2021 ASCO ANNUAL MEETING

ONCO NOUVELLE-AQUITAINE Réseau Régional de Cancérologie

BRIO BORDEAUX | Recherche Intégrée Oncologie

Les « Scoops » en sénologie

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ETUDE OLYMPIA

Tutt A et al., abstr. LBA1

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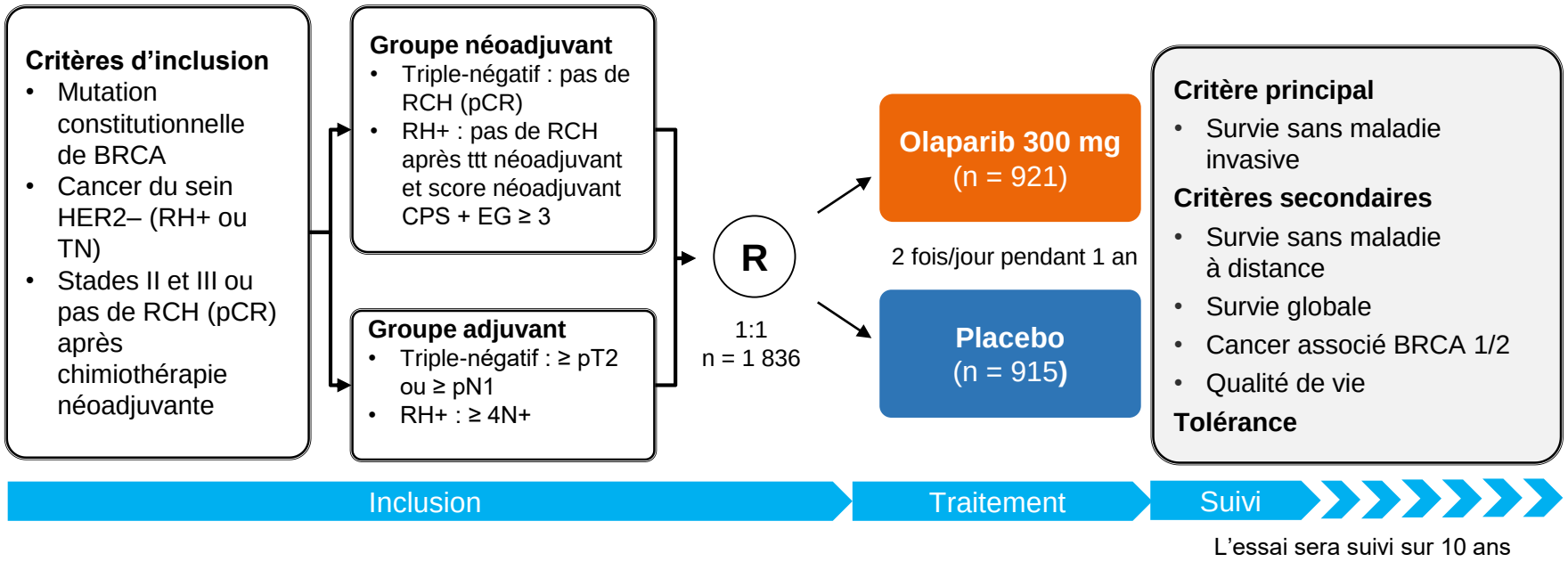
OLYMPIA
Schéma de l'étude

Étude de phase III randomisée en double aveugle



Facteurs de stratification
- RH+ versus TN
- Néoadjuvant versus adjuvant
- CT antérieure à base de platine (oui versus non)

Traitement adjuvant
- HT
- Biphosphonates
- Pas de seconde CT adjuvante

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Population de l'étude

Caractéristiques cliniques

	Olaparib (N = 921)	Placebo (N = 915)
Age, years, median (interquartile range)	**42** (36–49)	**43** (36–50)
BRCA gene affected in germline		
BRCA1	657 (**71.3%**)	670 (**73.2%**)
BRCA2	261 (**28.3%**)	239 (**26.1%**)
BRCA1 and *BRCA2*	2 (0.2%)	5 (0.5%)
Primary breast cancer surgery		
Mastectomy	698 (**75.8%**)	673 (**73.6%**)
Conservative surgery only	223 (24.2%)	240 (26.2%)
Missing	0 (0.0%)	2 (0.2%)
Hormone receptor status*		
Hormone receptor ≥ 1% / HER2-†	168 (**18.2%**)	157 (**17.2%**)
Triple Negative Breast Cancer‡	751 (**81.5%**)	758 (**82.8%**)
Menopausal status (female only)		
Premenopausal	572/919 (62.2%)	553/911 (60.7%)
Postmenopausal	347/919 (37.8%)	358/911 (39.3%)
Prior chemotherapy		
Adjuvant (ACT)	461 (**50.1%**)	455 (**49.7%**)
Neoadjuvant (NACT)	460 (**49.9%**)	460 (**50.3%**)
Anthracycline and taxane regimen	871 (**94.6%**)	849 (**92.8%**)
Neo(adjuvant) platinum-based therapy	247 (**26.8%**)	239 (**26.1%**)
Concurrent endocrine therapy (HR–positive only)	146/168 (86.9%)	142/157 (90.4%)

Caractéristiques anatomopathologiques

CPS+EG score* (Neoadjuvant only)

	Olaparib (n = 460)	Placebo (n = 460)
HR+/HER2-		
CPS+EG score ≤2†	13 (2.8%)	6 (1.3%)
CPS+EG score of 3 or 4	**88 (19.1%)**	**85 (18.5%)**
CPS+EG score of 5 or 6	3 (0.7%)	1 (0.2%)
Not recorded	0 (0.0%)	0 (0.0%)
Triple Negative Breast Cancer		
CPS+EG score ≤2	**151 (32.8%)**	**144 (31.3%)**
CPS+EG score of 3 or 4	**179 (38.8%)**	**197 (42.8%)**
CPS+EG score of 5 or 6	19 (4.1%)	14 (3.0%)
Not recorded	7 (1.5%)	13 (2.8%)

Pathological AJCC stage (Adjuvant only)

	Olaparib (n = 461)	Placebo (n = 455)
0	0 (0.0%)	0 (0.0%)
IA*	5 (1.1%)	2 (0.4%)
IB	15 (3.3%)	11 (2.4%)
IIA	**264 (57.3%)**	**250 (54.9%)**
IIB	**70 (15.2%)**	**75 (16.5%)**
IIIA	73 (15.8%)	70 (15.4%)
IIIB	0 (0.0%)	2 (0.4%)
IIIC	28 (6.1%)	41 (9.0%)
NA†	6 (1.3%)	4 (0.9%)

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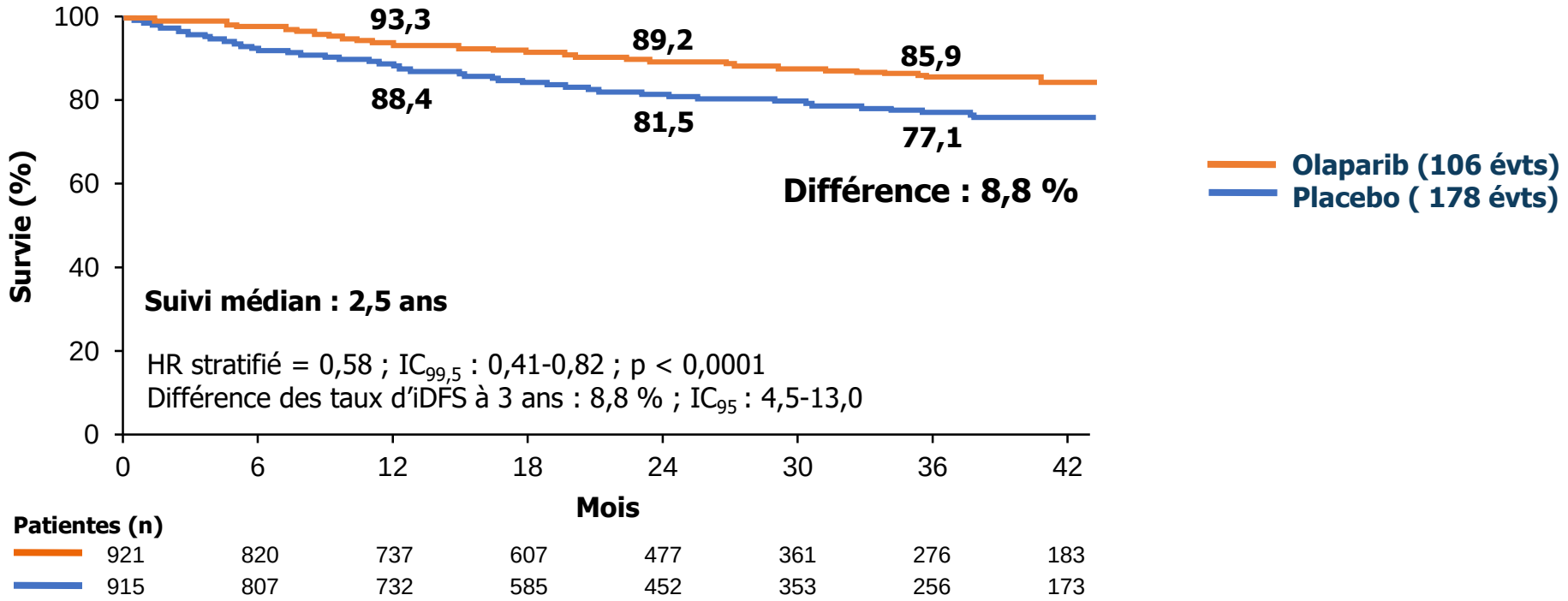
OLYMPIA
Résultats

Critère principal: Survie sans maladie invasive (SSMi)



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OLYMPIA
Résultats

Types d'évènements

	Olaparib (N = 921)	Placebo (N = 915)
Number of patients with a first IDFS event	**106 (11.5%)**	**178 (19.5%)**
Distant recurrence	**72 (7.8%)**	**120 (13.1%)**
Distant CNS Recurrence	22 (2.4%)	36 (3.9%)
Distant excluding CNS Recurrence	50 (5.4%)	84 (9.2%)
Regional (Ipsilateral) Recurrence	6 (0.7%)	14 (1.5%)
Local (Ipsilateral) Recurrence	7 (0.8%)	11 (1.2%)
Contralateral invasive breast cancer	8 (0.9%)	12 (1.3%)
Second primary non-breast malignancies	11 (1.2%)	21 (2.3%)
Ovarian	1 (0.1%)	4 (0.4%)
Peritoneal	0 (0.0%)	0 (0.0%)
Fallopian tube	1 (0.1%)	4 (0.4%)
Other	9 (1.0%)	13 (1.4%)
Deaths without a prior IDFS event*	2 (0.2%)	0 (0.0%)

There can only be one first IDFS event per patient
*1 death due to cardiac arrest and 1 patient with unknown cause of death

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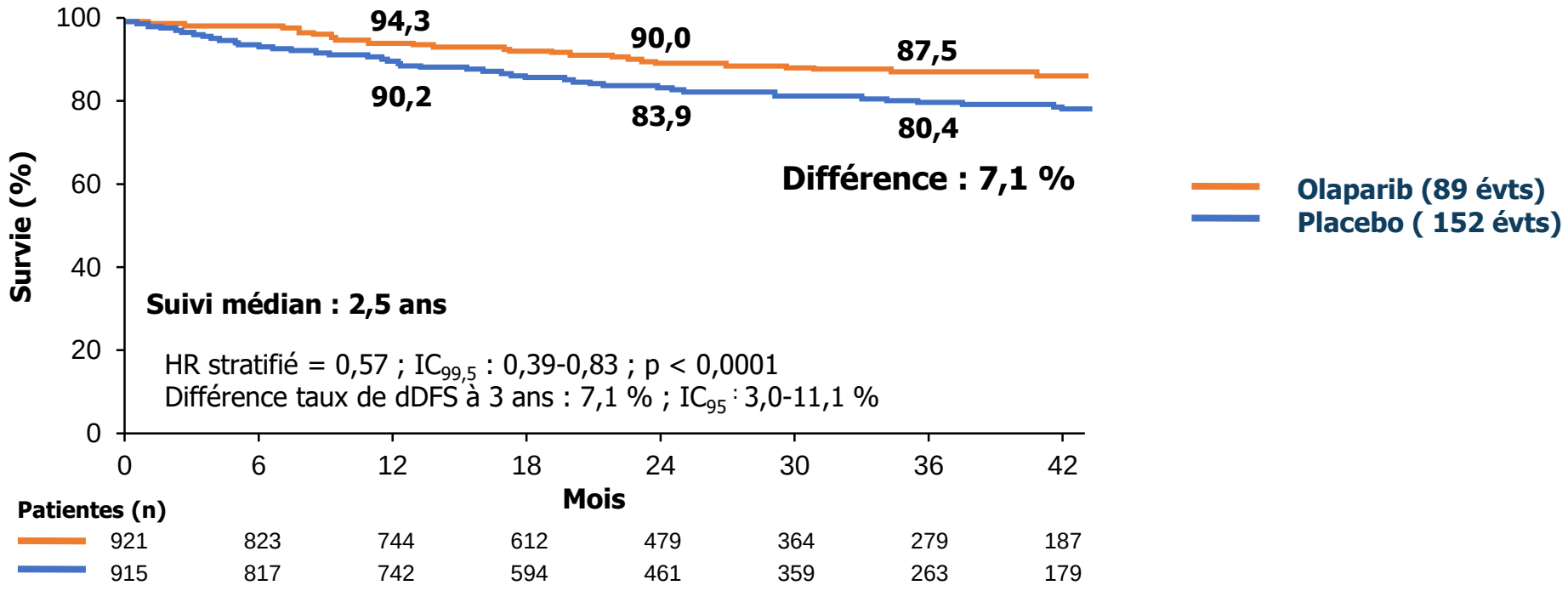
OLYMPIA
Résultats

Critère secondaire: Survie sans maladie à distance (SSMd)



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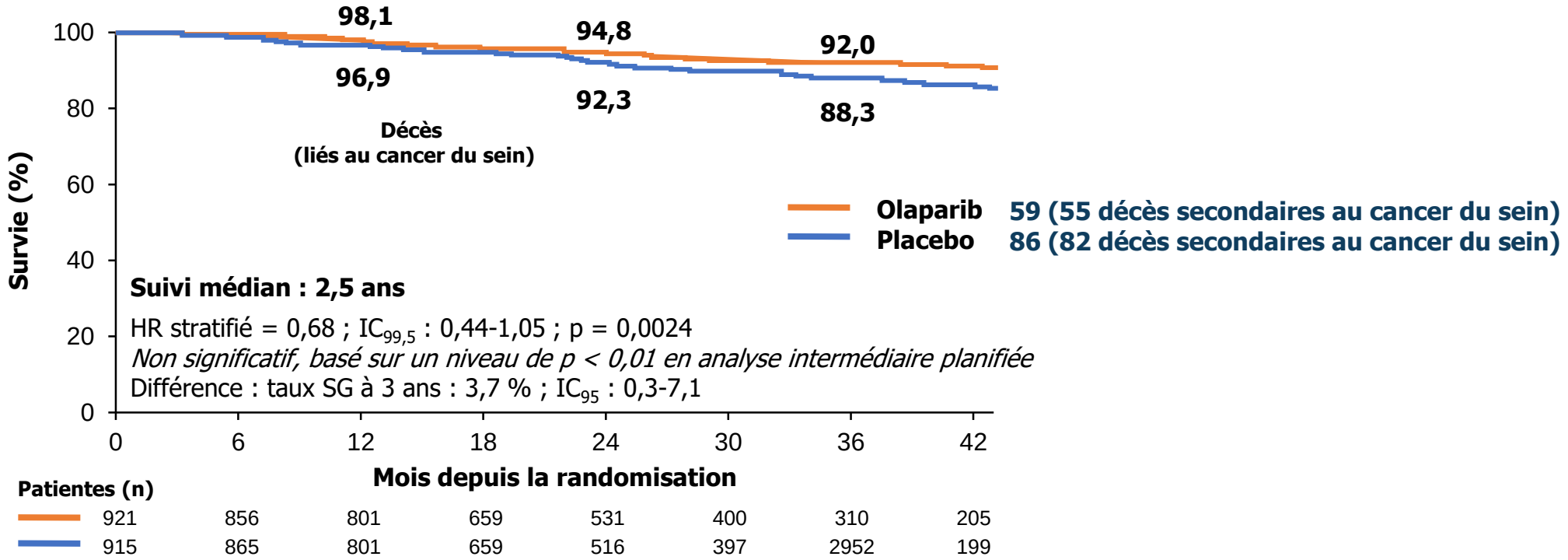
Résultats

Critère secondaire: Survie globale (SG)



→ Moins de décès dans le bras olaparib que dans le bras placebo, mais différence non statistiquement significative
→ Suivi de l'étude en cours

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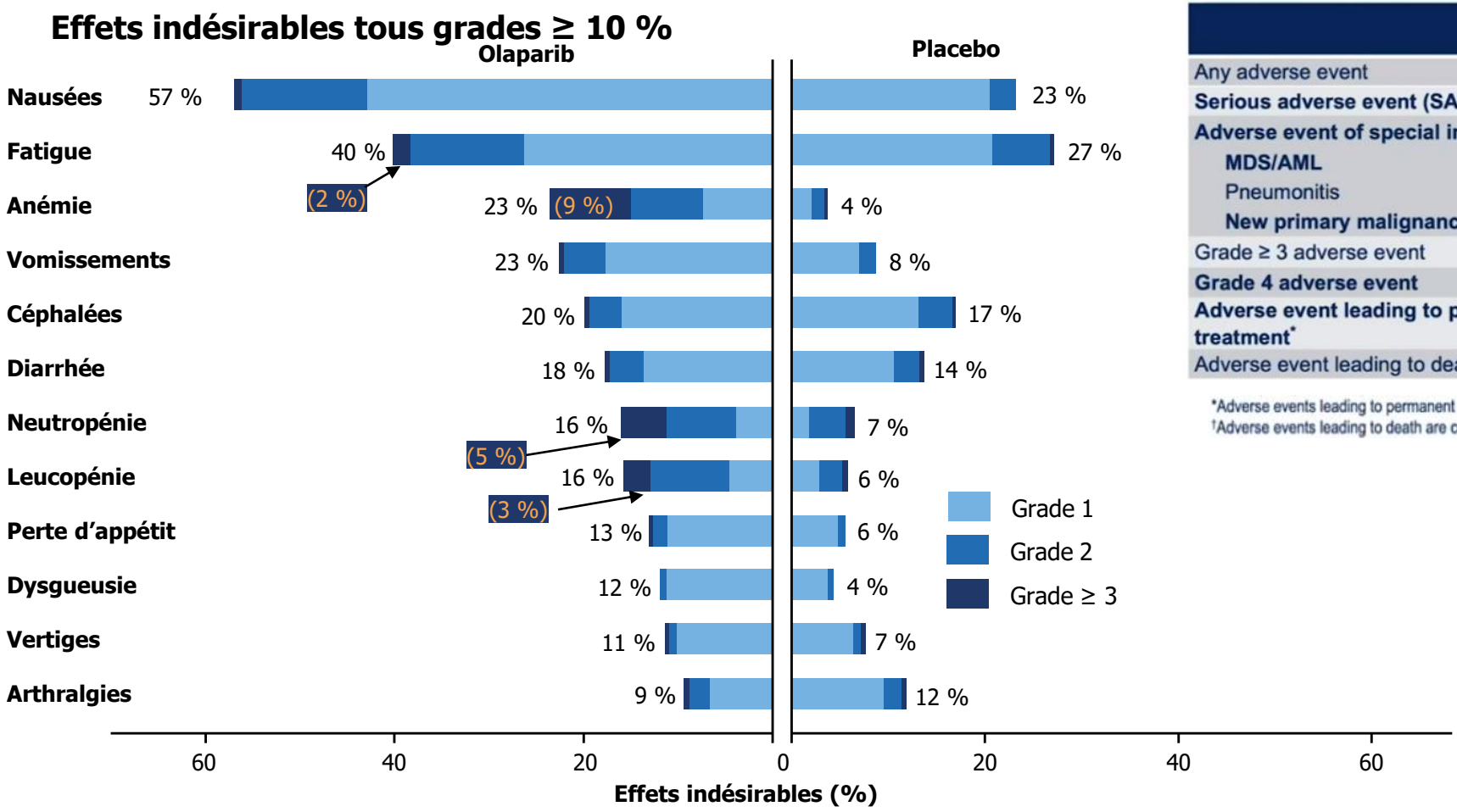
OLYMPIA
Résultats

Tolérance



	Olaparib (N = 911)	Placebo (N = 904)
Any adverse event	835 (91.7%)	753 (83.3%)
Serious adverse event (SAE)	**79 (8.7%)**	**76 (8.4%)**
Adverse event of special interest	**30 (3.3%)**	**46 (5.1%)**
MDS/AML	**2 (0.2%)**	**3 (0.3%)**
Pneumonitis	9 (1.0%)	11 (1.2%)
New primary malignancy	**20 (2.2%)**	**32 (3.5%)**
Grade ≥ 3 adverse event	221 (24.3%)	102 (11.3%)
Grade 4 adverse event	**17 (1.9%)**	**4 (0.4%)**
Adverse event leading to permanent discontinuation of treatment*	**90 (9.9%)**	**38 (4.2%)**
Adverse event leading to death†	1 (0.1%)	2 (0.2%)

*Adverse events leading to permanent discontinuation of treatment in the olaparib group that occurring in > 1% were; nausea, anemia and fatigue
†Adverse events leading to death are cardiac arrest (olaparib, n = 1), AML (placebo, n = 1), and ovarian cancer (placebo, n = 1)

Suivi pendant 10 ans

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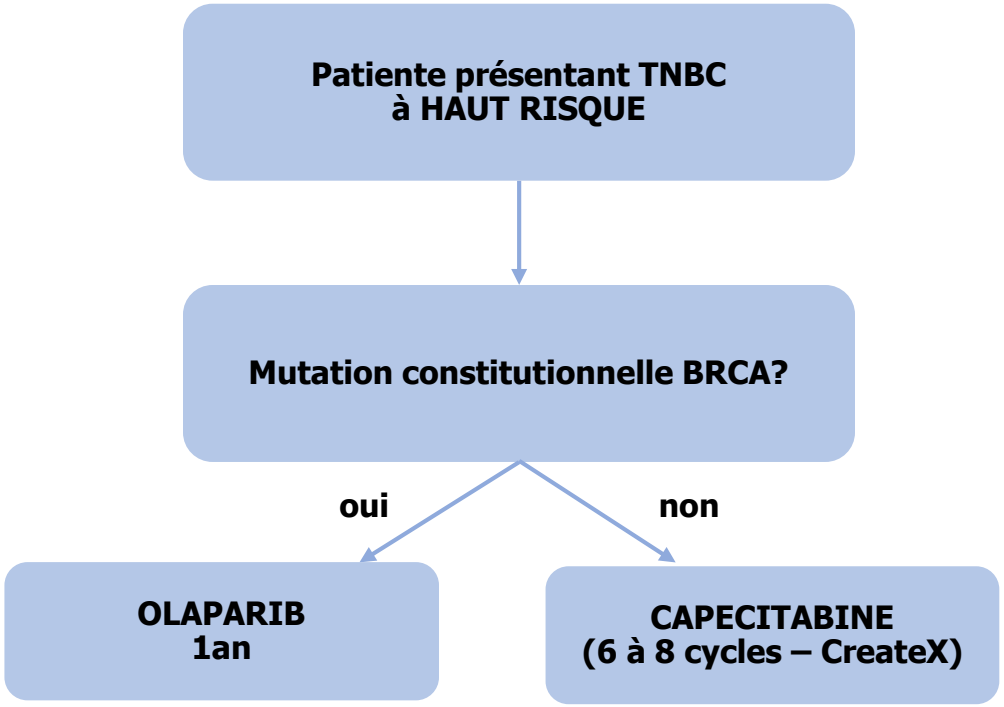
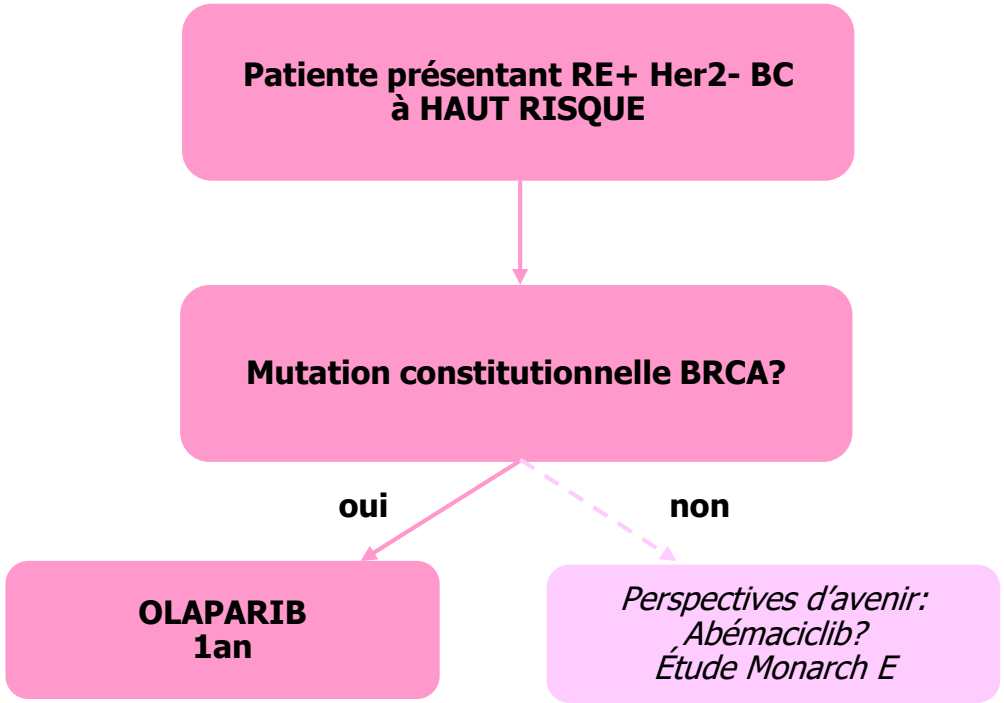
OLYMPIA
conclusions-discussions

- Changement de pratique





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ETUDE GUEPARNUEVO

Loibl S et al., abstr. 506

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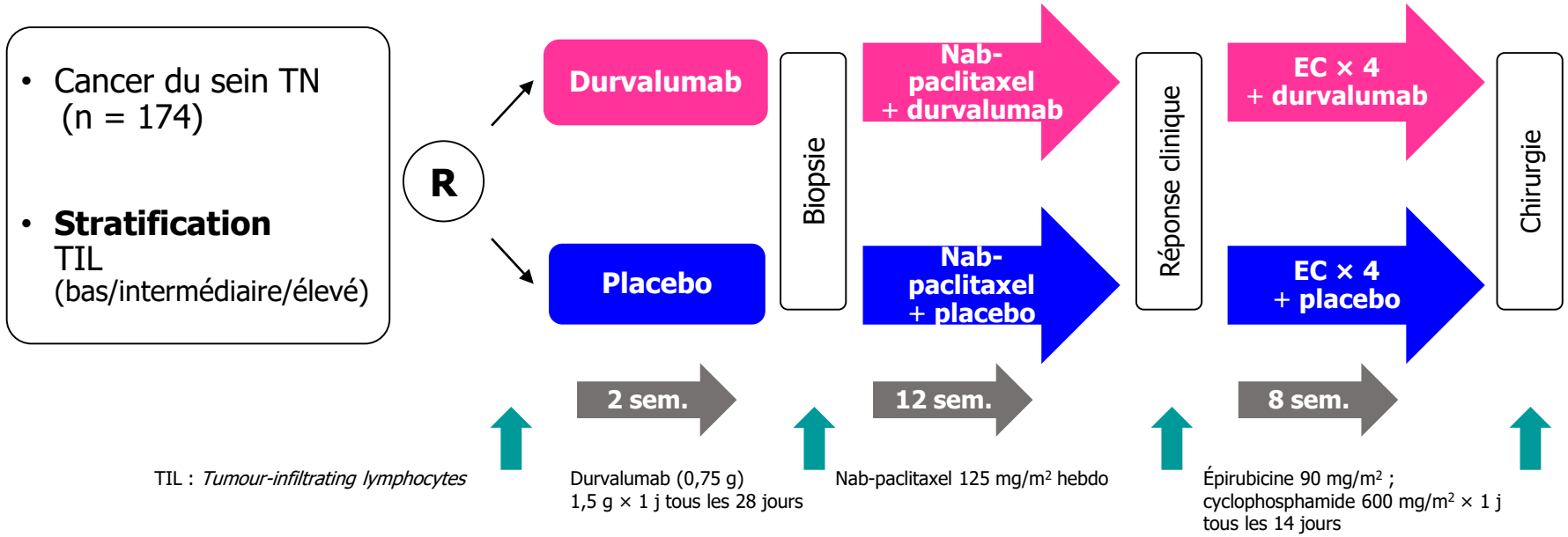
GueparNUEVO
Schéma de l'étude

Etude de phase II randomisée évaluant l'adjonction en néo adjuvant du durvalumab à la chimiothérapie dans les cancers du sein triple négatifs



→ Critère principal : taux de réponse complète pathologique (pCR) [ypT0, ypN0] : 53% vs 44% NCS
→ **Principaux critères secondaires: SSMi, SSMd, SG**

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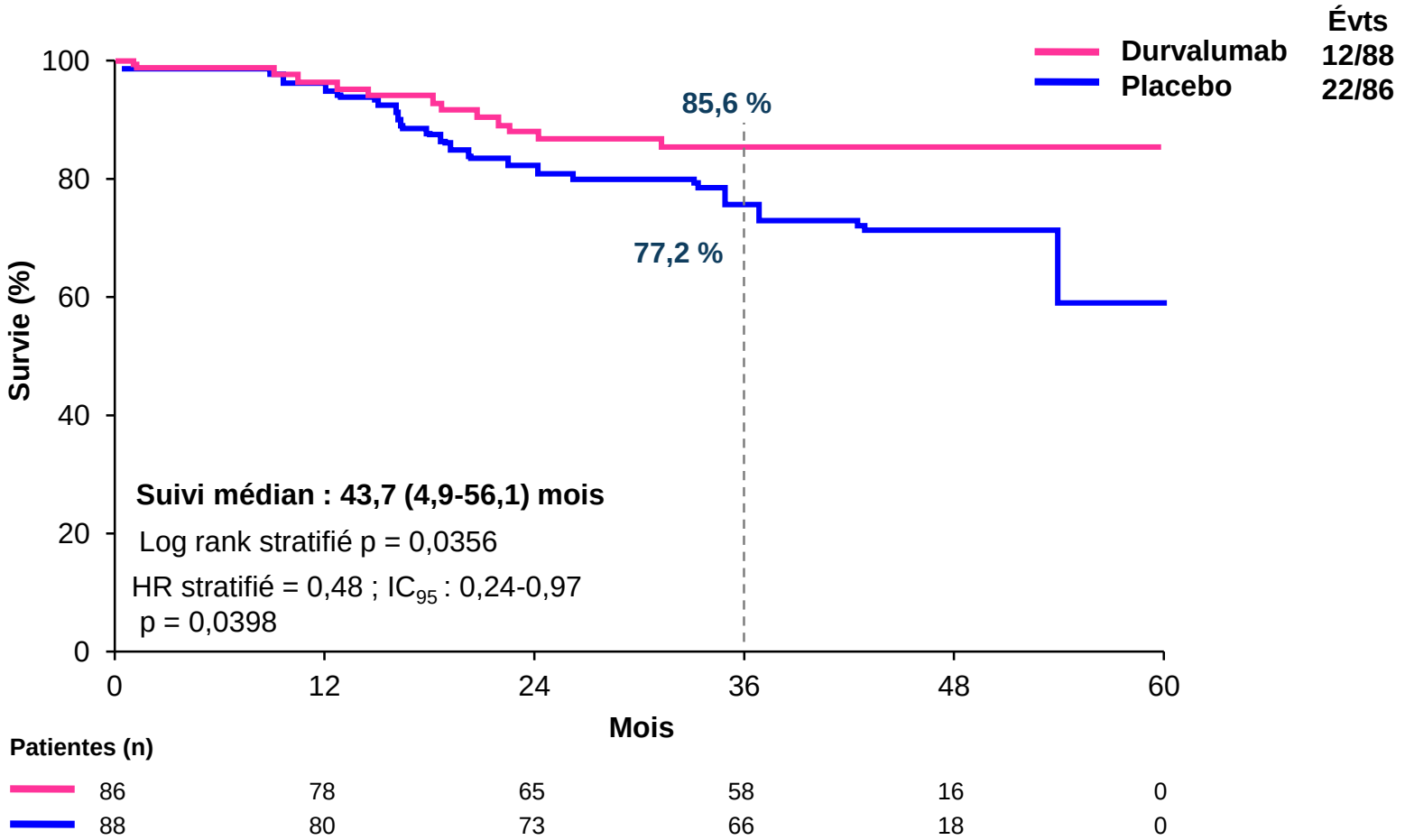
GueparNUEVO
Résultats de survie

Survie sans maladie invasive (SSMi)



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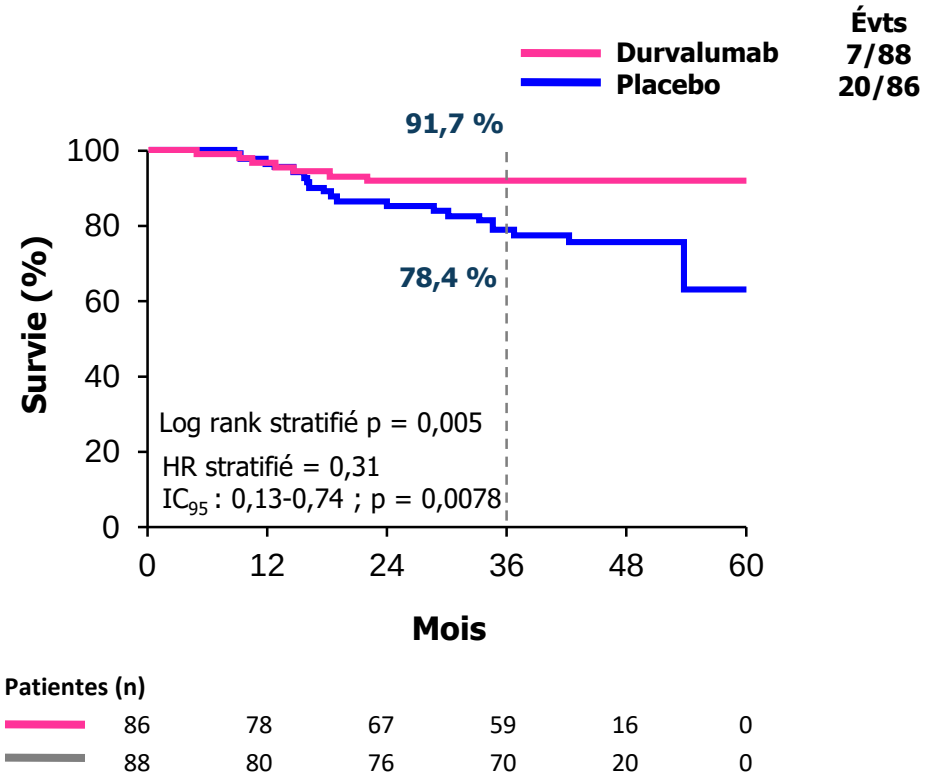
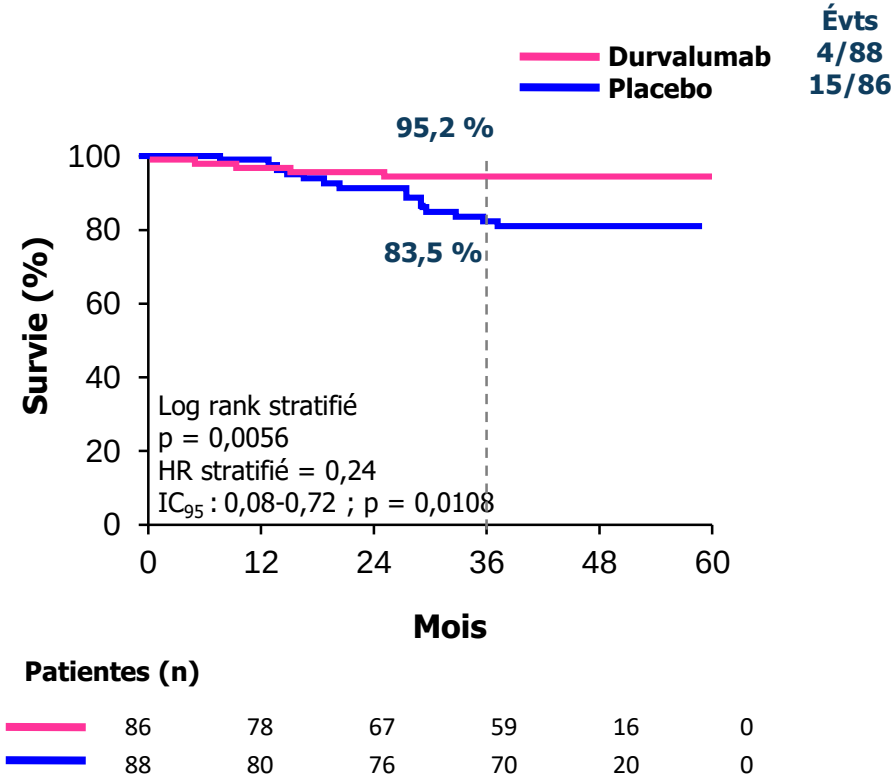
Résultats de survie

Survie sans maladie invasive à distance



Survie globale



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GeparNUEVO
Conclusions - Discussions

- Résultats encourageants (attendons résultats des phases III Impassion 31 et Keynote 522)
- Résultats en faveur d'une amélioration de la survie avec checkpoint inhibiteurs sans majoration majeure de la pCR
- Place de l'immunothérapie en adjuvant des TNBC