Poster 309P

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Antineoplastic Therapies After Alpelisib, or Placebo, + Fulvestrant in Patients With Hormone Receptor-Positive (HR+), Human Epidermal Growth Factor Receptor 2-Negative (HER2–), *PIK3CA*-Mutated Advanced Breast Cancer (ABC): An Analysis From SOLAR-1

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CONCLUSIONS

- This post hoc, descriptive analysis from the Phase III SOLAR-1 study demonstrated a numerically lower frequency of CT-based regimens chosen as the first subsequent ANP tx in the ALP than in the PBO arm in the population of patients who had at least one subsequent ANP treatment (47% vs 55%)
  - This trend was also observed within the subgroup of patients who progressed within 6 months, across regions, especially in Europe and North America (>20% lower), and in patients <65 years of age
- Patients who received ALP + FUL did not experience diminished duration of subsequent ANP tx (CT, HT, CDK4/6is, and mTORis) as measured by the restricted mean, thus patients continue to experience benefit while on subsequent ANP tx
  - This is consistent with previously reported data from SOLAR-1 showing a near double PFS2 benefit (4.6 month-longer median) and a 7.9-month numeric increase in median OS with ALP + FUL, as compared with PBO + FUL[6]; this suggests that treatment with ALP allows patients to derive a clinical benefit from subsequent therapies
- Together with the statistically significant PFS benefit observed in SOLAR-1, this study further supports the clinical benefit and early use of ALP + FUL in patients with HR+, HER2– *PIK3CA*-mutated ABC after progressing on endocrine therapy

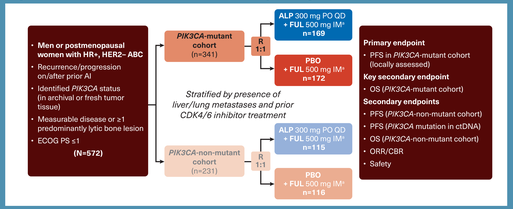
This study is sponsored by Novartis Pharmaceuticals Corporation.

Poster presented at the 2021 ESMO Annual Congress, held virtually on 16–21 September 2021.

INTRODUCTION

- Alpelisib (ALP) is the first and only α-selective phosphatidylinositol 3-kinase inhibitor (PI3Ki) and degrader approved in combination with fulvestrant (FUL) for the treatment of HR+, HER2–, *PIK3CA*-mutated ABC[1-3]
- ALP, in combination with FUL, demonstrated significant prolongation of progression-free survival (PFS) vs placebo (PBO) + FUL in patients with HR+, HER2–, *PIK3CA*-mutated ABC in the Phase III SOLAR-1 trial[4,5]
  - mPFS was 11.0 months for patients treated with ALP + FUL vs 5.7 months in patients treated with PBO + FUL (HR 0.65; one-sided *P*=0.00065)
  - The SOLAR-1 study design is shown in **Figure 1**
- Patients with *PIK3CA*-mutated disease in SOLAR-1 treated with ALP + FUL also experienced a 7.9-month numeric improvement in median overall survival, a 4.6-month–longer median PFS2 (time from randomisation to the first documented disease progression on first new subsequent antineoplastic [ANP] therapy [tx] after discontinuation of study treatment, or death from any cause) and a delay of 8.5 months in time to chemotherapy compared with the PBO + FUL arm[6]
- The objective of this analysis was to describe subsequent ANP tx and their outcome in patients with HR+, HER2– *PIK3CA*-mutated ABC from SOLAR-1

Figure 1. SOLAR-1 (NCT02437318) Study Design



[a]FUL given on Day 1 and Day 15 of the first 28-day cycle, then Day 1 of subsequent 28-day cycles.
AI, aromatase inhibitor; ALP, alpelisib; CBR, clinical benefit rate; CDK4/6, cyclin-dependent kinases 4 and 6; ctDNA, circulating tumour DNA; ECOG PS, Eastern Cooperative Oncology Group performance status; FUL, fulvestrant; IM, intramuscular; ORR, overall response rate; OS, overall survival; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; PFS, progression-free survival; PO, orally; QD, daily; R, randomisation.

METHODS

- Of 341 patients enrolled in SOLAR-1 with *PIK3CA*-mutated disease, 169 had received ALP + FUL and 172 had received PBO + FUL; 164 (95.3%) had discontinued study treatment in the PBO arm, vs 148 (87.6%) in the ALP arm
  - The main reason for study treatment discontinuation was disease progression in both arms (80.2%, n=138 in the PBO arm and 65.7%, n=111 in the ALP arm)
- From the patients who discontinued study treatment, a similar proportion received subsequent ANP tx (79.1%, n=117 in the ALP arm and 81.7%, n=134 in the PBO arm)
- This post hoc, descriptive analysis includes patients from SOLAR-1 with HR+, HER2–, *PIK3CA*-mutated ABC who had at least 1 subsequent ANP tx at the time of the data cutoff (23 April 2020)
  - This analysis focused solely on the *PIK3CA*-mutant cohort, which met the primary endpoint in SOLAR-1[4]

Analyses of Subsequent ANP Therapy

- First subsequent ANP tx were summarised into mutually exclusive groups:
  - Chemotherapy (CT)-based (CT ± other treatment)
  - Hormonal therapy (HT)-based (HT ± other treatment, except CT, cyclin-dependent kinase 4/6i inhibitor [CDK4/6i], mammalian target of rapamycin inhibitor [mTORi], and PI3Ki)
  - Targeted therapy (TT; includes HT + CDK4/6i and HT + mTORi; there was no occurrence of HT + PI3Ki)
- Duration of first subsequent ANP tx was summarised using the restricted mean survival time up to the maximum observed time in the ALP or PBO arms, whichever came first

Statistical Analyses

- The restricted mean survival time can be interpreted as the mean event-free survival time up to a prespecified point. It is defined as the area under the Kaplan-Meier curve from time 0 up to that given time point, for which the largest observed time is used. This methodology has been chosen in order to integrate the survival probabilities across all possible time points from the patients included in the study
- The restricted mean survival time for the first subsequent treatment is based on the difference between the restricted mean survival time: time to the end date minus time to the start date of first subsequent ANP tx
- The weighted logistic and Cox regressions were performed using inversed propensity scoring matching method (inverse probability treatment weighting) to ensure compatible patient characteristics between treatment arms
- Analyses are descriptive to serve for hypothesis generation

RESULTS

Demographics and Baseline Patient Characteristics

- Among those who received subsequent ANP tx, distribution of baseline disease characteristics and demographics varied in patients receiving a subsequent ANP tx
  - There were slightly more patients with visceral disease in the PBO arm (60%; n=81) compared with the ALP arm (55%; n=64) and more patients with primary endocrine resistance in the ALP arm (15%; n=17) compared with the PBO arm (11%; n=15)
- CT-based first subsequent ANP tx was more frequent in the PBO arm than in the ALP arm (55%, n=74 in PBO arm and 47%, n=55 in ALP arm) i
  - Among those <65 yrs (67 patients on PBO and 65 patients on ALP), CT-based first subsequent treatment was more frequent in the PBO arm (60%, n=40) than in the ALP arm (52%, n=34)
- Baseline characteristics for patients prior to randomisation are summarised in **Table 1** by first subsequent post-progression ANP tx; first, second, and third subsequent ANP tx received are described in **Supplemental Table 1**

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Table 1. Demographics and Disease Characteristics of Patients, Prior to SOLAR-1 Randomisation, by First Subsequent ANP Tx[a,b]

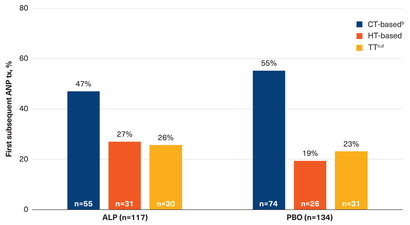
	All Patients With *PIK3CA*-Mutated Disease Who Received Subsequent Therapy					
	ALP + FUL (n=117)			PBO + FUL (n=134)		
Characteristics, n (%)	CT-based n=55	HT-based[c] n=31	TT n=30[d]	CT-based n=74	HT-based n=26	TT n=31[e]
Age, median (range), years	62.0 (35.0-87.0)	68.0 (44.0-79.0)	61.0 (37.0-83.0)	64.0 (45.0-80.0)	66.5 (44.0-89.0)	60.0 (43.0-81.0)
<65	34 (61.8)	12 (38.7)	19 (63.3)	40 (54.1)	9 (34.6)	18 (58.1)
≥65	21 (38.2)	19 (61.3)	11 (36.7)	34 (45.9)	17 (65.4)	13 (41.9)
Number of metastatic sites ≥3	16 (29.1)	6 (19.4)	11 (36.7)	27 (36.5)	6 (23.1)	10 (32.3)
Metastatic sites						
Bone only	13 (23.6)	9 (29.0)	6 (20.0)	12 (16.2)	6 (23.1)	9 (29.0)
Visceral	32 (58.2)	14 (45.2)	18 (60.0)	49 (66.2)	15 (57.7)	17 (54.8)
Liver and/or lung	32 (58.2)	14 (45.2)	16 (53.3)	49 (66.2)	15 (57.7)	17 (54.8)
Endocrine resistance status						
Primary resistance[f]	12 (21.8)	1 (3.2)	4 (13.3)	8 (10.8)	1 (3.8)	6 (19.4)
Secondary resistance[g]	39 (70.9)	19 (61.3)	22 (73.3)	64 (86.5)	18 (69.2)	19 (61.3)
Sensitive[h]	2 (3.6)	9 (29.0)	3 (10.0)	2 (2.7)	6 (23.1)	6 (19.4)
Line of advanced anti-cancer treatment						
First line	25 (45.5)	18 (58.1)	11 (36.7)	39 (52.7)	12 (46.4)	18 (58.1)
Second line	30 (54.5)	13 (41.9)	17 (56.7)	34 (45.9)	14 (53.8)	13 (41.9)

[a]1 and 3 patients in the ALP and PBO arms, respectively, received treatment that could not be classified into these categories. [b]Includes 29 patients who discontinued study treatment due to reasons other than progressive disease (n=18 in the ALP arm, n=11 in PBO arm). [c]HT includes FUL, exemestane, tamoxifen, letrozole, anastrozole + FUL, medroxyprogesterone acetate, tamoxifen citrate, and toremifene. [d]HT + CDK4/6i (n=15) and HT + mTORi (n=15). [e]HT + CDK4/6i (n=17) and HT + mTORi (n=14). [f]Primary resistance was defined as relapse <24 months while the patient was receiving adjuvant ET or progression <6 months while the patient was receiving ET in metastatic setting. [g]Secondary resistance was defined as relapse ≥24 months while the patient was receiving adjuvant ET, relapse <12 months after the end of adjuvant ET, or progression ≥6 months while the patient was receiving ET in the metastatic setting. [h]Sensitive was defined as those who do not have primary or secondary ET resistance.
ALP, alpelisib; ANP, antineoplastic; CT, chemotherapy; HT, hormone therapy; PBO, placebo; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; TT, targeted therapy; Tx, therapies.

Subsequent ANP Tx After Study Treatment Discontinuation

- **Figure 2** summarises the first subsequent ANP tx after discontinuation of study treatment
  - Despite the study being double blinded, a CT-based tx was chosen more frequently as first subsequent ANP tx in the PBO arm (55%, n=74) compared with the ALP arm (47%, n=55; weighted logistic regression: *P* value=0.132)
  - HT was administered more frequently in the ALP arm (27%, n=31) vs the PBO arm (19%, n=26), included FUL, exemestane, tamoxifen, letrozole, anastrozole + FUL, medroxyprogesterone acetate, and toremifene
  - TT was administered slightly more frequently in the ALP arm (26%, n=30) vs the PBO arm (23%, n=31), included HT, plus a CDK4/6i (palbociclib or ribociclib) or plus an mTORi (everolimus)

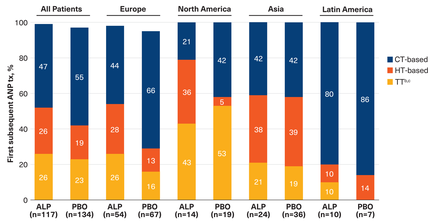
Figure 2. First Subsequent ANP Tx Received After Discontinuation of Study Treatment[a]



[a]1 and 3 patients in the ALP and PBO arms, respectively, received tx that could not be classified into these categories. [b]In the CRF there were 20 patients receiving CT + endocrine therapy and were included in the CT-based group given the presence of CT. [c]In the ALP arm, TT is categorised as follows: HT + CDK4/6i, n=15 and HT + mTORi, n=15. [d]In the PBO arm, TT is categorised as follows: HT + CDK4/6i, n=17 and HT + mTORi, n=14.
ALP, alpelisib; ANP, antineoplastic; CDK4/6i, cyclin-dependent kinases 4 and 6 inhibitor; CT, chemotherapy; HT, hormone therapy; PBO, placebo; mTORi, mammalian target of rapamycin inhibitor; TT, targeted therapy; Tx, therapies.

- Among the 251 patients included in this study, the *PIK3CA*-mut cohort included 86 vs 87 (ALP vs PBO arms) patients in Europe, 19 vs 24 patients in North America, 32 vs 38 patients in Asia, and 14 vs 17 patients in Latin America
- **Figure 3** summarises the first subsequent ANP tx after discontinuation of study treatment by medication type and region
  - Rates and patterns of subsequent therapy varied across regions
  - Across all regions, CT-based treatment as first subsequent ANP tx was used more commonly in the PBO arm compared with the ALP arm in Europe and North America; similar use was observed across both treatment arms in Asia and Latin America
  - CT-based treatment was the most frequently used first subsequent ANP tx in all regions regardless of arm, except in North America, where TT was more commonly used (49%, n=16), possibly due to commercial availability of CDK4/6is at the time the study was conducted

Figure 3. First Subsequent ANP Tx by Medication Type and Region[a]



First subsequent therapy, n (%)	117 (69)	134 (78)	54 (63)	67 (77)	14 (74)	19 (79)	24 (75)	36 (95)	10 (71)	7 (41)
CT-based	55 (47)	74 (55)	24 (44)	44 (66)	3 (21)	8 (42)	10 (42)	15 (42)	8 (80)	6 (86)
HT-based	31 (26)	26 (19)	15 (28)	9 (13)	5 (36)	1 (5)	9 (38)	14 (39)	1 (10)	1 (14)
TT	30 (26)	31 (23)	14 (26)	11 (16)	6 (43)	10 (53)	5 (21)	7 (19)	1 (10)	0

[a]1 and 3 patients in the ALP and PBO arms, respectively, received tx that could not be classified into these categories. [b]In the ALP arm, TT is categorised as follows: All patients—HT + CDK4/6i, n=15 and HT + mTORi, n=15; Europe—HT + CDK4/6i, n=9 and HT + mTORi, n=5; North America—HT + CDK4/6i, n=4, and HT + mTORi, n=2; Asia—HT + CDK4/6i, n=2 and HT + mTORi, n=3; Latin America—HT + CDK4/6i, n=0, and HT + mTORi, n=1. [c]In the PBO arm, TT is categorised as follows: All patients—HT + CDK4/6i, n=17 and HT + mTORi, n=14; Europe—HT + CDK4/6i, n=5 and HT + mTORi, n=6; North America—HT + CDK4/6i, n=8, and HT + mTORi, n=2; Asia—HT + CDK4/6i, n=4 and HT + mTORi, n=3; Latin America—HT + CDK4/6i, n=0, and HT + mTORi, n=0.
ALP, alpelisib; ANP, antineoplastic; CDK4/6i, cyclin-dependent kinases 4 and 6 inhibitor; CT, chemotherapy; HT, hormone therapy; PBO, placebo; mTORi, mammalian target of rapamycin inhibitor; TT, targeted therapy; Tx, therapies.

- Among the 129 patients whose disease progressed within ≤6 months on study treatment and took subsequent ANP tx, CT-based therapy was used more frequently (60%, n=78) than among the 122 patients whose disease progressed after >6 months (42%, n=51)
- Within this group of rapid progressors:
  - The percentage of CT-based tx as first subsequent therapy was higher in the PBO than in the ALP arm (64% vs 56%; **Figure 4**)
  - Based on a weighted Cox regression, mPFS during study treatment was 3.7 months (95% CI, 3.48-4.30) in the ALP arm and 1.9 months (95% CI, 1.8-2.0) in the PBO arm (HR 0.50; 95% CI, 0.3-0.7, *P* value=0.0004)
- In SOLAR-1, long-term disease control was defined as PFS ≥18 months; among those who took at least one subsequent ANP tx, 203 and 48 had PFS <18 and ≥18 months, respectively
  - First subsequent ANP tx by duration of PFS (<18 and ≥18 months) is shown in **Supplemental Table 2**
  - CT-based first subsequent ANP tx was more commonly used in those with PFS <18 months, regardless of arm (55%, n=112) than those with PFS ≥18 months (35%, n=17)

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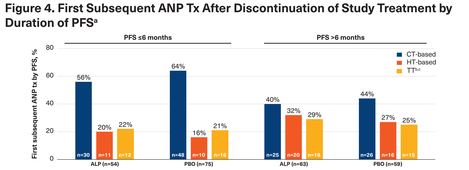
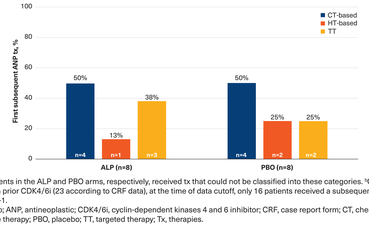
Figure 4. First Subsequent ANP Tx After Discontinuation of Study Treatment by Duration of PFS[a]



[a]1 and 3 patients in the ALP and PBO arms, respectively, received tx that could not be classified into these categories. [b]Among patients with PFS ≤6 months, ALP arm: HT + CDK4/6i, n=5 and HT + mTORi, n=6; PBO arm: HT + CDK4/6i, n=12 and HT + mTORi, n=11. [c]Among patients with PFS >6 months, ALP arm: HT + CDK4/6i, n=13 and HT + mTORi, n=5; PBO arm: HT + CDK4/6i, n=12 and HT + mTORi, n=3.
ALP, alpelisib; ANP, antineoplastic; CDK4/6i, cyclin-dependent kinases 4 and 6 inhibitor; CT, chemotherapy; HT, hormone therapy; PBO, placebo; PFS, progression-free survival; TT, targeted therapy; Tx, therapies.

- For the 20 patients who entered SOLAR-1 after treatment with a prior CDK4/6i, 16 received CT-based treatment, the most-common first subsequent ANP tx in the ALP and PBO arms (**Figure 5**)
  - Most patients in this small group, similar to the full population in this analysis, had CT-based treatment as subsequent therapy, regardless of treatment arm; however, some patients still received TT or HT-based tx
  - TT (HT + mTORi) included everolimus, exemestane, and fulvestrant
  - CT-based tx included paclitaxel, capecitabine, doxorubicin, cyclophosphamide, and bevacizumab
  - HT-based tx included exemestane and fulvestrant

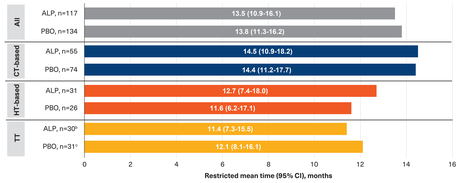
Figure 5. First Subsequent ANP Tx for Patients Entering SOLAR-1 After Prior CDK4/6i and Who Had at Least One Subsequent ANP Tx Following Study Treatment Discontinuation[a,b]



[a]1 and 3 patients in the ALP and PBO arms, respectively, received tx that could not be classified into these categories. [b]Out of all patients with prior CDK4/6i (23 according to CRF data), at the time of data cutoff, only 16 patients received a subsequent treatment after SOLAR-1.
ALP, alpelisib; ANP, antineoplastic; CDK4/6i, cyclin-dependent kinases 4 and 6 inhibitor; CRF, case report form; CT, chemotherapy; HT, hormone therapy; PBO, placebo; TT, targeted therapy; Tx, therapies.

- Restricted mean duration of first subsequent ANP tx was similar between ALP and PBO arms: CT-based, HT-based, and TT as first subsequent treatments was 14.5, 12.7, and 11.4 months in the ALP arm, and 14.4, 11.6, and 12.1 months in the PBO arm, respectively (**Figure 6**)
  - This suggests that patients still derive a benefit from subsequent treatment after ALP

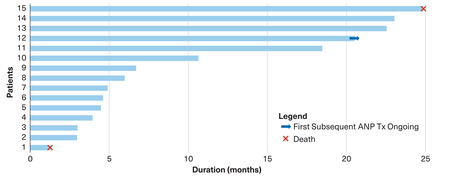
Figure 6. Duration of the First Subsequent ANP Tx[a] by Treatment Arm Using the Restricted Mean Time From KM Curves



[a]1 and 3 patients in the ALP and PBO arms, respectively, received tx that could not be classified into these categories. [b]HT + CDK4/6i (n=15) and HT + mTORi (n=15). [c]HT + CDK4/6i (n=17) and HT + mTORi (n=14).
ALP, alpelisib; ANP, antineoplastic; CDK4/6i, cyclin-dependent kinases 4 and 6 inhibitor; CT, chemotherapy; HT, hormone therapy; KM, Kaplan-Meier; mTORi, mammalian target of rapamycin inhibitor; PBO, placebo; TT, targeted therapy; Tx, therapies.

- In the ALP arm, 15 patients received HT+ CDK4/6i as first subsequent ANP tx; duration of this tx is shown in **Figure 7**

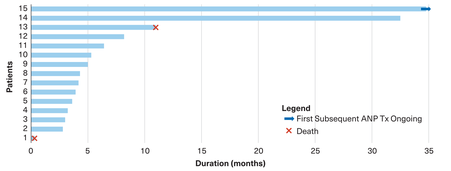
Figure 7. Duration of First Subsequent ANP Tx in Patients Receiving CDK4/6i[a] after Discontinuation of ALP[b]



[a]CDK4/6i includes palbociclib and ribociclib. [b]All patients discontinued study treatment due to progressive disease, with the exception of patients 5 and 11 who discontinued due to patient/guardian decision.
ALP, alpelisib; ANP, antineoplastic; CDK4/6i, cyclin-dependent kinases 4 and 6 inhibitor; Tx, therapies.

- In the ALP arm, 15 patients received HT + mTORi as first subsequent ANP tx; duration of this tx is shown in **Figure 8**

Figure 8. Duration of First Subsequent ANP Tx in Patients Receiving mTORi[a] after Discontinuation of ALP[b]



[a]mTORi was everolimus. [b]All patients discontinued study treatment due to progressive disease, with the exception of patient 14 who discontinued due to patient/guardian decision.
ALP, alpelisib; ANP, antineoplastic; mTORi, mammalian target of rapamycin inhibitor; Tx, therapies.

Acknowledgements

The authors wish to thank the patients who participated in the SOLAR-1 study and their families; members of the SOLAR-1 steering committees, all study investigators, and site staff; members of the independent data monitoring committees, and Dr. Bella Kaufman.

This study was funded by Novartis Pharmaceuticals Corporation.

Medical writing assistance was provided by Monica E. Burgett, PhD, of Healthcare Consultancy Group, LLC, and funded by Novartis Pharmaceuticals Corporation.

Disclosures

Fabrice André declares institutional funding for speaker and advisory fees from Roche, AstraZeneca, Daiichi Sankyo, Pfizer, Novartis, and Eli Lilly; research grants paid to the institution from Novartis, AstraZeneca, Pfizer, Eli Lilly, Daiichi Sankyo, and Roche; and travel fees paid to institution from AstraZeneca, GlaxoSmithKline, Novartis, and Roche. **Hope S. Rugo** declares institutional research funding from Pfizer, Merck, Novartis, Eli Lilly, Genentech, OBI, Odonate, Daiichi-Sankyo, Eisai, Seattle Genetics, MacroGenics, Sermonix, and Immunomedics; travel support from Daiichi-Sankyo, Mylan, Pfizer, Merck, AstraZeneca, Novartis, and MacroGenics; honoraria from Puma and Mylan; and a limited consulting role with Samsung. **Dejan Juric** declares grants and personal fees from Novartis, Genentech, Eisai, EMD Serono, Syros, and Pieris Pharma; personal fees from Ipsen, Vibliome, Relay Therapeutics, and Mapkure; and grants from Takeda, Amgen, Celgene, Placon Therapeutics, InventisBio, and Infinity Pharmaceuticals. **Gábor Rubovsky** declares consulting fees from Novartis; speaker/lecture fees from Novartis, Roche, Lilly; participation in a data safety monitoring board or advisory board from Novartis and Roche. **Toshinari Yamashita** declares fees paid to the institution from Chugai, Taiho, Nippon Kayaku, Kyowa Kirin; lecture fees from Chugai, Eisai, Novartis, Taiho, Nippon Kayaku, AstraZeneca, Kyowa Kirin, Pfizer Japan, Eli Lilly, Daiichi Sankyo. **Salomon M. Stemmer** declares fees paid to the institution from Novartis; research funding paid to the institution from Teva, Clovis Oncology, AstraZeneca, Can-Fite BioPharma, Puma Biotechnology, Lilly, GEICAM, Bristol-Myers Squibb, Roche, MSD, Halozyme, Bioline Rx, Incyte, Silenseed, Tiziana Life Sciences, CTG Pharma, Syncore, Moderna Therapeutics, Exelixis, and Rafael Pharmaceuticals; stock and other ownership interest at Can-Fite BioPharma, TyrNovo, CTG Pharma, VYPE, and DocBioMD; and patents, royalties, and other intellectual property in combo patent, check point inhibitors, CTG Pharma, and VYPE. **Yen-Shen Lu** declares grants from Novartis, MSD and Roche; consulting fees from Novartis, MSD, Pfizer, Eli Lilly; speaker fees from MSD, Pfizer, Eli Lilly, Eisai, Daiichi Sankyo, Roche; travel/meeting fees from Roche, Pfizer, Novartis; advisory boards from MSD, Pfizer, Eli Lilly, Roche; received supply of drug for clinical trial from Pfizer. **Michelle Miller** is an employee of Novartis and holds Novartis stock or stock options. **Inés Lorenzo** is an employee of Novartis and holds Novartis stock or stock options. **Huilin Hu** is an employee of Novartis. **Eva Ciruelos** declares consulting or advisory role for Lilly, Novartis, MSD, AstraZeneca, Pfizer, and Roche; speaker for Roche, Lilly, and Pfizer; and travel, accommodations, and expenses from Roche and Pfizer.

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