EFFICACIA E PROFILO DI TOSSICITÀ DI NAB-PACLITAXEL SETTIMANALE NEL TRATTAMENTO DELLA NEOPLASIA MAMMARIA IN FASE METASTATICA: L'ESPERIENZA DELL'UNIVERSITÀ DI FIRENZE

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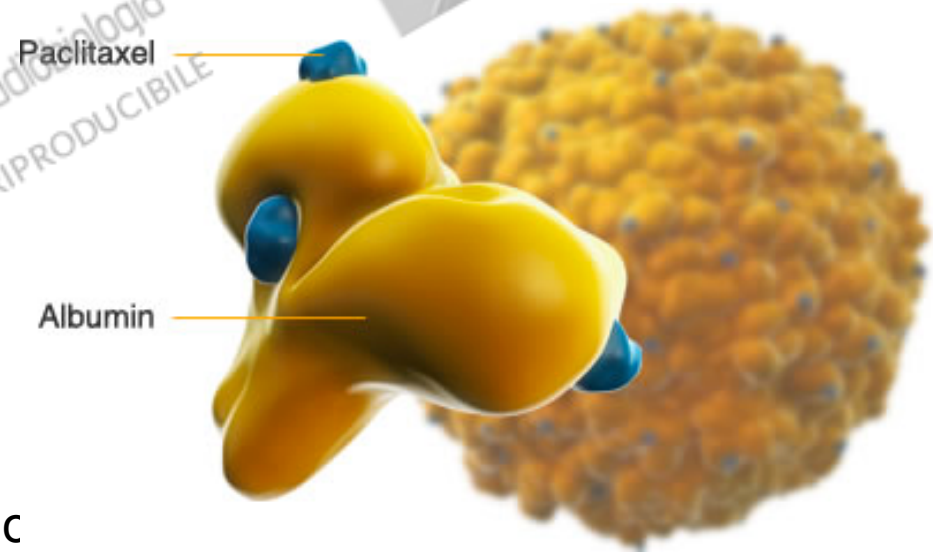
Nab-Paclitaxel ABI-007 (Abraxane®)

Nanoparticle albumin-bound paclitaxel

- colloidal suspension of paclitaxel and human serum albumin
- physiological transport of lipophilic molecules in bloodstream
- interaction with albumin receptors
- higher doses of paclitaxel with shorter infusion schedules and no premedicatic



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ORIGINAL REPORT

Phase III Trial of Nanoparticle Albumin-Bound Paclitaxel Compared With Polyethylated Castor Oil–Based Paclitaxel in Women With Breast Cancer

William J. Gradishar, Sergei Tjulandin, Neville Davidson, Heather Shaw, Neil Desai, Paul Bhar, Michael Hawkins, and Joyce O'Shaughnessy

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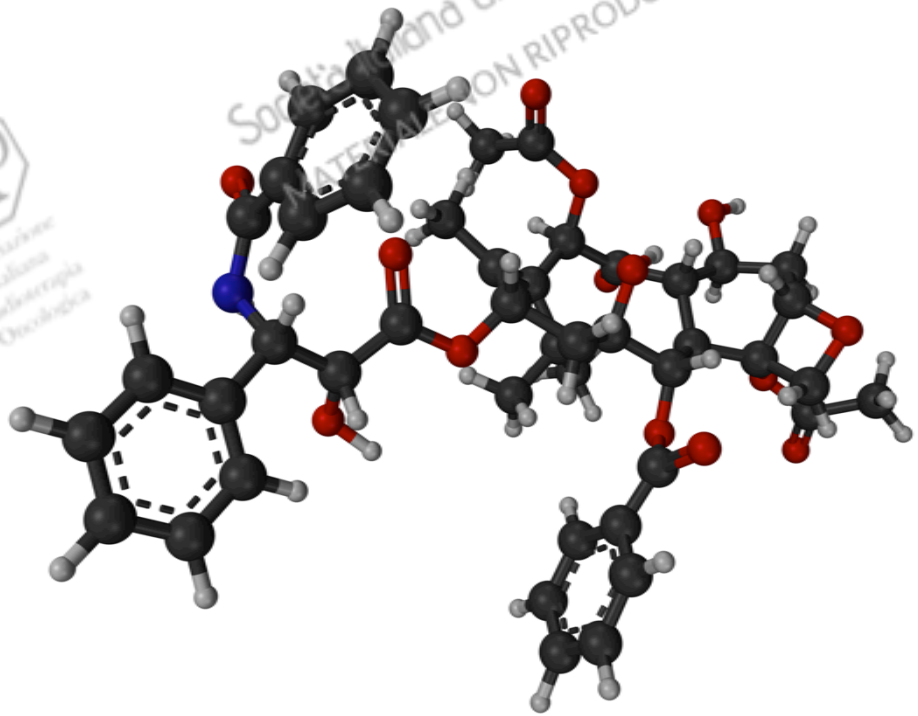
- ORR ABI-007 vs standard paclitaxel = 33% vs 19%; P 0.001
- TTP ABI-007vs standard paclitaxel = 23.0 vs 16.9 weeks; hazard ratio [HR] 0.75; P 0.006, log-rank test

⇒ ABI-007 was superior to standard paclitaxel for both ORR and TTP in all patients with MBC

⇒ ABI-007 was well tolerated and no severe hypersensitivity reactions to ABI-007 occurred despite the absence of corticosteroid premedication

Aim of the study

To evaluate efficacy and safety of nab-paclitaxel in MBC treated in our institution



Materials and Methods

- N = 23 patients
- Period of treatment = from 2011 to 2016
- Weekly nab-paclitaxel 150mg/m²

Patient demographics and disease characteristics

Characteristics	**N (%)** **23**
Median age at diagnosis, y (range)	45.2 (32-65)
Stage at initial diagnosis	
Stage I-II	15 (65.2)
Stage III-IV	8 (34.7)
HR + (ER/PgR+)	22 (95.6)
HER2 amplification	6 (26)
Molecular Subtypes	
Luminal A	6 (26)
Luminal B-HER2-	7 (30.4)
Luminal B-HER2+	6 (26)
Triple negative	1 (4.3)
HER2 like	0

Materials and Methods

Before treatment with nab-paclitaxel

Treatment exposure	
Treatment	**N (%) 23**
Neoadjuvant CMT	4 (17.3)
Surgery	
Mastectomy	8 (34.7)
BCS	14 (60.8)
Adjuvant	
CMT	6 (26)
CMT + RT	12 (52.1)
RT	3 (13)

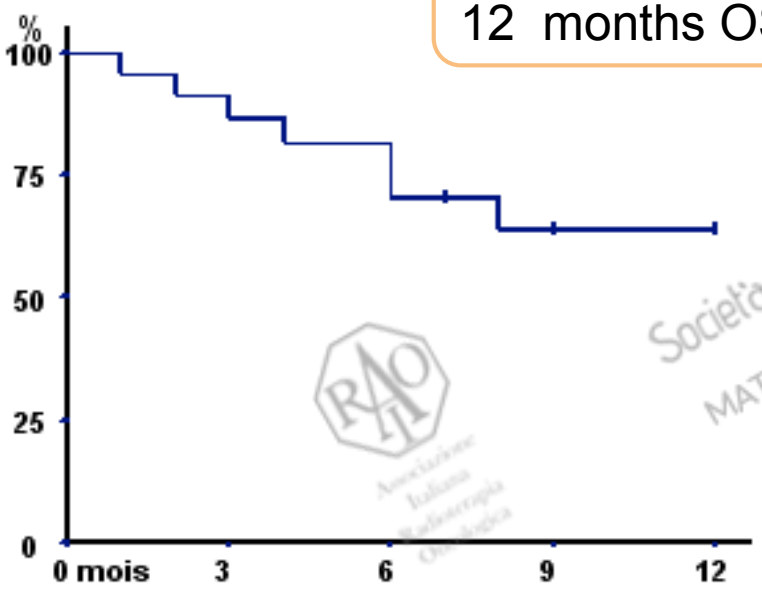
At time of treatment with nab-paclitaxel

Treatment exposure	
Treatment	**N (%) 23**
Median age	51.4
Median of previous chemotherapy metastatic lines (range)	3 (1-9)
1	3 (13)
2	6 (26)
3	4 (17.3)
>4	10 (43.4)
Previous anthracyclines ± taxanes	
Y	18 (78.2)
N	5 (21.7)

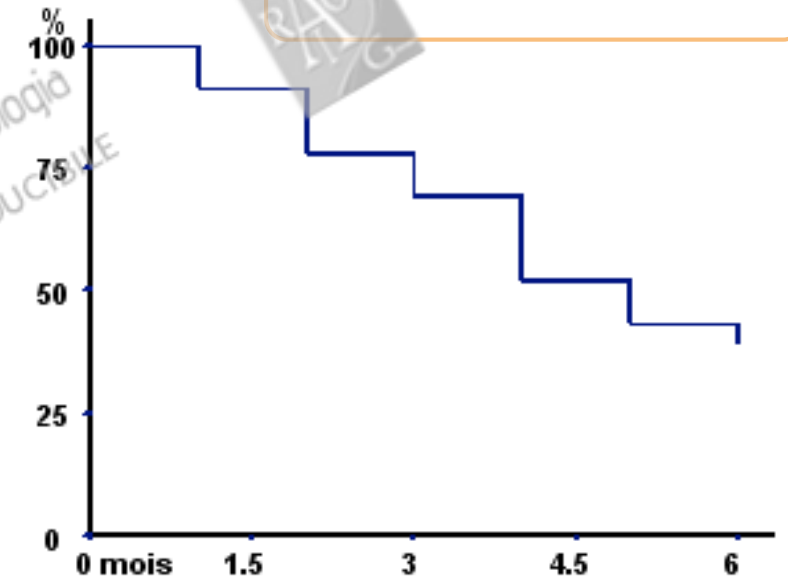
Results

Median follow-up of 48 months (3-62)

6 months OS: 73.9%
12 months OS: 65.2%



6 months PFS: 39.1%



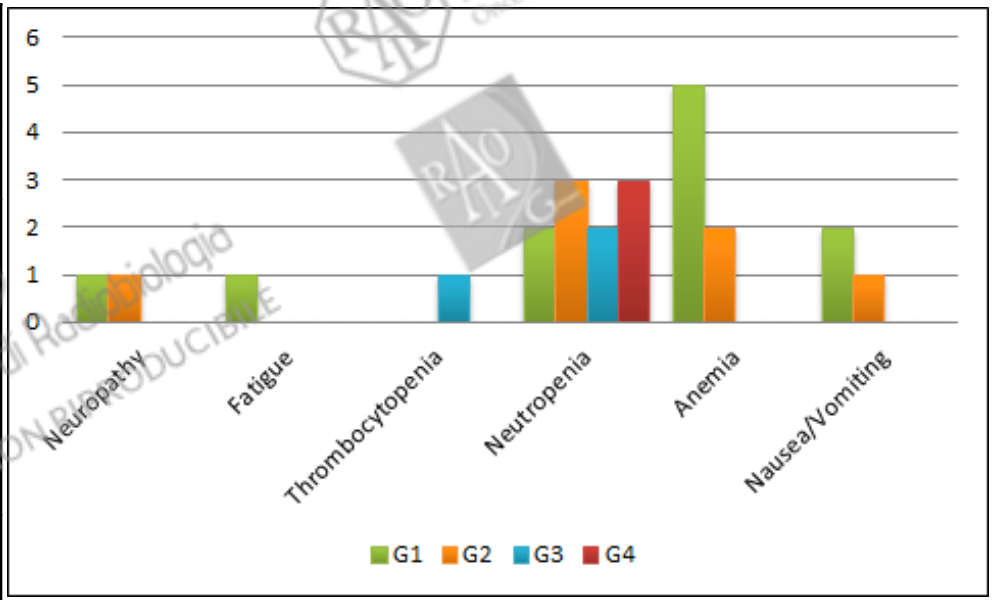
Clinical benifit (PR+SD): 26%

Median duration of response: 7 months

Mean nab-paclitaxel cycles (range): 5 (1-11)

Toxicity

Side Effect	G1 N (%)	G2 N (%)	G3 N (%)	G4 N (%)
Neuropathy	1 (4.3)	1 (4.3)	0	0
Fatigue	1 (4.3)	0	0	0
Thrombocytopenia	0	0	1 (4.3)	0
Neutropenia	2 (8.6)	3 (13)	2 (8.6)	3 (13)
Anemia	5 (21.7)	2 (8.6)	0	0
Nausea/Vomiting	2 (8.6)	1 (4.3)	0	0



- 6 pts (26%) needed dose reduction, 125mg/m²

Conclusions

- According to previously published results, these data demonstrated efficacy and a favorable safety profile
- The absence of premedication and the shorter administration time are important advances especially in MBC patients (QoL!)
- Valid therapeutic option for those patient population who received the most active agents in the adjuvant and/or metastatic setting

Grazie per l'attenzione