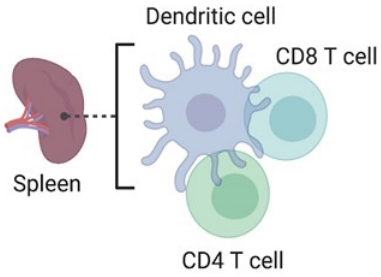


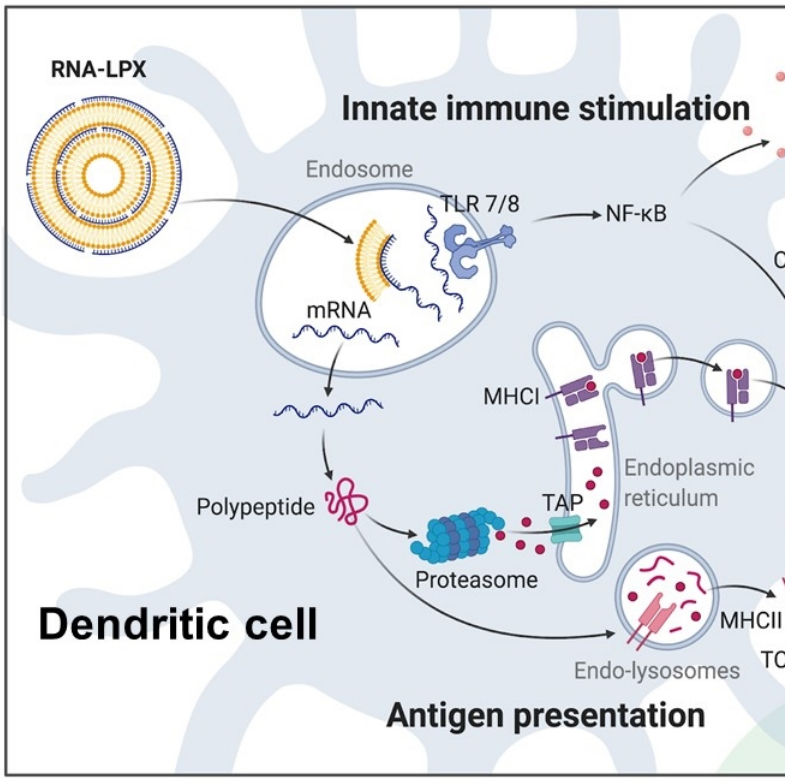
Türeci et al. *Clin Canc Res*. 2016; Vormehr et al. *Annu Rev Med*. 2019; Sahin et al. *Science*. 2018.

Proposed Dual MOA of RO7198457: Innate Immune S and Neoantigen Presentation



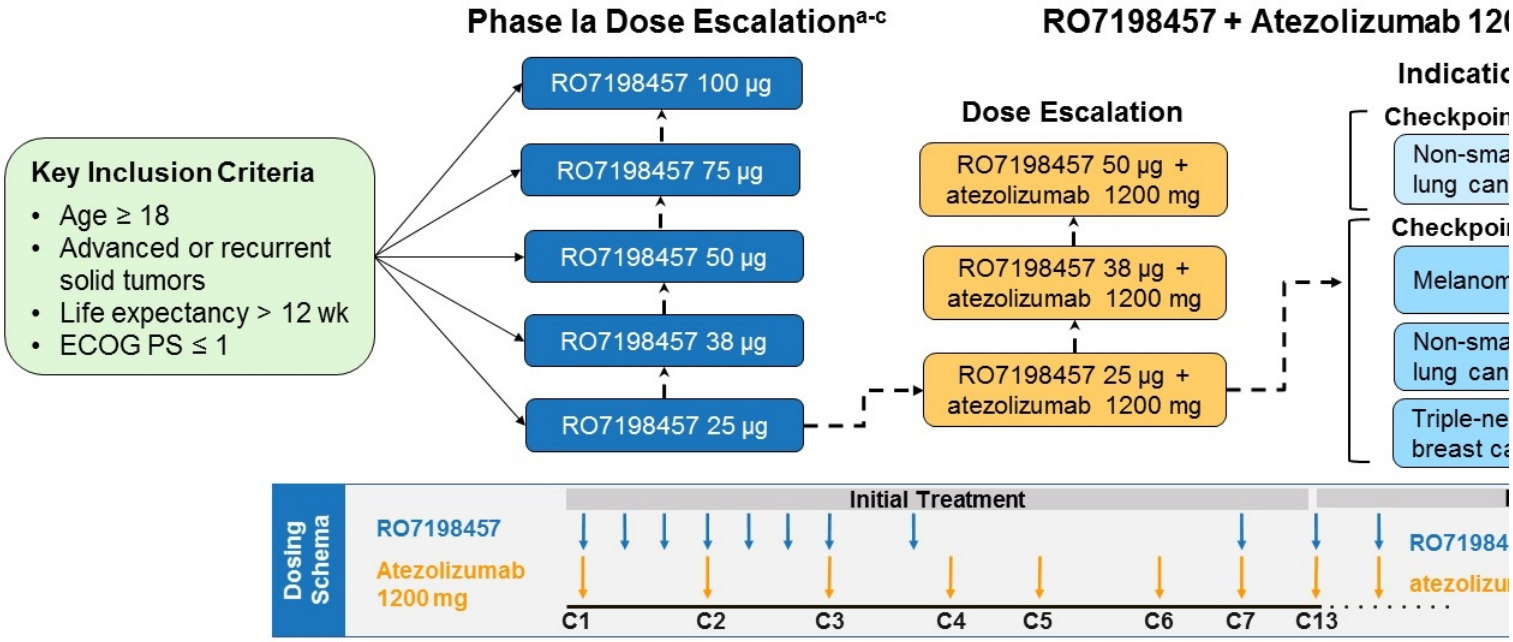
Preferential delivery of RNA-LPX to dendritic cells in the spleen





TCR, T-cell receptor. Kranz et al. Nature. 2016.

Phase Ib Study of RO7198457 in Combination With A in Advanced Solid Malignancies



1 Primary objective
- Safety and tolerability

2 Secondary objectives
- MTD, RP2D, pharmacodynamic activity, pre

C, cycle; DLT, dose-limiting toxicity; MTD, maximum tolerated dose; PD, progressive disease; q3w, every 3 weeks; RP2D, recommended Phase 2 dose.
[a] 3 + 3 dose escalation: 21-day DLT window; backfill enrollment at cleared dose levels; [b] Phase Ia patients with disease progression or loss of clinical benefit may cross over to combination therapy in Phase Ib. [c] Braiteh F, et al. AACR II 2020. Poster CT169. NCT03289962.
Data cutoff: January 10, 2020.

Patient Demographics and Disease Characteristics

	Dose Escalation	Expansion
	Total (n = 30)	**CPI Experienced (n = 42)**
Median age (range), years	57.5 (35-77)	61.5 (36-82)
Male, n (%)	17 (56.6)	25 (59.5)
ECOG PS, n (%)		
0	15 (50.0)	19 (45.2)
1	15 (50.0)	23 (54.8)
Most common tumor types, n (%)		
Colon cancer	9 (30.0)	–
NSCLC	–	30 (71.4)
Melanoma	5 (16.7)	8 (19.0)
Rectal cancer	3 (10.0)	–
RCC	3 (10.0)	–
TNBC	–	–
UC		–
Median number (range) of prior systemic therapies for metastatic disease, n	4 (1 - 9)	3 (1-10)
Prior checkpoint inhibitor, n (%)	13 (43.3)	42 (100)
PD-L1 (Ventana SP142), n (%)		
< 5% IC and TC	24 (80.0)	21 (50.0)
≥ 5% IC or TC	5 (16.7)	12 (28.6)
Missing	1 (3.3)	9 (21.4)

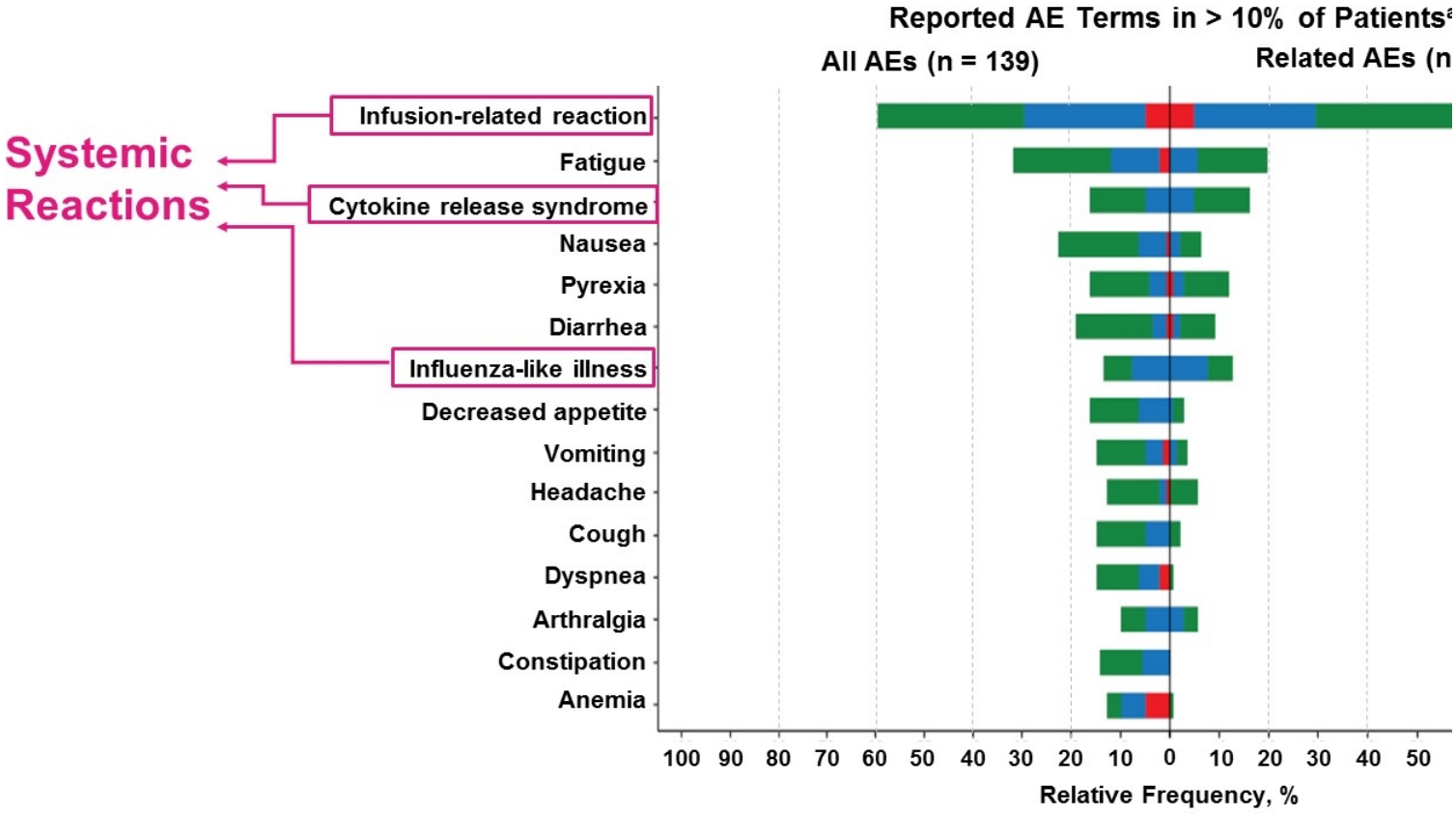
CPI, checkpoint inhibitor; IC, tumor-infiltrating immune cell; NSCLC, non-small cell lung cancer; RCC, renal cell cancer; TC, tumor cell; TNBC, triple-negative breast cancer; UC, urothelial cancer. Data cutoff: January 10, 2020.

Patient Exposure and Disposition

	RO7198457 IV Dose + Atezolizumab 1200 mg			
	15 µg (n = 27)	**25 µg (n = 95)**	**38 µg (n = 11)**	**(**
DLT, n (%)	0	0	0	
RO7198457 dose reduction, n (%)	1 (3.7)	2 (2.1)	1 (9.1)	2
Median (range) treatment duration with RO7198457, days	65 (8-253)	57 (1-400)	64 (35-441)	36
Median (range) treatment duration with atezolizumab, days	104 (1-316)	64 (1-462)	106 (21-504)	22
Continuing treatment, n (%)	9 (33.3)	22 (23.2)	2 (18.3)	
Discontinued RO7198457 only, n (%)	0	1 (1.1)[a]	0	
Discontinued both study treatments, n (%)	18 (66.7)	72 (75.8)	9 (81.8)	9
Reasons for RO7198457 discontinuation, n (%)				
Disease progression	15 (55.6)	61 (64.2)	8 (72.7)	6
Death[b]	1 (3.7)	4 (4.2)	0	
AE	0	5 (5.3)	1 (9.1)	2
Withdrawal by patient	1 (3.7)	1 (1.1)	0	
Other	1 (3.7)	2 (2.1)	0	1
Discontinued treatment due to disease progression prior to completing 6 weeks of therapy, n (%)	2 (7.4)	19 (20.0)	1 (9.1)	2

AE, adverse event. [a] Patient discontinued atezolizumab at the same time as RO7198457. However, atezolizumab discontinuation information was not completed until after data cut. [b] Four deaths were due to malignant neoplasm progression. One death was due to malignant pericardial effusion. No deaths were related to study drugs. Data cutoff: January 10, 2020.

AEs Occurring in Patients Treated With RO7198457 +



- No increase in immune-mediated AEs compared with atezolizumab single-agent experience (data

[a] A serious AE of malignant neoplasm progression was reported in 14% of patients (data not shown). Data cutoff: January 10, 2020.

Systemic Reactions Were Transient and Generally M in the Outpatient Setting

Individual Signs and Symptoms of Systemic Reactions (CRS/IRR/ILI) in ≥ 5 Patients

	RO7198457 IV Dose + Atezolizumab 1200 mg IV q3w				
n (%)	15 µg (n = 27)	25 µg (n = 95)	38 µg (n = 11)	50 µg (n = 9)	All Patients (N = 142)
Pyrexia	10 (37.0)	60 (63.2)	10 (90.9)	6 (66.7)	86 (60.6)
Chills	11 (40.7)	58 (61.1)	8 (72.7)	7 (77.8)	84 (59.2)
Nausea	2 (7.4)	14 (14.7)	2 (18.2)	2 (22.2)	20 (14.1)
Tachycardia	1 (3.7)	8 (8.4)	2 (18.2)	3 (33.3)	14 (9.9)
Headache	3 (11.1)	7 (7.4)	2 (18.2)	0	12 (8.5)
Vomiting	1 (3.7)	9 (9.5)	2 (18.2)	0	12 (8.5)
Hypertension	1 (3.7)	5 (5.3)	0	2 (22.2)	8 (5.6)
Hypotension	3 (11.1)	3 (3.2)	1 (9.1)	0	7 (4.9)
Myalgia	2 (7.4)	4 (4.2)	1 (9.1)	0	7 (4.9)
Back pain	0	4 (4.2)	1 (9.1)	1 (11.1)	6 (4.2)
Fatigue	1 (3.7)	4 (4.2)	0	0	5 (3.5)
Hypoxia	0	3 (3.2)	1 (9.1)	1 (11.1)	5 (3.5)

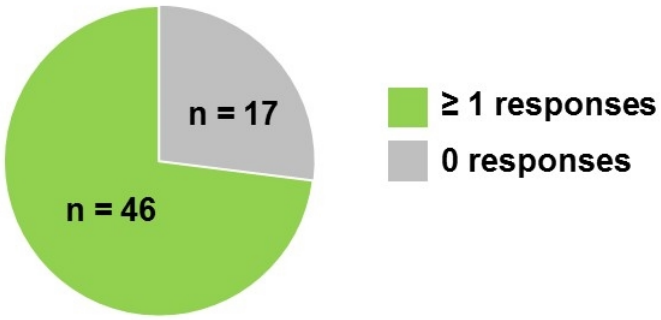
CRS, cytokine release syndrome (CTCAE v.5.0); IRR, infusion-related reaction; ILI, influenza-like illness. Data cutoff: January 10, 2020.

Median T Resolution o

RO7198457 IV Dose + Atezolizumab 1200 mg IV q3w	Media Onset T (n
15 µg	5.7 (1
25 µg	4.0 (
38 µg	4.1 (
50 µg	3.2 (

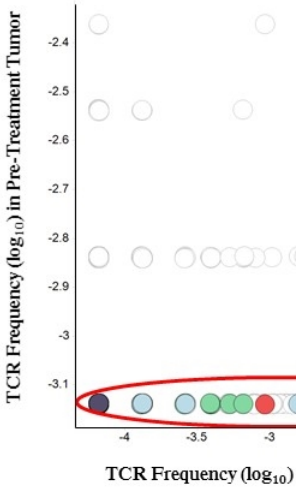
RO7198457 + Atezolizumab Induced Neoantigen-Spe Responses in the Majority of Patients

- Induction of pro-inflammatory cytokines with each dose was observed, similar to findings in the Phase Ia[a]
- Ex vivo T-cell responses were detected (ELISPOT and MHC multimers) in nearly 73% of patients evaluated (n = 63)



- Median number of 2.6 neoantigen-specific responses (range, 1-9). Ex vivo data are not available for all vaccine targets due to limited material availability and T-cell fitness
- Both CD4 and CD8 T-cell responses were detected in patients where it was possible to delineate them (n = 14)
- In vitro stimulation with ELISPOT as a more sensitive measure of immune response to RO7198457 is ongoing

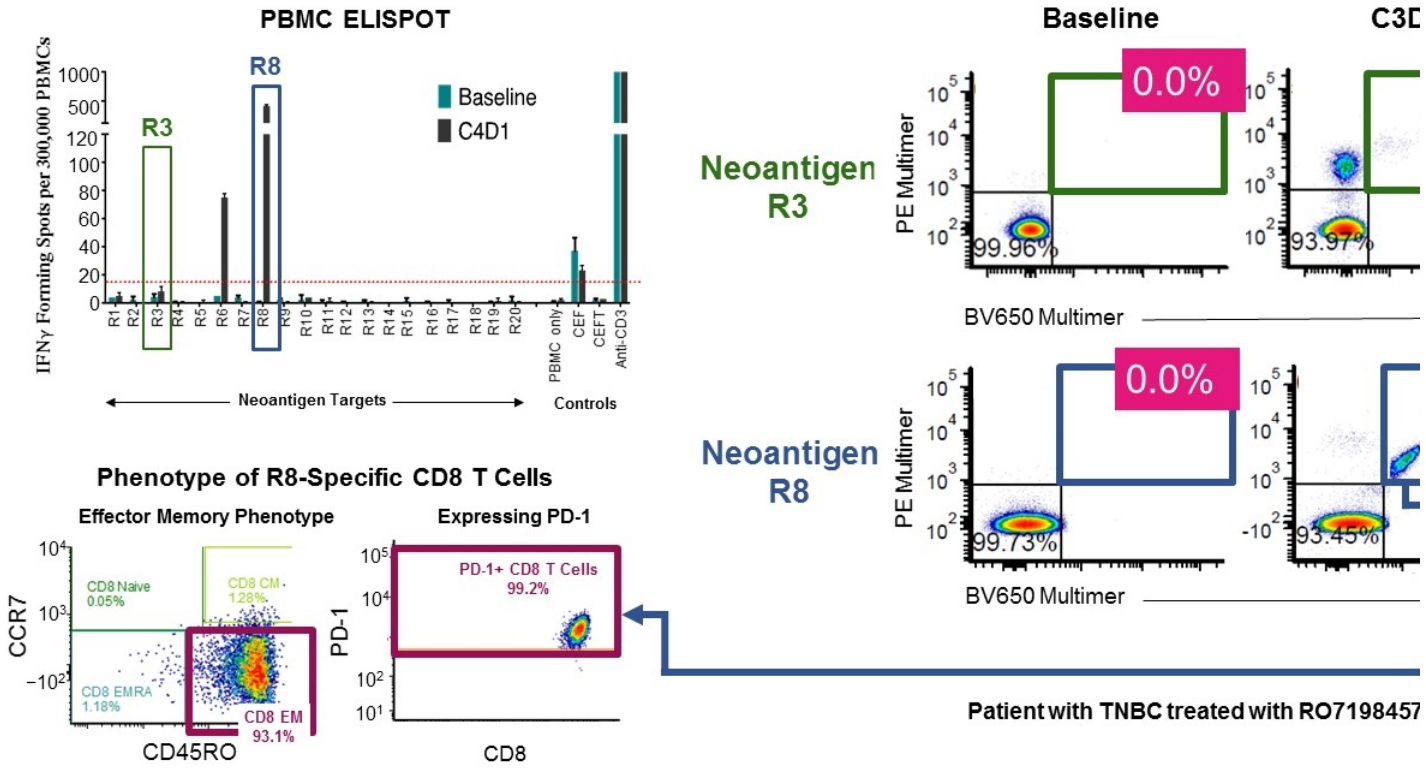
- Preliminary evidence sugge stimulated T cells in the tum with RO7198457 38 µg + at



[a] See Braiteh et al. AACR II 2020. Poster CT169. [b] In collaboration with Adaptive Biotechnologies. Data cutoff: January 10, 2020.

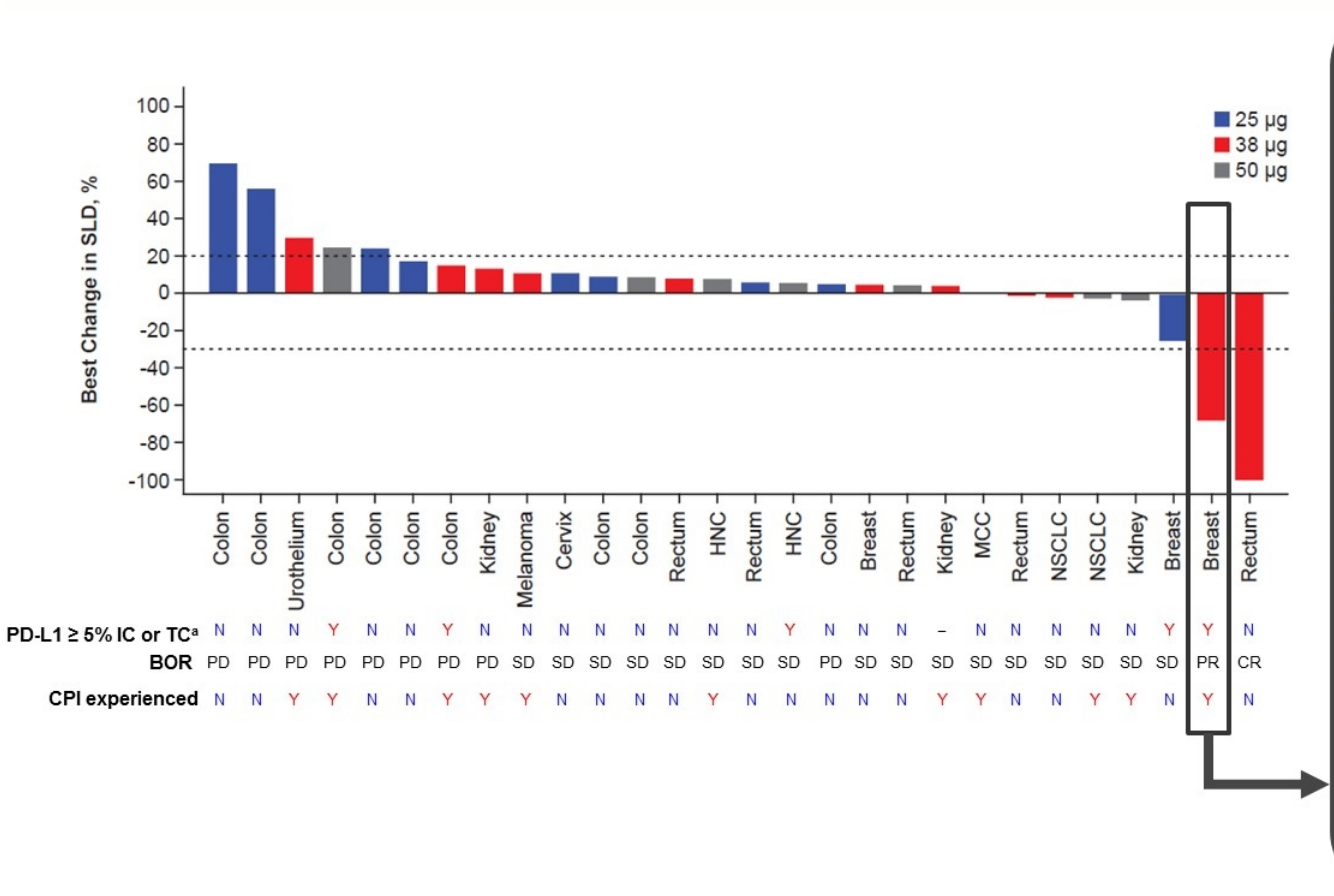
Ex Vivo T-Cell Responses Induced by RO7198457 +

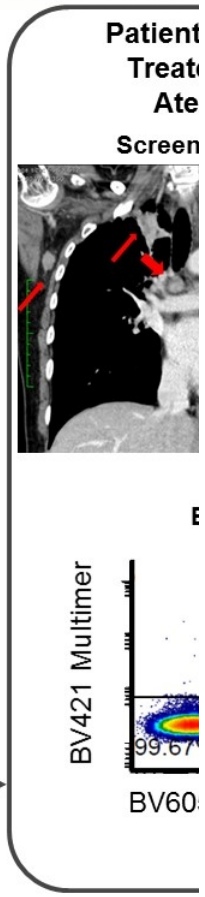
- The magnitude of CD8 T cells induced by RO7198457 can reach > 5% in peripheral blood, with pr phenotype and high expression of PD-1



D, day; IFN, interferon; PBMC, peripheral blood mononuclear cell; PD-1, programmed death-1; SD, stable disease.
[a] Best response of SD; PD-L1 ≥ 5% IC or TC.

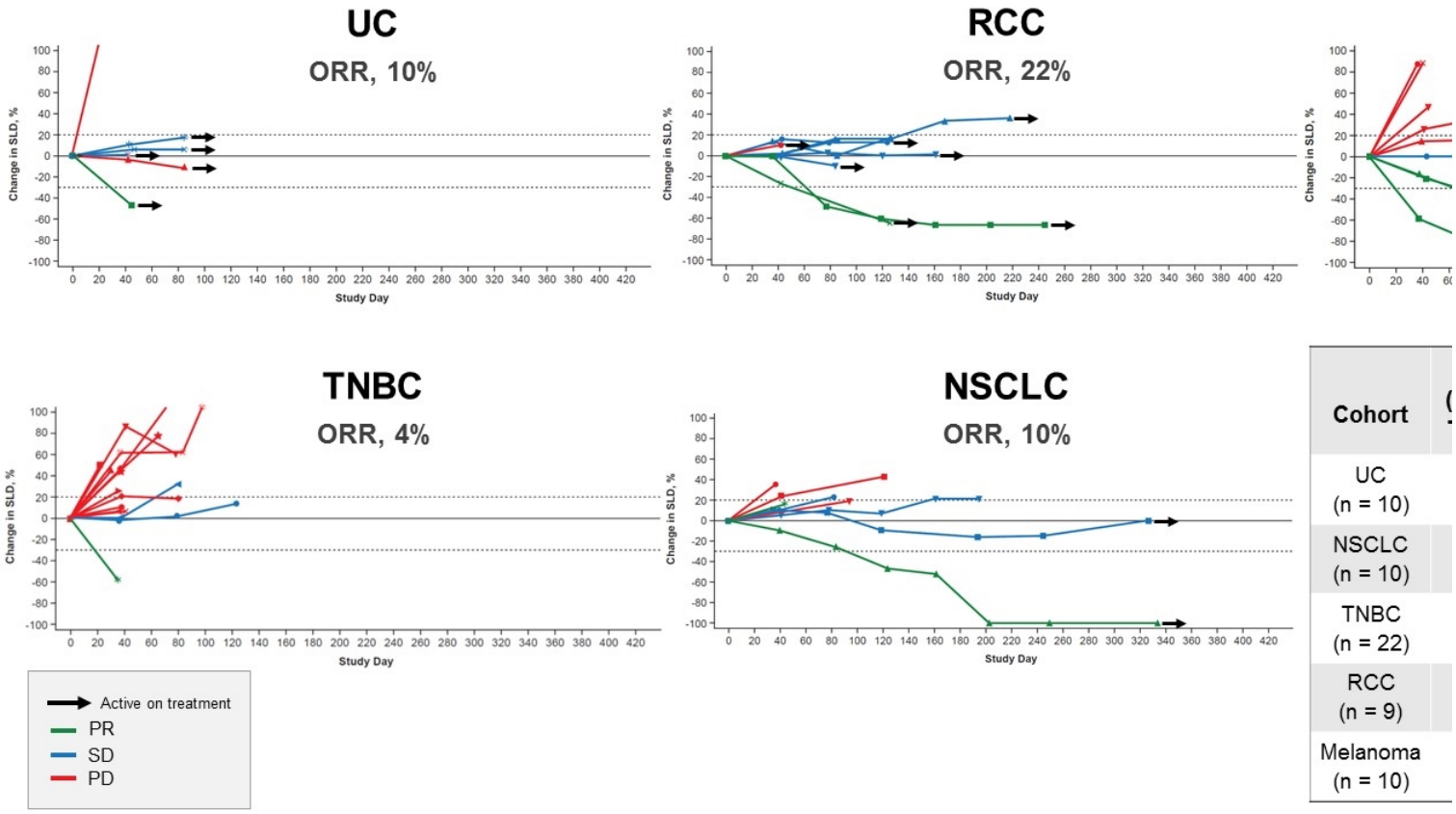
Dose Escalation: RO7198457 + Atezolizumab Clinica





BOR, best overall response; CR, complete response; HNC, head and neck cancer; MCC, Merkel cell carcinoma; N, no; PR, partial response; Y, yes.
[a] PD-L1 expression on IC/TC analyzed by the Ventana SP142 assay. Data cutoff: January 10, 2020.

CPI–Naive Dose Expansion Activity: RO7198457 25



Cohort	
UC (n = 10)	
NSCLC (n = 10)	
TNBC (n = 22)	
RCC (n = 9)	
Melanoma (n = 10)	

ORR, objective response rate.
[a] PD-L1 expression on IC/TC analyzed by the Ventana SP142 assay.
Data cutoff: January 10, 2020.

Summary and Conclusions

- RO7198457 combined with atezolizumab was generally well tolerated
  - MTD was not reached and no DLTs were observed
  - Treatment-related AEs were primarily systemic reactions, manifesting as lo
    ILI symptoms that were transient, reversible and manageable in the outpatie
- RO7198457 in combination with atezolizumab induced the release of pro-inflamm
  peripheral T-cell responses in the majority of patients
  - Preliminary evidence suggests infiltration of RO7198457–stimulated T cells
    more detailed analysis of intra-tumoral immune responses is being evaluate
    biomarker cohort
- Delineation of the efficacy of combination treatment and correlation with immune
  investigation in 2 ongoing randomized Phase II studies of RO7198457:
  - RO7198457 + pembrolizumab for the first-line treatment of patients with me
  - RO7198457 + atezolizumab as adjuvant treatment in patients with NSCLC

Acknowledgments

- We thank all of the patients who participated in this study and their families
- We also thank the investigators and clinical research staff at the following clinical sites:

Royal Marsden Hospital
Princess Margaret Cancer Centre
University Hospital Essen
The Angeles Clinic and Research Institute
HonorHealth Research Institute
Herbert Irving Comprehensive Cancer Center, Columbia University
Smilow Cancer Center, Yale University
UCSF Helen Diller Family Comprehensive Cancer Center
Karolinska University Hospital
Comprehensive Cancer Center Nevada
Providence Cancer Center EACRI
CHU Liege and Liege University
Johannes Gutenberg-Universitat Mainz
Stephenson Cancer Center, The University of Oklahoma
UMC Utrecht
Barts Cancer Institute

University of Colorado Cance
Cancer Research Institute Gh
Memorial Sloan Kettering Ca
Translational Cancer Researc
Massachusetts General Hosp
Seattle Cancer Care Alliance
Dana-Farber Cancer Institute
Uppsala University
University of Southampton
Sarah Cannon Research Inst
Stanford University School of
Netherlands Cancer Institute
Ottawa Hospital Cancer Cent
Lungenfachklinik Immenhaus
University Clinic of Navarra, C

- We thank the Genentech multimer group: Alberto Robert, Leesun Kim, Oliver Zill, Martine Darwis
- Editorial assistance for this presentation was provided by Charli Dominguez, PhD, of Health Intera F. Hoffmann-La Roche, Ltd