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DECEMBER 5-9, 2023 | @SABCSSanAntonio

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Efficacy and safety of first-line atezolizumab, bevacizumab, and paclitaxel in patients with advanced triple-negative breast cancer (aTNBC): the ATRACTIB phase II trial.

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Disclosure Information

María Gion:

I have the following relevant financial relationships to disclose:

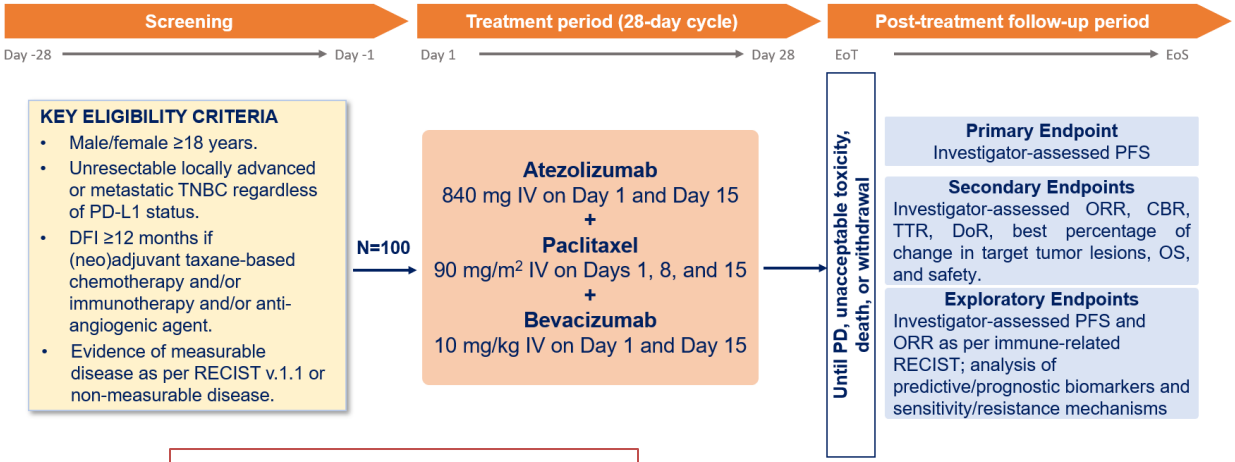
- Consultant for: Daiichi-Sankyo/AstraZeneca, Gilead, Novartis, Pfizer
- Honoraria: F. Hoffman La Roche
- Travel grants: F. Hoffman La Roche, AstraZeneca, Pfizer

Acknowledgements

The ATRACTIB team is extremely grateful to all the patients and their families. We warmly acknowledge all the trial teams of the participating sites, and the trial unit staff at the study sponsor.

This study is sponsored by Medica Scientia Innovation Research (MEDSIR) and funded by Hoffmann-La Roche.

ATRACTIB Phase II trial



Median follow-up 16.7 months (range 1.1 - 34.1).

100 patients included

23 treatment ongoing

Data cut-off:
15th sept 2023

77 Discontinued treatment
62 Disease progression
6 Adverse events
4 Consent withdrawal
1 Sepsis*
4 Other**

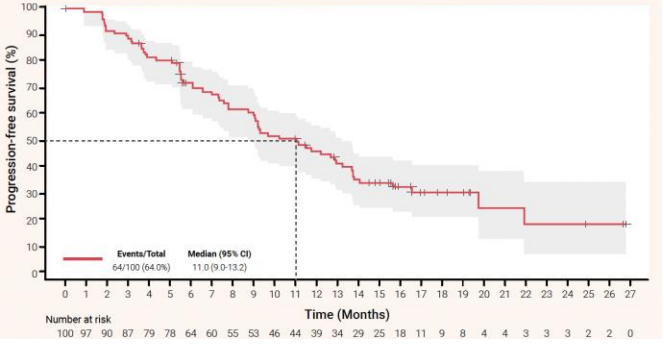
Characteristics, n (%)	Overall (N=100)
Prior early breast cancer disease, n (%)	71 (71%)
Taxane-based chemotherapy, n (%)	61 (86.0%)
De novo metastatic disease, n (%)	29 (29%)

PD-L1 expression#, n (%)	
SP142 (ICs; N=85)	
Negative (<1%)	83 (97.6%)
Positive (≥1%)	2 (2.4%)

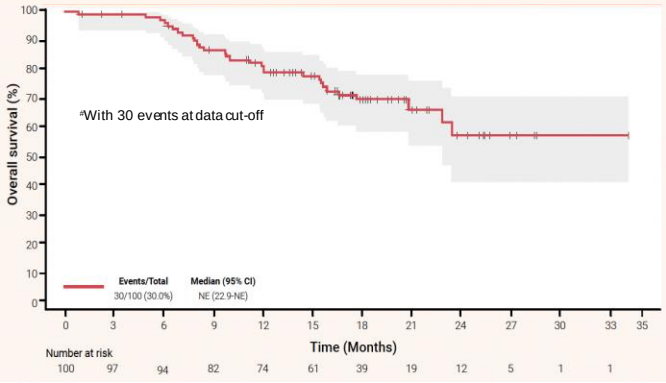
*Did not receive treatment while prolonged hospitalization. **Radical surgical treatment scheduled.
#Centrally assessed using SP142 (ICs) and 22C3 (CPS) antibodies.
ATZ, atezolizumab; BVZ, bevacizumab; CBR, clinical benefit rate; CPS, combined positive score; DFI, disease-free interval; DoR, duration of response; ICs, tumor-infiltrating immune cells; IHC, immunohistochemistry; IV, Intravenous therapy; ORR, overall response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed cell death-ligand 1; PFS, progression-free survival; PTX, paclitaxel; RECIST, Response Evaluation Criteria in Solid Tumors, TNBC, triple-negative breast cancer; TTR, time to response.

Efficacy and Safety results

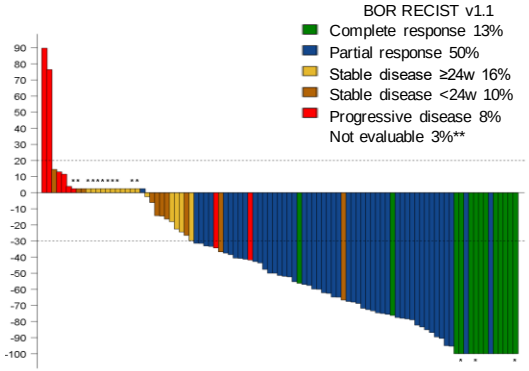
mPFS 11.0 months (95% CI, 9.0 – 13.2)



Estimated 18-month OS[#] 69.4% (95% CI, 58.4% - 78.1%)



Best percentage change in sum of target lesions (%)



Tumor response, n (%)	Confirmed	Unconfirmed
ORR	55.0% (95% CI, 44.7% - 65.0%)	63.0% (95% CI, 52.8% - 72.4%)
CR	11	13
PR	44	50
SD ≥24 w	22	16
SD <24 w	12	10
PD	8	8
NE	4	3
CBR	77.0% (95% CI, 67.5% - 84.8%)	79.0% (95% CI, 69.7% - 86.5%)
Duration of response (median), months		
	10.0 (95% CI, 7.2 – 13.8)	

Summary of TEAEs, most frequent TEAEs (>25%) and irAEs n(%)

TEAEs, n (%)	Overall (N=100)	Treatment-related
Any TEAEs	100 (100.0%)	97 (97.0%)
Grade 3/4 TEAEs	61 (61.0%)	47 (47.0%)
Any serious TEAEs	34 (34.0%)	18 (18.0%)
ECIs	42 (42.0%)	42 (42.0%)
TEAEs leading to treatment discontinuation of:		
Atezolizumab	14 (14%)	-
Bevacizumab	15 (15%)	-
Paclitaxel	40 (40%)	-
TEAEs leading to death	0 (0.0%)	0 (0.0%)
Dose adjustments		
Reduction of Paclitaxel	22 (22.0%)	22 (22.0%)

Most frequent TEAEs, n (%)	Any grade	Grade 3/4
Non-hematologic		
Peripheral neuropathy[‡]	68 (68.0%)	13 (13.0%)
Fatigue	62 (62.0%)	7 (7.0%)
Diarrhea	42 (42.0%)	3 (3.0%)
Alopecia	41 (41.0%)	0 (0.0%)
Stomatitis	37 (37.0%)	3 (3.0%)
Nausea	31 (31.0%)	0 (0.0%)
Hypertension	30 (30.0%)	9 (9.0%)
Hematologic		
Neutropenia	27 (27.0%)	12 (12.0%)

irAEs, n (%)	Any grade	Grade 3/4
Any irAEs	12 (12.0%)	5 (5.0%)
Thyroid disorders	6 (6.0%)	0 (0.0%)
Immune-mediated hepatitis	3 (3.0%)	3 (3.0%)
Nephritis	2 (2.0%)	2 (2.0%)
Addison's disease	1 (1.0%)	0 (0.0%)

*Patients with only non-target lesions. **Three patients discontinued before post-baseline assessment due to Progressive Disease in one patient and to withdrawal of consent in two patients. ‡ Peripheral neuropathy (SMQ), includes Neuropathy peripheral, Neurotoxicity, Polyneuropathy, and Toxic neuropathy (MedDRA v.25.1).
ATZ, atezolizumab; BVZ, bevacizumab; BOR, best overall response; CBR, Clinical Benefit Rate; CI, confidence interval; CR, Complete Response; ECI, events of clinical interest; NE, Not Evaluable; PR, Partial Response; PTX, paclitaxel; SD, Stable Disease; TEAEs, treatment-emergent adverse events.

Conclusions

- **ATZ + BVZ + PTX demonstrated robust antitumor activity in first-line therapy for aTNBC patients:**
  - mPFS 11 months (95% CI, 9-13 months). PD-L1 negative 97.6% (SP142 < 1%, ICs; N=85)
  - ORR 55% (95% CI 44.7% - 65.0%). DoR 10 months (95% CI 7.2-13.8)
  - Estimated 18-month OS 69.4% (95% CI, 58.4% - 78.1%)

- **mPFS with this combination seems to be very promising, especially considering that most of tumors were PD-L1 negative.**

- **The combination of ATZ + BVZ + PTX has a manageable safety profile, with no new safety signals.**

- **These results merit further research on immunotherapy and bevacizumab combinations for patients with PD-L1-negative aTNBC.**