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)

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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 22, 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 1a study sponsored by Genentech to evaluate RO7198457, an individualized Neoantigen Specific Immunotherapy (iNeST), 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 22, 2020

EXHIBIT INDEX

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

A Phase Ia Study to Evaluate RO719845 Individualized Neoantigen-Specific Immunotherapy (iNeST), in Patients With Advanced or Metastatic Solid Tumo

Braiteh F,[1] LoRusso P,[2] Balmanoukian A,[3] Klempner S,[3] Camidge DR,[4] Hellmann MI Bendell J,[7] Mueller L,[8] Sabado R,[8] Twomey P,[8] Delamarre L,[8] Huang J,[8] Yadav M,[8] Zha P,[8] Muller F,[10] Derhovanessian E,[10] Tureci O,[10] Sahin U,[10] Siu LL[11]

[1]Comprehensive Cancer Center Nevada, Las Vegas, NV; [2]Smilow Cancer Center, Yale University, New Haven, CT; [3]The Angeles Clinic and [4]Division of Medical Oncology, University of Colorado School of Medicine and Developmental Therapeutics Program, University of Colo [5]Memorial Sloan Kettering Cancer Center, New York, NY; [6]HonorHealth, Scottsdale, AZ; [7]Sarah Cannon Research Institute/Tennessee Onc South San Francisco, CA; [9]F. Hoffmann-La Roche, Ltd, Basel, Switzerland; [10]BioNTech SE, Mainz, Germany; [11]Princess Margaret Ca

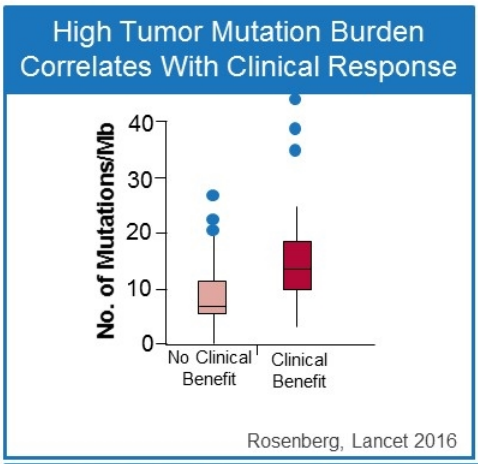
Disclosures

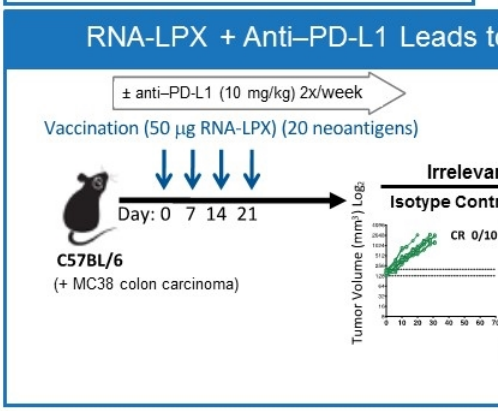
- Dr Braiteh has the following relationships to disclose:
  - Honoraria from Abbott Nutrition, Amgen, ARIAD, Astellas Pharma, AstraZene Ingelheim, Bristol Myers Squibb, Celgene, Daiichi Sankyo, Genentech/Roche Immunomedics, Incyte, Insys Therapeutics, Ipsen, Lexicon, Lilly, Puma Biote Pharmaceutical
  - Consulting/advisory roles for Ambry Genetics, Amgen, AstraZeneca, Bayer, I Bristol Myers Squibb, Celgene, Clovis Oncology, Genentech/Roche, Incyte, I Ipsen, Lexicon, Lilly, Merck, Merrimack, Pfizer, Regeneron and Sanofi
  - Speakers' bureau participation for Amgen, AstraZeneca, Boehringer Ingelhei Squibb, Celgene, Genentech/Roche, Incyte, Insys Therapeutics, Ipsen, Lilly, Pfizer and Taiho Pharmaceutical
  - Travel/accommodations/expenses from Amgen, AstraZeneca/MedImmune, E Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Clovis Oncology, Exeli Insys Therapeutics, Ipsen, Lexicon, Merrimack, Novartis, Pfizer, Regeneron, Sanofi, Taiho Pharmaceutical and Tesaro.

Background

- 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 (RG6180) is a systemically administered RNA-Lipoplex Neoantigen Specific immunoTherapy (iNeST) designed to promote anti-tumor immunity by priming de novo and boosting pre-existing neoantigen-specific T-cell responses

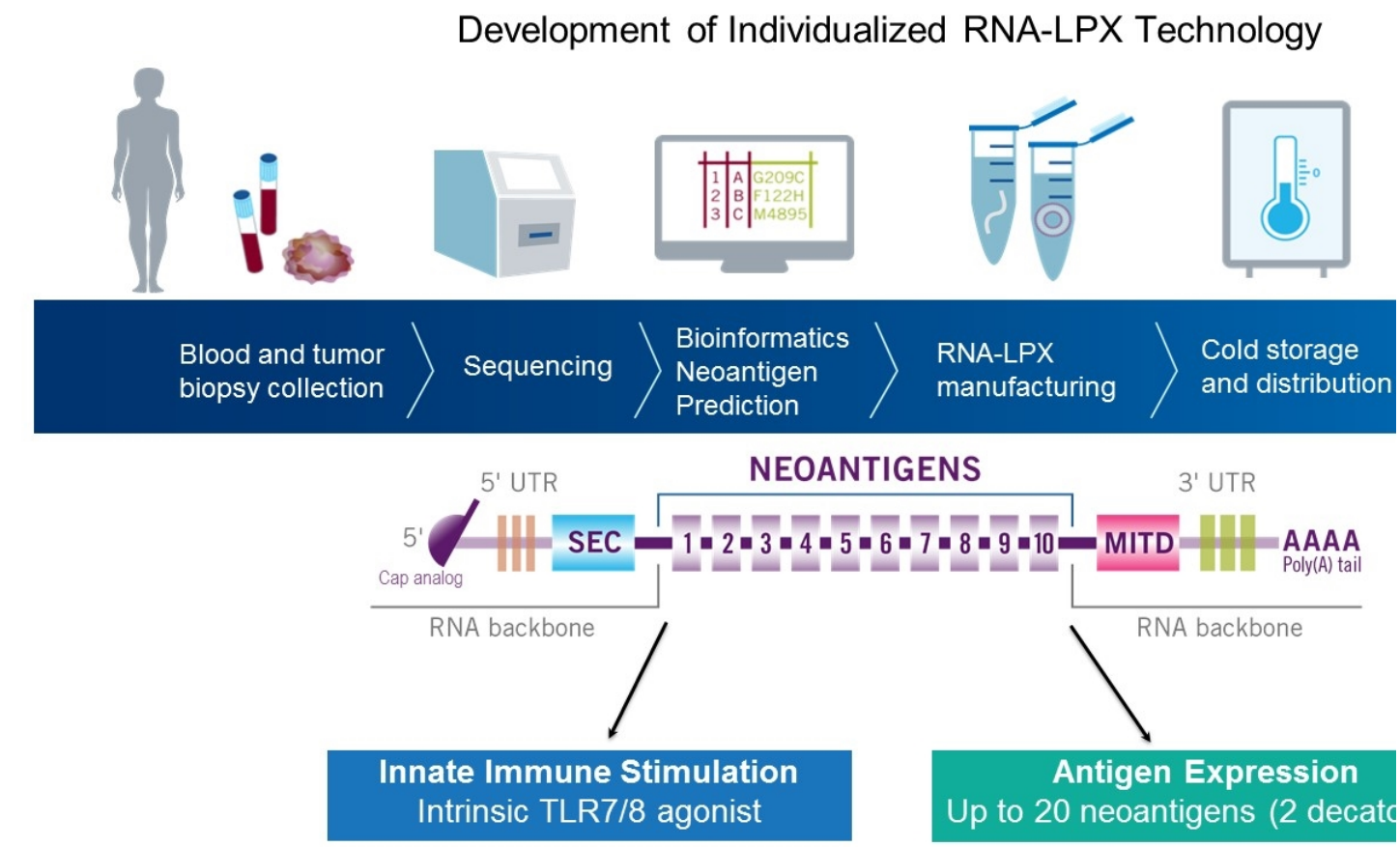
Individual Immune Responses
Need for Individ





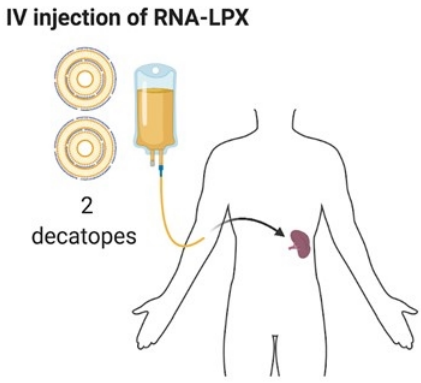
LPX, lipoplex.

Targeting Neoantigens Requires an Individualized A

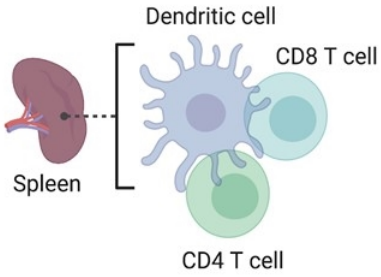


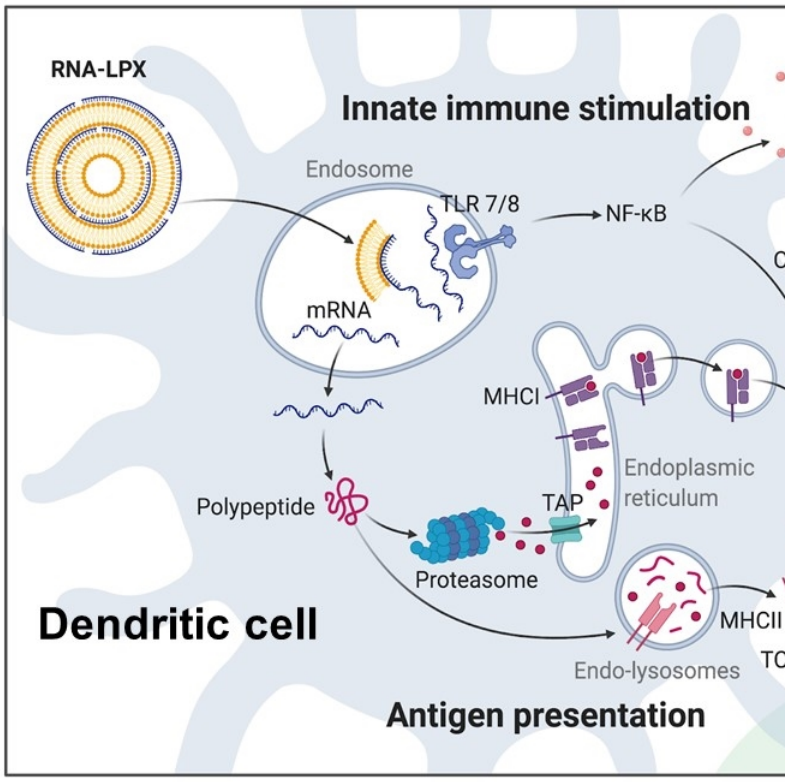
Türeci et al. *Clin Canc Res*. 2016; Vormehr et al. *Annu Rev Med*. 2019; Sahin et al. *Science*. 2018.

Proposed Dual MOA of RO7198457: TLR7/8 Stimulat Neoantigen Presentation



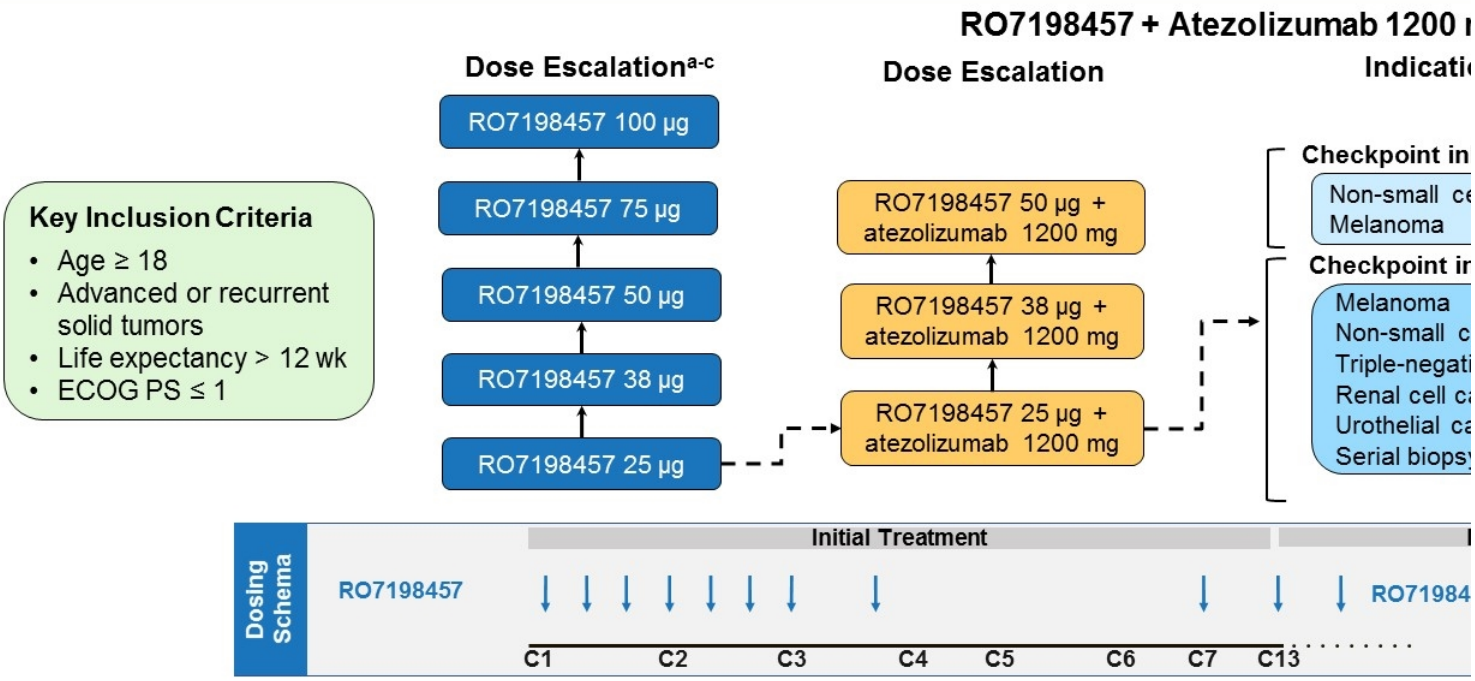
Preferential delivery of RNA-LPX to dendritic cells in the spleen





MHC, Major histocompatibility complex; TCR, T-cell receptor. Kranz et al. *Nature*. 2016.

Methods: Phase Ia Study of RO7198457 monotherap
Solid Malignancies



1 Primary objective
- Safety and tolerability

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

C, cycle; CPI, checkpoint inhibitor; ECOG PS, Eastern Cooperative Oncology Group performance status; MTD, maximum tolerated dose; PD, progressive disease; q3w, RP2D, recommended Phase 2 dose.
[a] 3 + 3 dose escalation: 14-day DLT window; backfill enrollment at cleared dose levels. [b] Phase Ia patients with disease progression or loss of clinical benefit may cross o combination therapy in Phase Ib. [c] See Lopez JS, et al. AACR II 2020. Oral CT301.

Results: Patient Demographics and Disease Charact

	Dose (N
Median (range) age, years	59 (
Female, n (%)	2
ECOG PS, n (%)	
0	1
1	1
Most common tumor types, n (%)	
Breast cancer (HER2+ or HR+)	6
Prostate cancer	5
Ovarian cancer	4
Bone sarcoma	4
Endometrial cancer	
Gastric cancer	
Soft tissue sarcoma	
Median (range) number of prior systemic therapies for metastatic disease, n	5 (
Prior checkpoint inhibitors, n (%)	1
PD-L1 (Ventana SP142), n (%)	
<5% IC and TC	2
≥5% IC or TC	3

ECOG PS, Eastern Cooperative Oncology Group performance status; HER, human epidermal growth factor receptor; HR, hormone receptor; IC, tumor-infiltrating immune cell; PD-L1, programmed death-ligand 1; TC, tumor cell. Data cutoff: January 10, 2020.

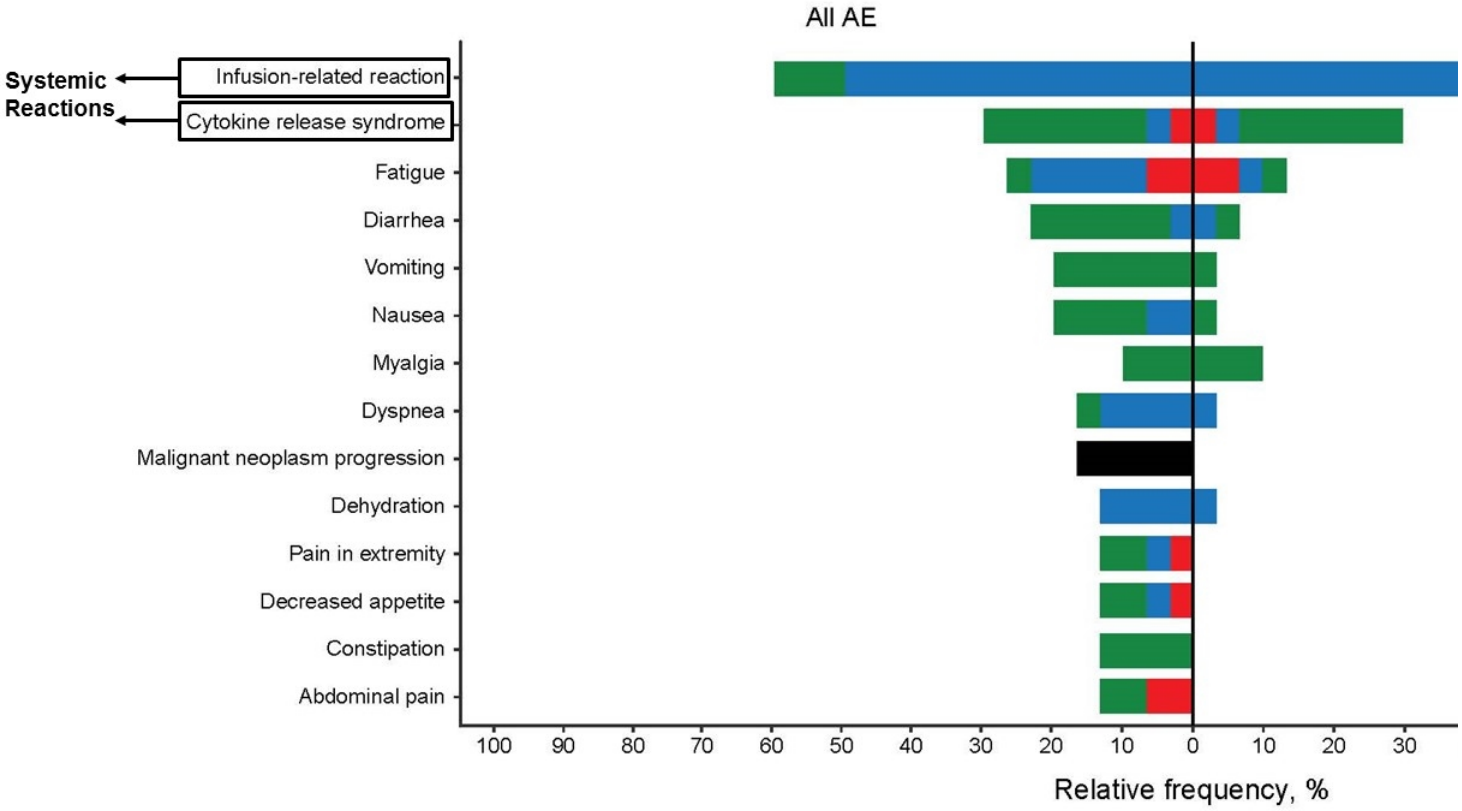
Results: Exposure and Disposition of Patients Durin

	RO7198457 IV Dose			
	25 µg (n = 13)	38 µg (n = 5)	50 µg (n = 4)	75 µg (n = 8)
DLT, n (%)	0	0	0	0
RO7198457 dose reduction, n (%)	0	1 (20)	0	0
Median (range) treatment duration, days	43 (1 - 123)	42 (15 - 128)	40 (15 - 254)	40 (9 - 69)
Continuing treatment, n (%)	0	1 (20)	1 (25)	0
Discontinued study treatment, n (%)	13 (100)	4 (80)	3 (75)	8 (100)
Reasons for treatment discontinuation, n (%)				
Crossover[b]	5 (38)	2 (40)	2 (50)	2 (25)
Disease progression	4 (31)	1 (20)	1 (25)	5 (62)
Death	0	0	0	0
AE	0	0	0	0
Withdrawal by subject	4 (31)	1 (20)	0	0
Other	0	0	0	1 (12)
Discontinued treatment due to disease progression prior to completing 6 weeks of therapy, n (%)	4 (31)	0	2 (50)	2 (25)

AE, adverse event; DLT, dose-limiting toxicity. [a] DLT event was Grade 3 cytokine release syndrome (CTCAE v5.0). [b] Phase Ia patients with disease progression or loss of clinical benefit could cross over to combination therapy in Phase Ib. Data cutoff: January 10, 2020.

Results: Adverse Events in Patients Treated With RC

AEs Reported in > 10% of Patients Treated With



[a] A serious AE of malignant neoplasm progression was reported in 16% of patients (data not shown). [b] Per CTCAE v5.0. Data cutoff: January 10, 2020.

Results: Systemic Reactions (IRR, CRS, ILI) Were Tr Generally Manageable in the Outpatient Setting

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

n (%)	25 µg RO7198457 (n = 13)	38 µg RO7198457 (n = 5)	50 µg RO7198457 (n = 4)	75 µg RO7198457 (n = 8)	100 µg RO7198457 (n = 1)	All Patients (N=31)
Chills	8 (62)	4 (80)	4 (100)	8 (100)	1 (100)	25 (81)
Pyrexia	6 (46)	2 (40)	3 (75)	5 (63)	1 (100)	17 (55)
Nausea	3 (23)	2 (40)	4 (100)	3 (38)	0	12 (39)
Headache	3 (23)	1 (20)	1 (25)	1 (13)	0	6 (19)
Vomiting	3 (23)	1 (20)	1 (25)	0	0	5 (16)
Hypotension	0	1 (20)	0	2 (25)	1 (100)	4 (13)
Hypoxia	0	1 (20)	0	1 (13)	1 (100)	3 (10)
Myalgia	2 (15)	0	0	1 (13)	0	3 (10)
Tachycardia	0	0	1 (25)	2 (25)	0	3 (10)
Neck pain	1 (8)	1 (20)	0	0	0	2 (7)
Sinus tachycardia	1 (8)	1 (20)	0	0	0	2 (7)
Tremor	0	1 (20)	1 (25)	0	0	2 (7)

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

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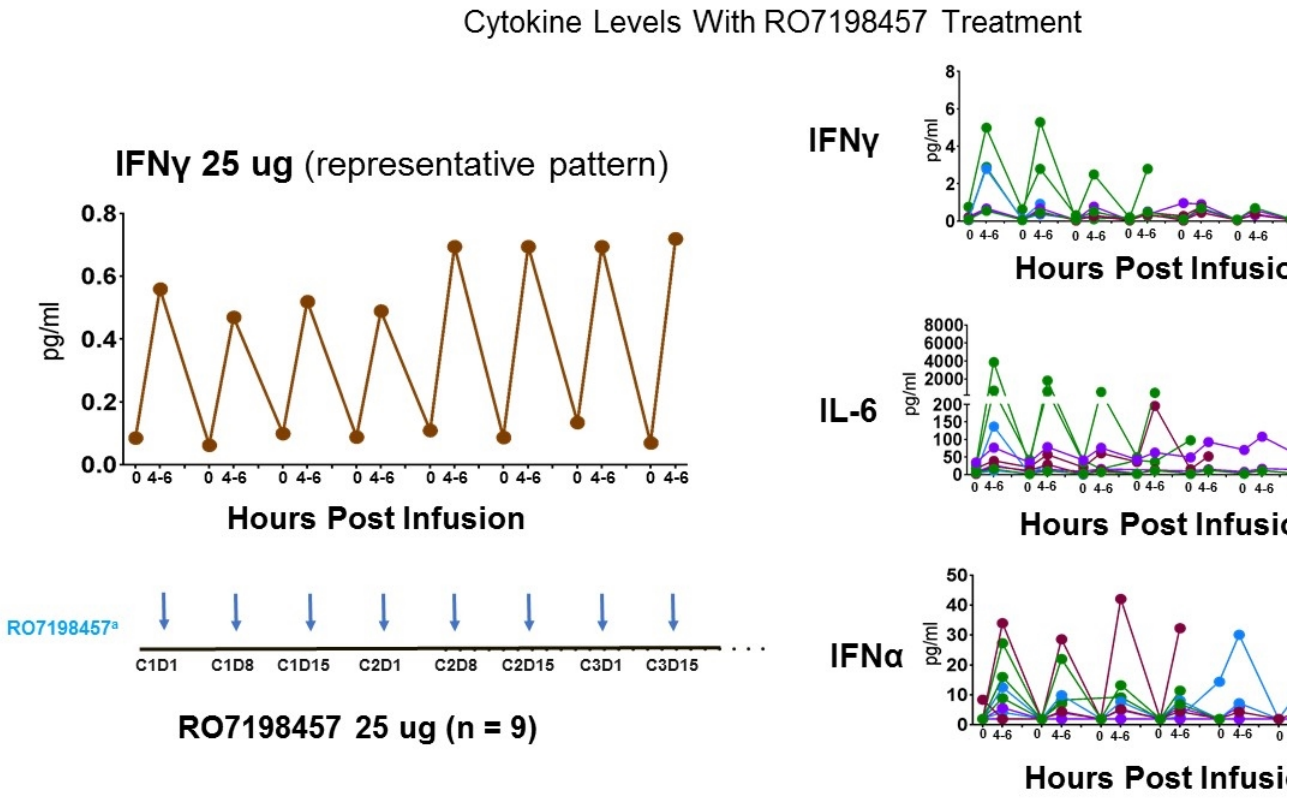
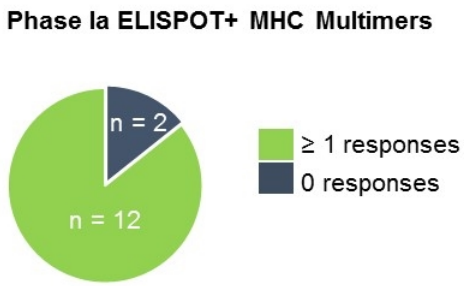
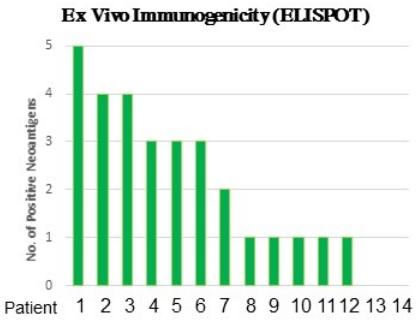
Results: RO7198457 Induced Pulsatile Release of Pro-Infla Cytokines, Consistent With the Innate Immune Agonist Act

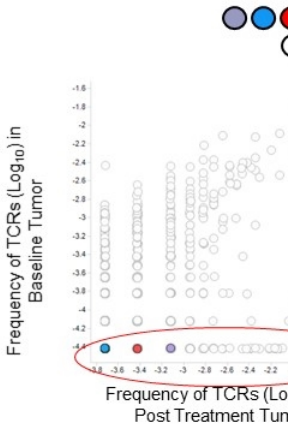


C, cycle; D, day; IFN, interferon; IL, interleukin. Data cutoff: January 10, 2020.

Results: Immune Monitoring of T-Cell Responses In
by RO7198457



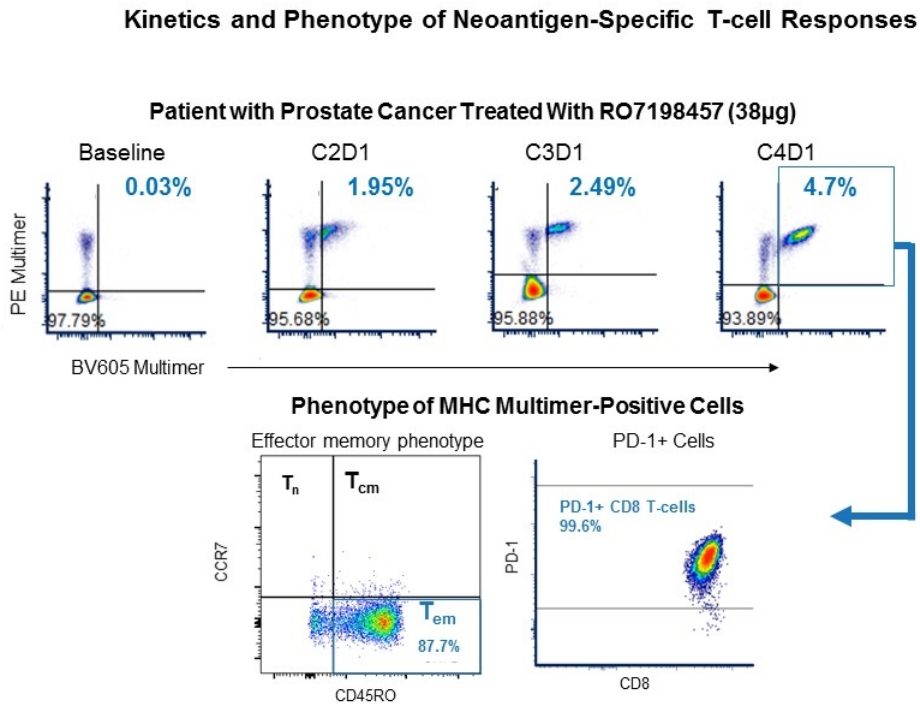




- Ex vivo T-cell responses were detected in 86% of patients evaluated to date
  - Median number of 2 neoantigen-specific responses (range of 1-5). Ex vivo data were not availa targets due to limited material and T-cell fitness
  - In vitro stimulation ELISPOT as a more sensitive measure of immune response to RO7198457 i
- Preliminary evidence suggests infiltration of RO7198457-stimulated T cells in the tumor (patient with treated with RO7198457 75 µg)[a]

[a] In collaboration with Adaptive Biotechnologies. Data cutoff: January 10, 2020.

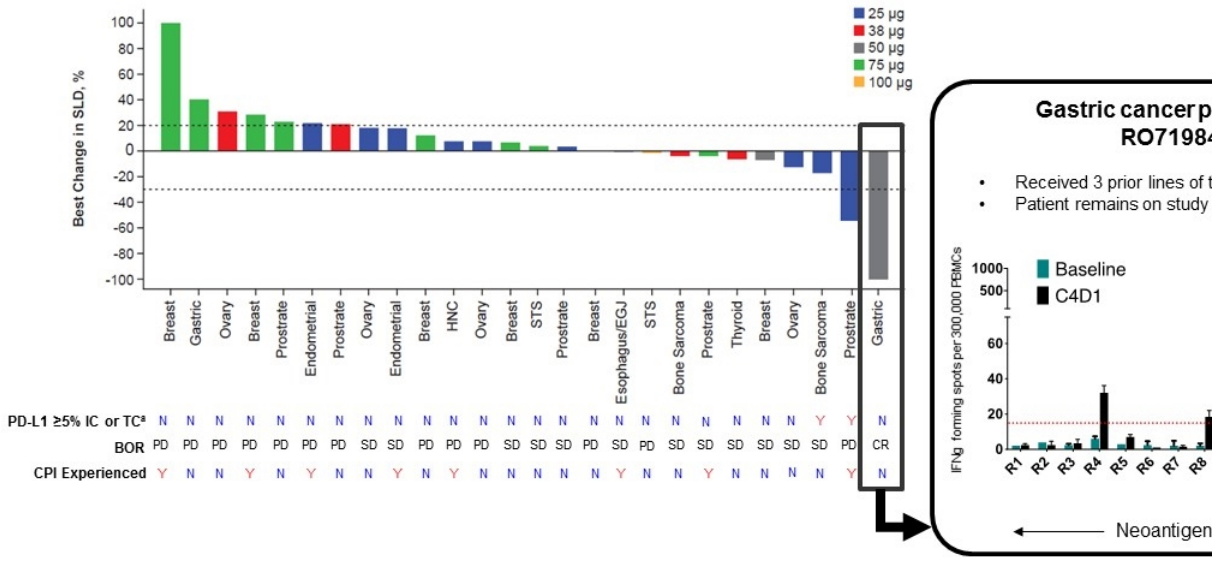
Results: Immune Monitoring of Peripheral Blood–De Responses Induced by RO7198457



PD-1, programmed death-1.

Results: RO7198457 Clinical Activity

Single-Agent Activity of RO7198457



BOR, best overall response; CPI, checkpoint inhibitor; CR, complete response; HNC, Head and neck cancer; N, no; PR, partial response; SD, stable disease; STS, Soft tissue sarcoma; Y, yes; N, no.

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

Conclusions

- RO7198457 was generally well tolerated
  - One DLT of Grade 3 CRS occurred in the 100 µg dose cohort; the maximum tolerated dose wa
  - Treatment-related AEs were primarily transient systemic reactions, manifesting as low-grade C Systemic reactions were generally manageable in the outpatient setting
- Results from comprehensive immune monitoring were reflective of the dual mechanism of action of
  - Induction of pulsatile release of pro-inflammatory cytokines with each dose
  - Induction of neoantigen-specific T-cell responses was observed
  - Preliminary evidence suggests infiltration of RO7198457-stimulated T cells in the tumor; a more tumoral immune responses is being evaluated in dedicated biomarker cohort
- One CR was observed in a patient with gastric cancer
- A Phase Ib study of RO7198457 in combination with atezolizumab is ongoing (see Lopez JS, et al. oral CT301)
- Two randomized Phase II studies of RO1798457 are ongoing:
  - RO7198457 + pembrolizumab for the first-line treatment of patients with melanoma (NCT03815
  - RO7198457 + atezolizumab as adjuvant treatment in patients with non-small cell lung cancer (N

Acknowledgments

- We thank all of our patients who participated in this study and their families
- We also would like to thank the investigators and clinical research staff at the following clinical sit
  - Comprehensive Cancer Center Nevada
  - Smilow Cancer Center, Yale University
  - The Angeles Clinic and Research Institute
  - University of Colorado School of Medicine and Developmental Therapeutics Program
  - Memorial Sloan Kettering Cancer Center
  - HonorHealth
  - Sarah Cannon Research Institute/Tennessee Oncology
  - Princess Margaret Cancer Centre, Toronto, Canada
- We thank the Genentech multimer group: Alberto Robert, Leesun Kim, Oliver Zill, Martine Darwish
- Editorial assistance for this presentation was provided by Charli Dominguez, PhD, of Health Intera F. Hoffmann-La Roche, Ltd