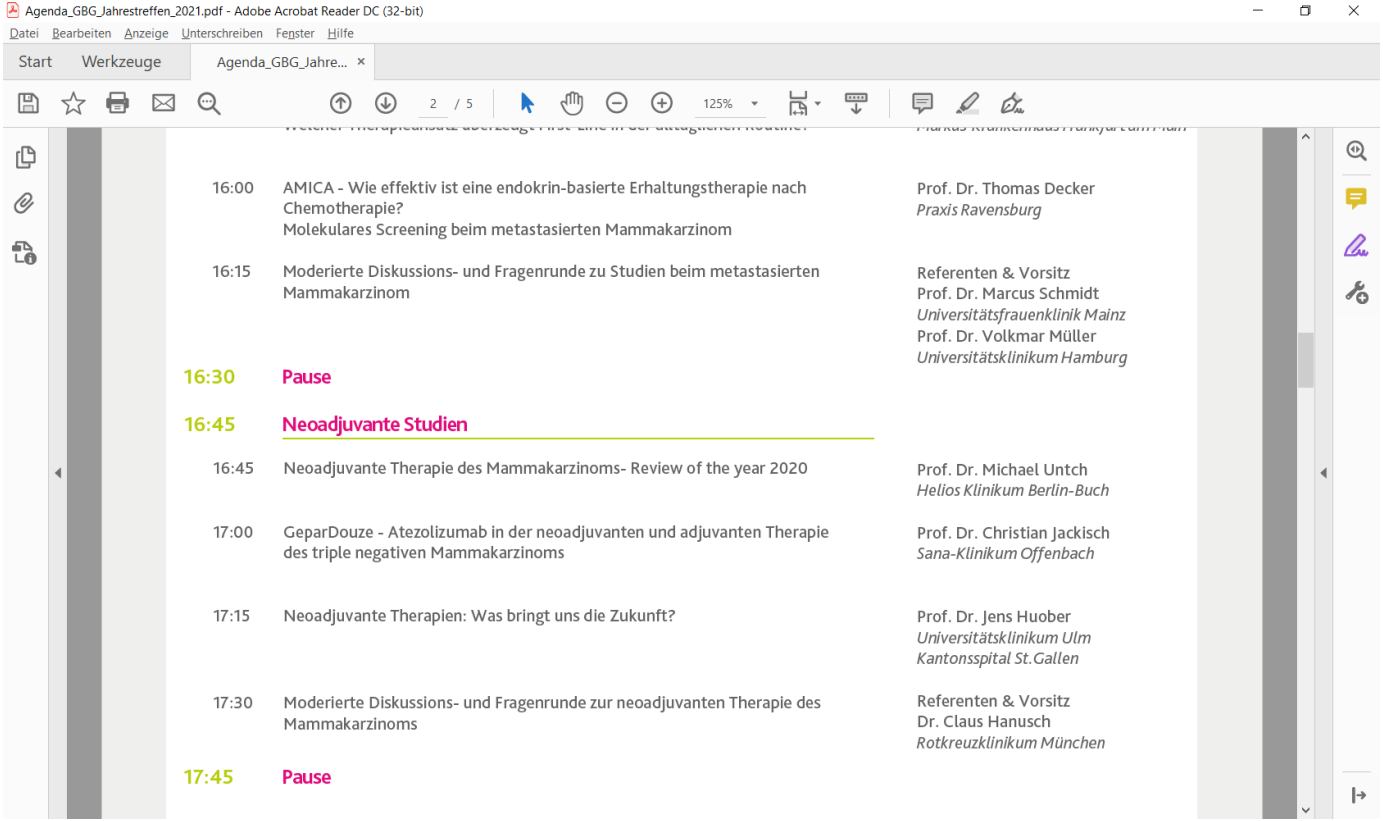
GBG Jahrestreffen 2021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Datei Bearbeiten Anzeige Unterschreiben Fenster Hilfe

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16:00	AMICA - Wie effektiv ist eine endokrin-basierte Erhaltungstherapie nach Chemotherapie? Molekulares Screening beim metastasierten Mammakarzinom	Prof. Dr. Thomas Decker *Praxis Ravensburg*
16:15	Moderierte Diskussions- und Fragenrunde zu Studien beim metastasierten Mammakarzinom	Referenten & Vorsitz Prof. Dr. Marcus Schmidt *Universitätsfrauenklinik Mainz* Prof. Dr. Volkmar Müller *Universitätsklinikum Hamburg*
16:30	**Pause**	
16:45	**Neoadjuvante Studien**	
16:45	Neoadjuvante Therapie des Mammakarzinoms- Review of the year 2020	Prof. Dr. Michael Untch *Helios Klinikum Berlin-Buch*
17:00	GeparDouze - Atezolizumab in der neoadjuvanten und adjuvanten Therapie des triple negativen Mammakarzinoms	Prof. Dr. Christian Jackisch *Sana-Klinikum Offenbach*
17:15	Neoadjuvante Therapien: Was bringt uns die Zukunft?	Prof. Dr. Jens Huober *Universitätsklinikum Ulm* *Kantonsspital St.Gallen*
17:30	Moderierte Diskussions- und Fragenrunde zur neoadjuvanten Therapie des Mammakarzinoms	Referenten & Vorsitz Dr. Claus Hanusch *Rotkreuzklinikum München*
17:45	**Pause**	

Interessenskonflikte

- Abbvie
- Amgen GmbH München
- Astra Zeneca
- BMS
- Celgene GmbH München
- Daichii Sankyo
- Eisai GmbH München
- Janssen Cilag
- Johnsen&Johnsen
- Lilly Deutschland
- MSD Merck
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- Myriad Genetics GmbH Zürich
- Odonate
- Pfizer GmbH Berlin
- PUMA Biotechnology
- Riemser
- Roche Pharma AG, Grenzach Wyhlen
- Sanofi Aventis Deutschland GmbH
- Sividon Diagnostics Köln
- TEVA Pharmaceuticals Ind. Ltd. und . Berlin

Honorare für Ad boards, Vorträge und Kongressreisen wurden an den Arbeitgeber bezahlt

EUROPEAN BREAST CANCER RESEARCH ASSOCIATION OF SURGICAL TRIALISTS

AXSANA

AGO-B BREAST STUDY GROUP AWOgyn

San Antonio Breast Cancer Symposium® - December 8-11, 2020

AXillary Surgery After NeoAdjuvant treatment:

an international prospective multicenter cohort study of the EUBREAST study group to evaluate different surgical methods of axillary staging in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy

Maggie Banys-Paluchowski [1], Elmar Stickeler [2], Jana de Boniface [3], Oreste Gentilini [4], Marc Thill [5], Steffi Hartmann [6], Marina Mangold [7], Christine Solbach [8], Jens-Uwe Blohmer [9], Michael Untch [10], Matilda Appelgren [11], Hans-Christian Kolberg [12], Thorsten Kühn [13], on behalf of EUBREAST study group

BACKGROUND

The optimal surgical staging of the axilla in breast cancer (BC) patients who convert from a clinically positive to a clinically negative node status (cN+ → ycN0, Fig. 1) through neoadjuvant chemotherapy (NACT) is still unclear. For many decades, axillary lymph node dissection (ALND) has been considered standard of care in this setting. However, ALND is associated with high morbidity and may therefore lead to reduced quality of life in BC patients (Fig. 2).

Various forms of axillary staging surgery after NACT are currently in use internationally with the aim to ensure oncological safety and to avoid over-therapy (ALND, TLNB, TAD, SLNB) [1]. The choice of the appropriate technique generally depends on the national and international recommendations and surgeon's preference. So far, no comparative data on the oncological outcome or the morbidity of the different procedures are available. Further research is needed to safely de-escalate the extent of axillary surgery in this patient group.

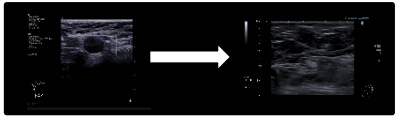


Fig. 1. Ultrasound image of a typical axillary lymph node metastasis prior to NACT (cN+; left) and unsuspicious lymph nodes after NACT (ycN0; right).

Fig. 2. Lymphedema of the right arm 12 years after ALND.

REFERENCES

1. Banys-Paluchowski et al., Arch Gynecol Obster 2020, Axillary ultrasound for prediction of response to neoadjuvant therapy in the context of surgical strategies to axillary dissection…

STUDY DESIGN (NCT04373655)

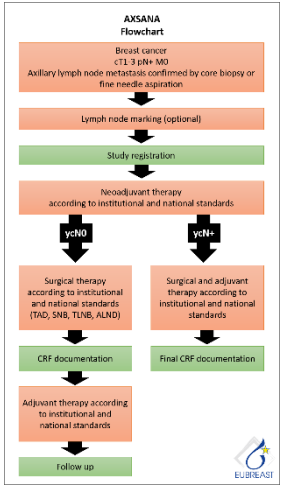
Prospective multicenter cohort study

Target accrual: 3000 pts.

Study duration: 5 years (enrollment) + 5 years (follow up)

Primary endpoints
- 5-year invasive disease-free survival
- 3-year axillary recurrence rate
- HRQOL (evaluated using 4 standardized questionnaires [EORTC QLQ-C 30, BR 23, Lymph ICF and SOC-13] at baseline and 1, 3, 5 years after surgery)

Secondary endpoints are the feasibility and performance of different axillary staging techniques (detection rate, number of removed lymph nodes and association with complications, arm morbidity and quality of life, operating time and use of clinical and economic resources); impact of learning curve, and the detailed mapping of surgical and oncological treatment standards in different countries.



KEY ELIGIBILITY CRITERIA

Inclusion criteria
- Primary invasive breast cancer (confirmed by core biopsy)
- cN+ (confirmed by core biopsy or FNA)
- cT1-3
- Scheduled for NACT
- Female / male pts. ≥ 18 years old

Exclusion criteria
- Distant metastasis
- Recurrent or inflammatory BC
- Extramammary breast cancer
- Pregnancy
- < 4 cycles of NACT administered
- Pts. not suitable for surgical treatment

CURRENT STATUS

First patient recruited: June 2020
Current accrual (Oct 2020): 36 pts.
Open study sites: 28

Heads of National Steering Committees

Austria	Florentia Peintinger
Germany	Maggie Banys-Paluchowski
Greece	Michalis Kontos
Hungary	Zoltan Matrai
Italy	Oreste Gentilini
Poland	Dawid Murawa
Portugal	David Pinto
Romania	Eduard-Alexandru Bonci
Russia	Petr Krivorotko
Spain	Isabel Rubio
Sweden	Jana de Boniface
Switzerland	Maria Luisa Gasparri

For more information visit axsana.eubreast.com

Affiliations
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Poster # OT-03-01

e-Poster Presentation
SABCS 2020

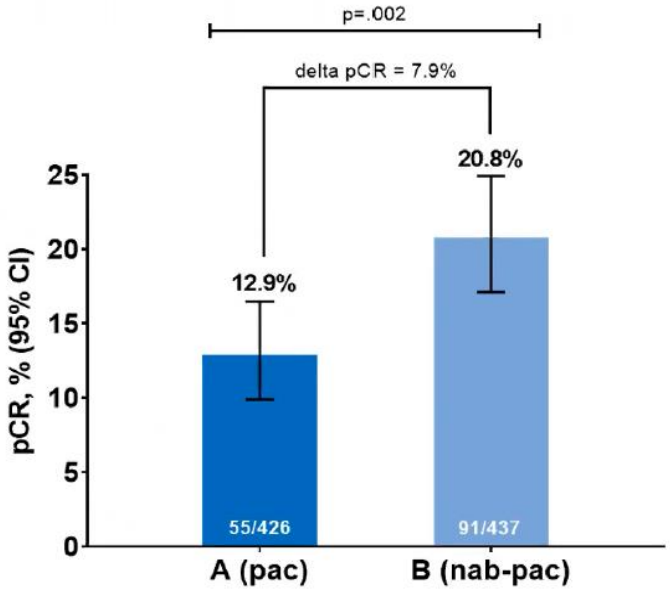
Trastuzumab deruxtecan (T-DXd; DS-8201) vs trastuzumab emtansine (T-DM1) in high-risk patients with HER2-positive, residual, invasive early breast cancer after neoadjuvant therapy: a randomized, phase 3 trial (DESTINY-Breast05)

Charles E. Geyer Jr,[1] Michael Untch,[2] Aleix Prat,[3] Priya Rastogi,[4] Naoki Niikura,[5] Elton Mathias,[6] Lee Anne McLean,[6] Yibin Wang,[6] Sibylle Loibl[7]

[1]NSABP Foundation and Houston Methodist Cancer Center, Houston, TX; [2]AGO B and Helios Hospital Berlin-Buch, Berlin, Germany; [3]Hospital Clínic Barcelona, Barcelona, Spain; [4]NSABP Foundation and University of Pittsburgh, Pittsburgh, PA; [5]Department of Breast and Endocrine Surgery, Tokai University School of Medicine, Kanagawa, Japan; [6]Daiichi Sankyo, Inc, Basking Ridge, NJ; [7]German Breast Group, Neu-Isenburg, Germany

ADAPT HR+/HER2- trial chemotherapy part

Primary endpoint analysis: pCR (ypT0/ypTis/ypN0) by study ar



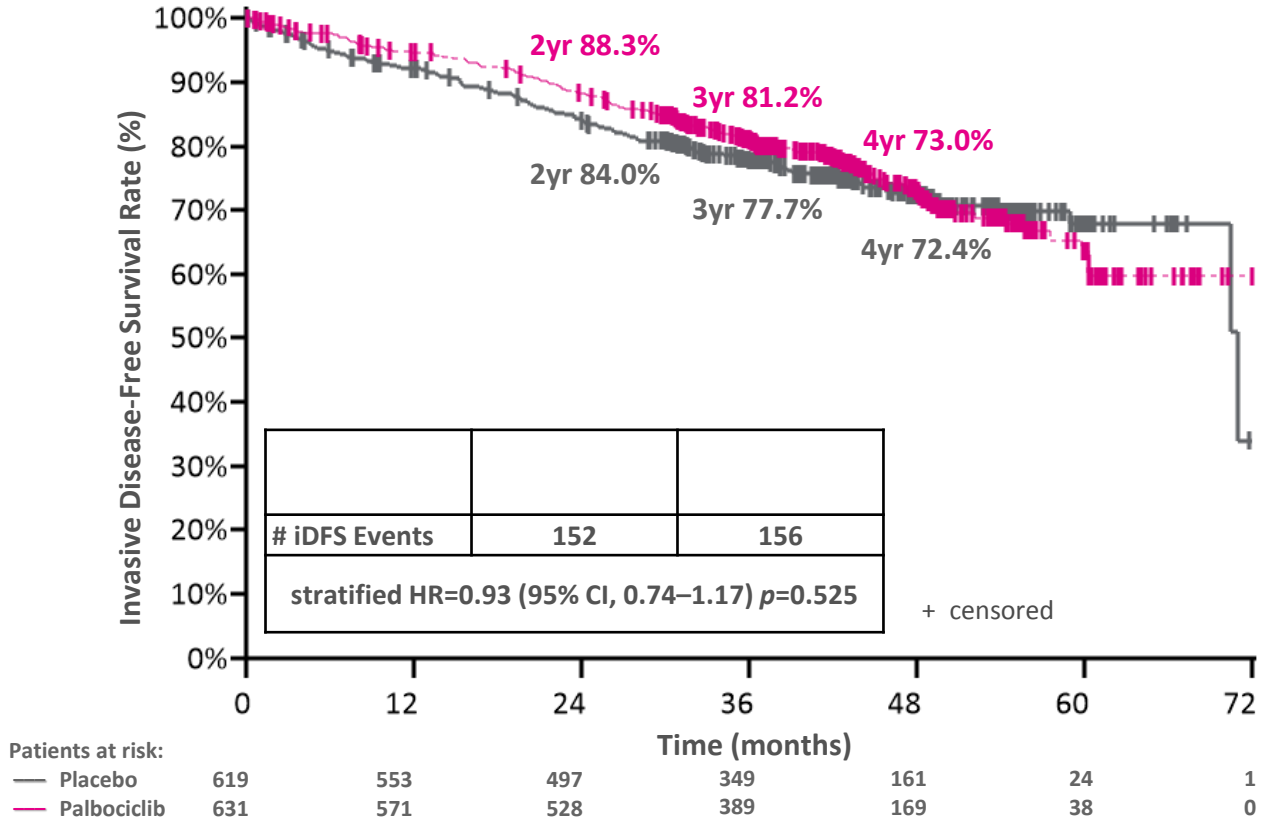
GBG-78 - BIG 1-13 - NSABP-B-54-I

Phase III study of palbociclib combined with endocrine therapy in patients with hormone-receptor-positive, HER2-negative primary breast cancer and high relapse risk after neoadjuvant chemotherapy: First results from PENELOPE-B

Sibylle Loibl, Frederik Marmé, Miguel Martin, Michael Untch, Hervé Bonnefoi, Sung-Bae Kim, Harry Bear, Nicole Mc Carthy, Mireia Melé Olivé, Karen Gelmon, José García-Sáenz, Catherine M. Kelly, Toralf Reimer, Masakazu Toi, Hope S. Rugo, Sabine Seiler, Valentina Nekljudova, Carsten Denkert, Michael Gnant, Andreas Makris, Nicole Burchardi, Gunter von Minckwitz

on behalf of the PENELOPE-B investigators

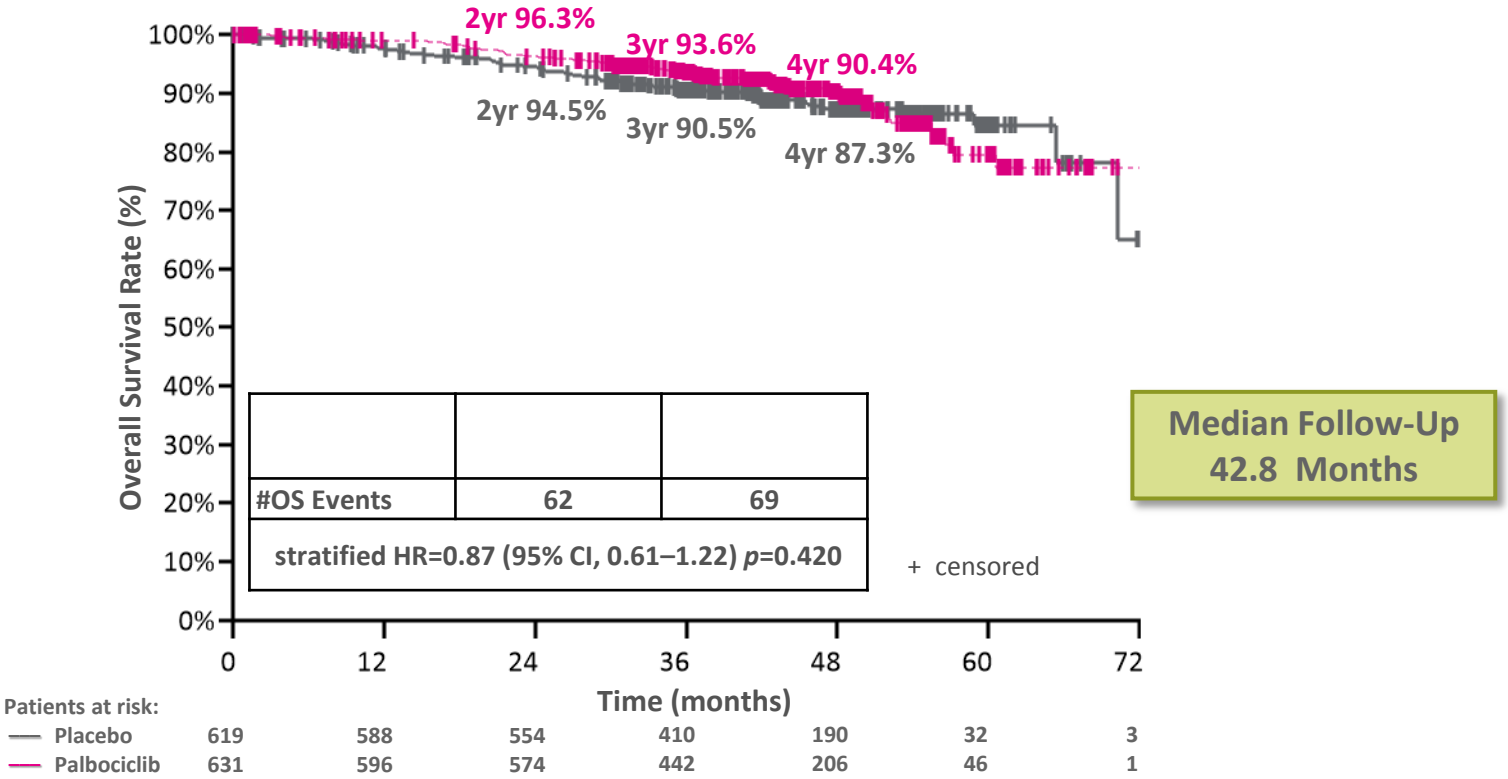
Results Primary Endpoint iDFS



Median Follow-Up
42.8 Months

* Weighted log-rank test based on the CHW method, taking into account the adaptive sample size re-estimation and group-sequential nature of the design

Overall Survival (Interim Analysis)



Median Follow-Up
42.8 Months

Summary and Conclusion

- After a median follow-up of 43 months, the addition of 1 year-palbociclib to endocrine therapy in patients with HR+/HER2- breast cancer at high-risk of relapse after NACT did not improve iDFS
  - Stratified HR 0.93, 95% CI [0.74, 1.16]; 2-sided CHW p=0.525
  - Estimated 3 year iDFS rate: 81.2% with palbociclib vs 77.7% with placebo
- At interim analysis no difference was observed for OS
- Compliance was lower in the palbociclib arm vs placebo
  - 80.5% vs 84.5% completed therapy
  - 88.6% vs 90.3% received at least 7 cycles of study treatment
  - Relative total dose intensity (RTDI) was 82% vs 99%
- No new safety signals were observed

- This is the first study showing mature iDFS results on a CDK4/6 inhibitor as part of (postneo)adjuvant therapy
- To date the results of Penelope-B do not support the addition of 1 year palbociclib to endocrine therapy
- Long term follow-up from other adjuvant CDK4/6 studies must be awaited
- Further translational research and subgroup analyses are ongoing

Survival analysis of the randomized phase III GeparOcto trial comparing neoadjuvant chemotherapy (NACT) of iddEPC versus weekly paclitaxel, liposomal doxorubicin (plus carboplatin in triple-negative breast cancer, TNBC) (PM(Cb)) for patients (pts) with high-risk early breast cancer (BC)

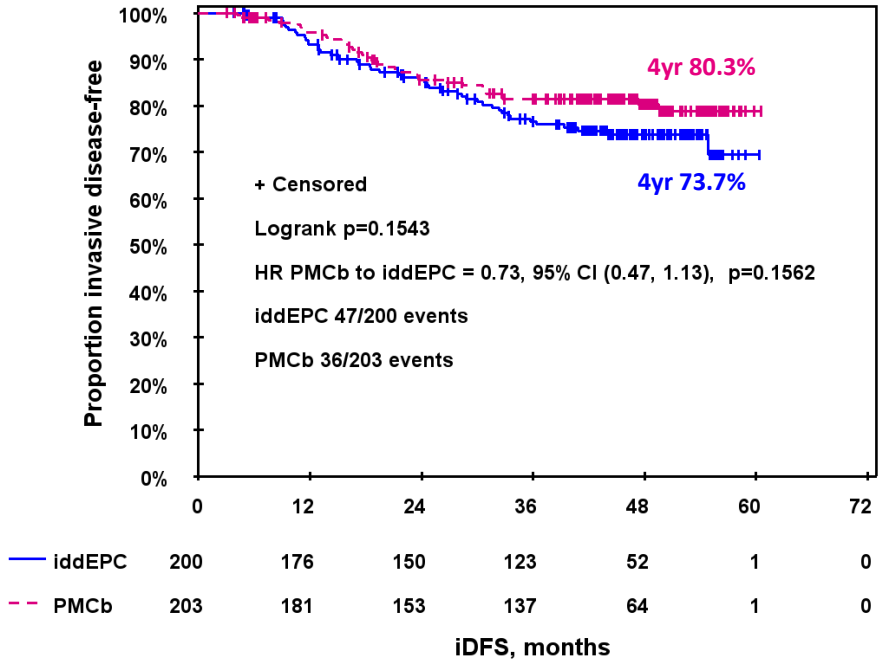
Andreas Schneeweiss, Volker Möbus, Hans Tesch, Peter Klare, Carsten Denkert, Karin Kast, Claus Hanusch, Theresa Link, Michael Untch, Christian Jackisch, Jens-Uwe Blohmer, Peter A. Fasching, Christine Solbach, Jens Huober, Kerstin Rhiem, Valentina Nekljudova, Kristine Lübbe, Sibylle Loibl

- A joint study of the AGO Breast and German Breast Group

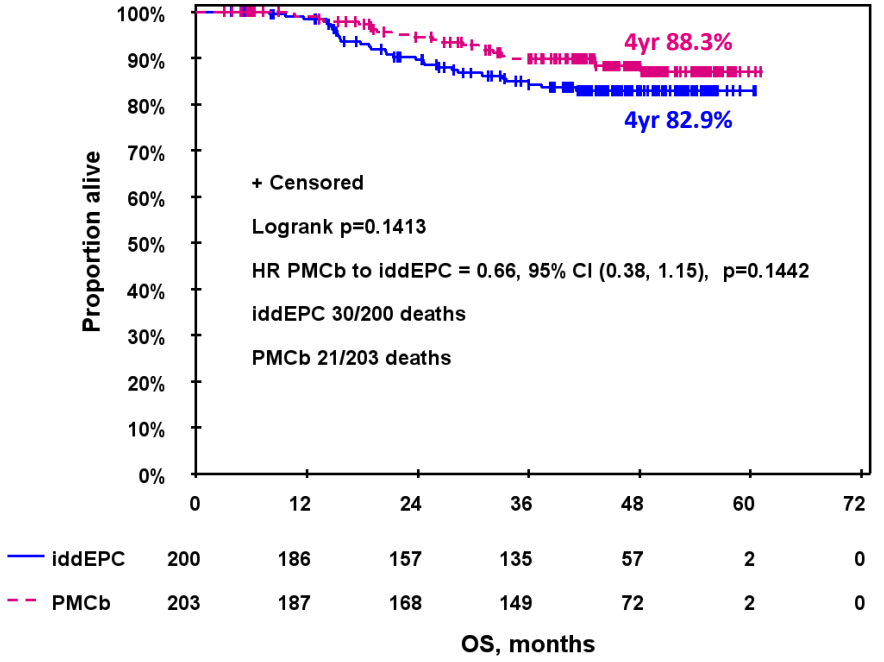
iDFS and OS in Subgroups

TNBC

iDFS



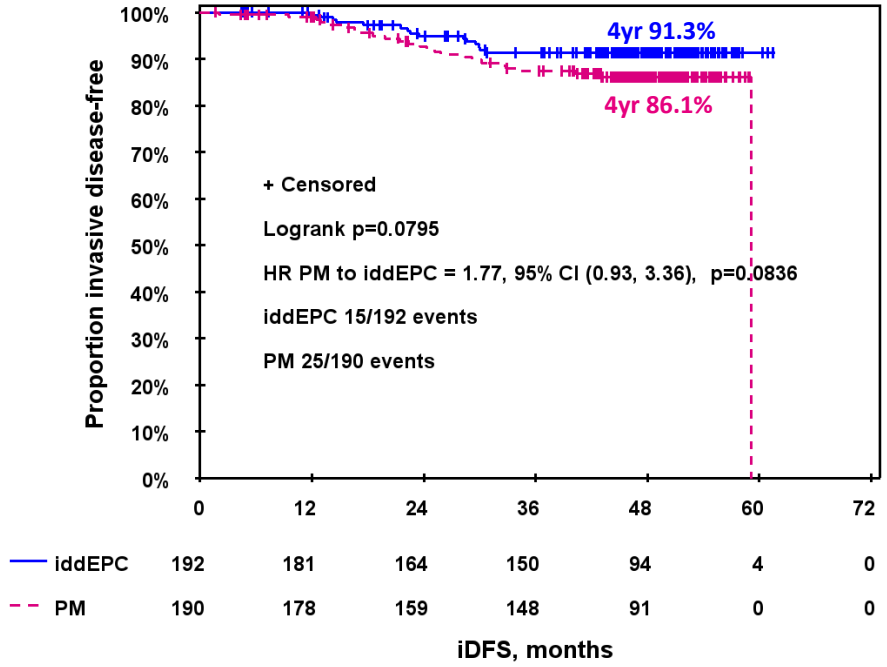
OS



iDFS and OS in Subgroups

HER2+

iDFS



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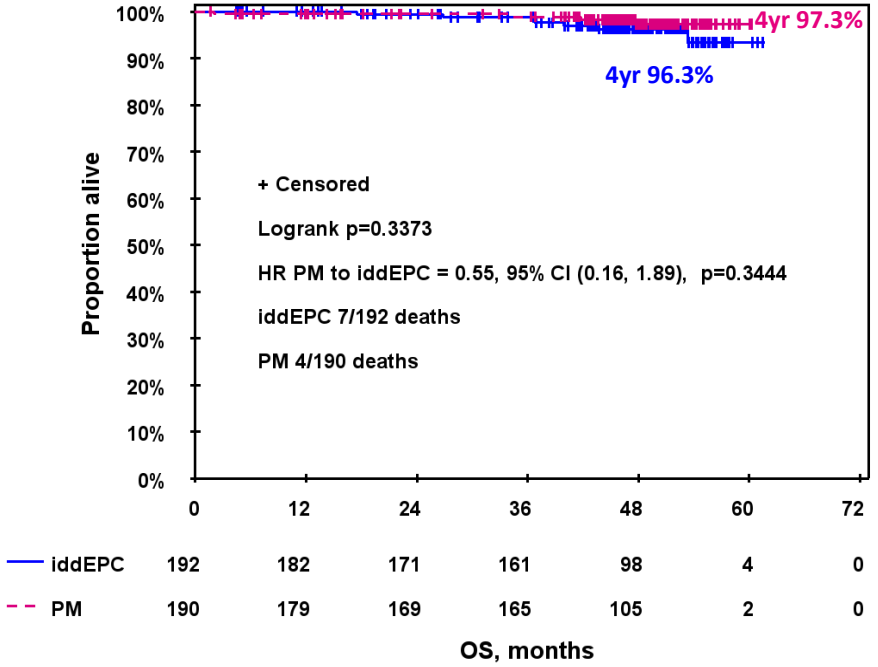
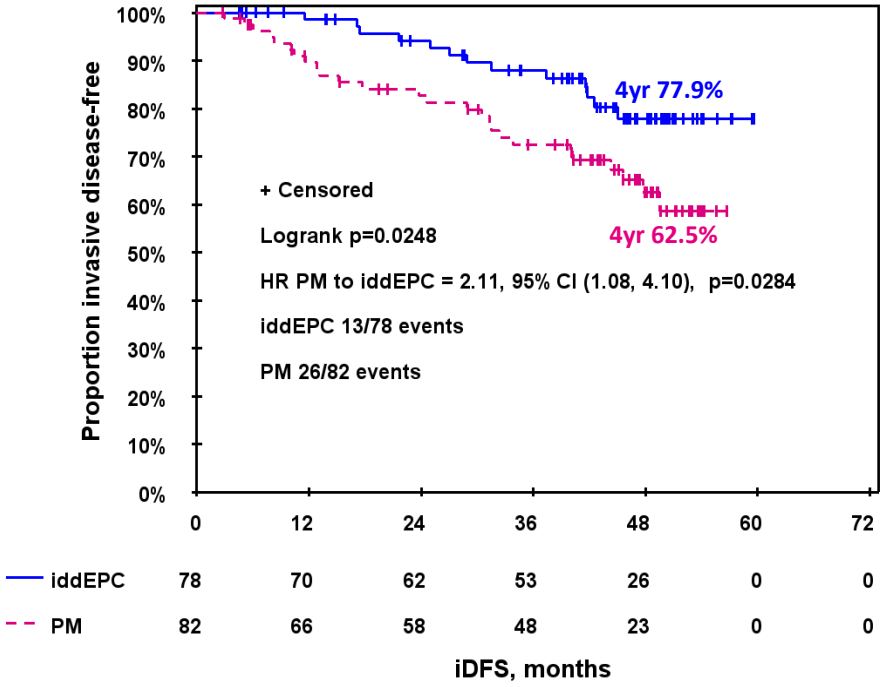
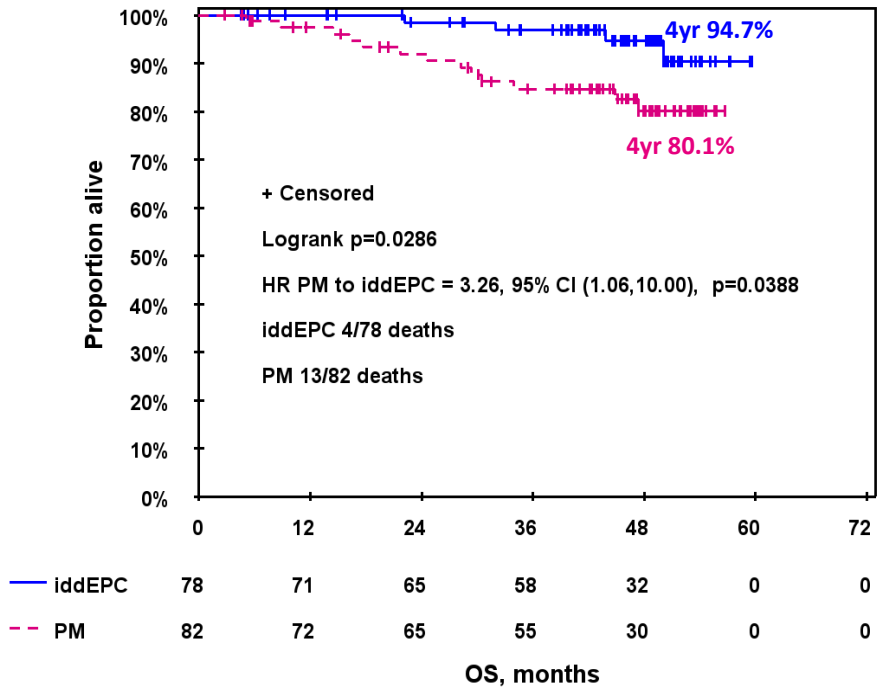


iDFS and OS in Subgroups

iDFS HR+/HER2- OS

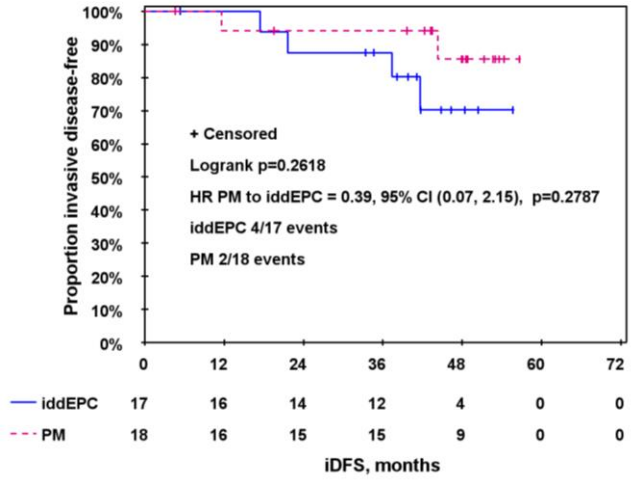




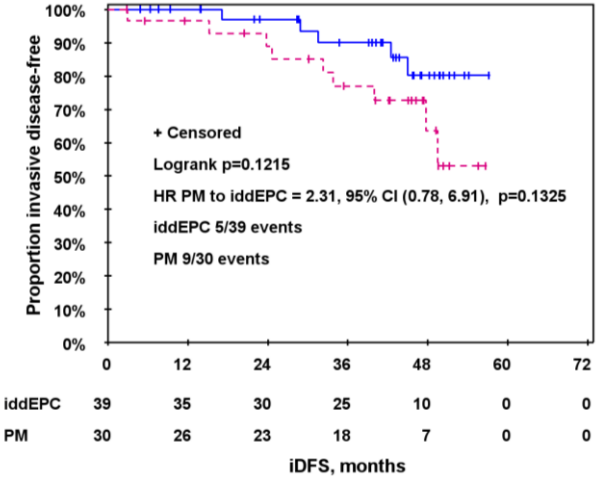
iDFS and OS in Subgroups

iDFS according to CPS-EG Score in HR+/HER2-

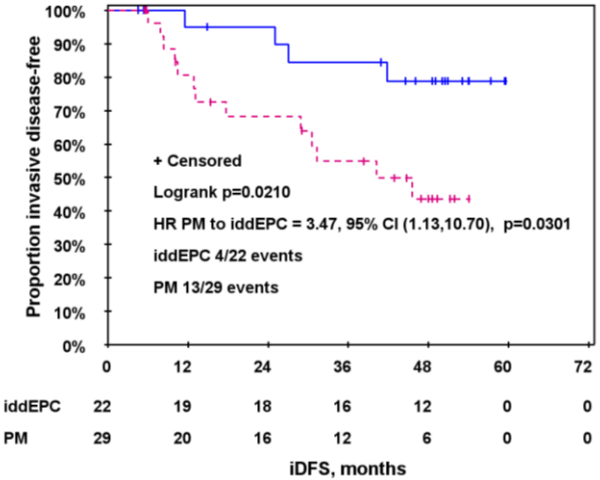
CPS-EG 0-1*



CPS-EG 2



CPS-EG 3-5



*Of note, these results should be interpreted with caution due to the small number of events

Summary and Conclusions

- With a median follow-up of 47 months there was no significant difference in iDFS and OS following NACT with iddEPC or PM(Cb) for the entire cohort
- No significant difference in iDFS and OS was observed in the subgroup of patients with HER2+ and TNBC
- **Patients with HR+/HER2- BC, however, had better iDFS and OS following iddEPC supporting the concept of an additional effect of NACT in patients with luminal-like HER2- BC which is not indicated by intermediate prognostic marker like pCR and CPS-EG score**
- **Cyclophosphamide might play an important role in adjuvant treatment of patients with high-risk HR+/HER2- BC**

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VIRTUAL 2020 ESMO congress

- GBG 88

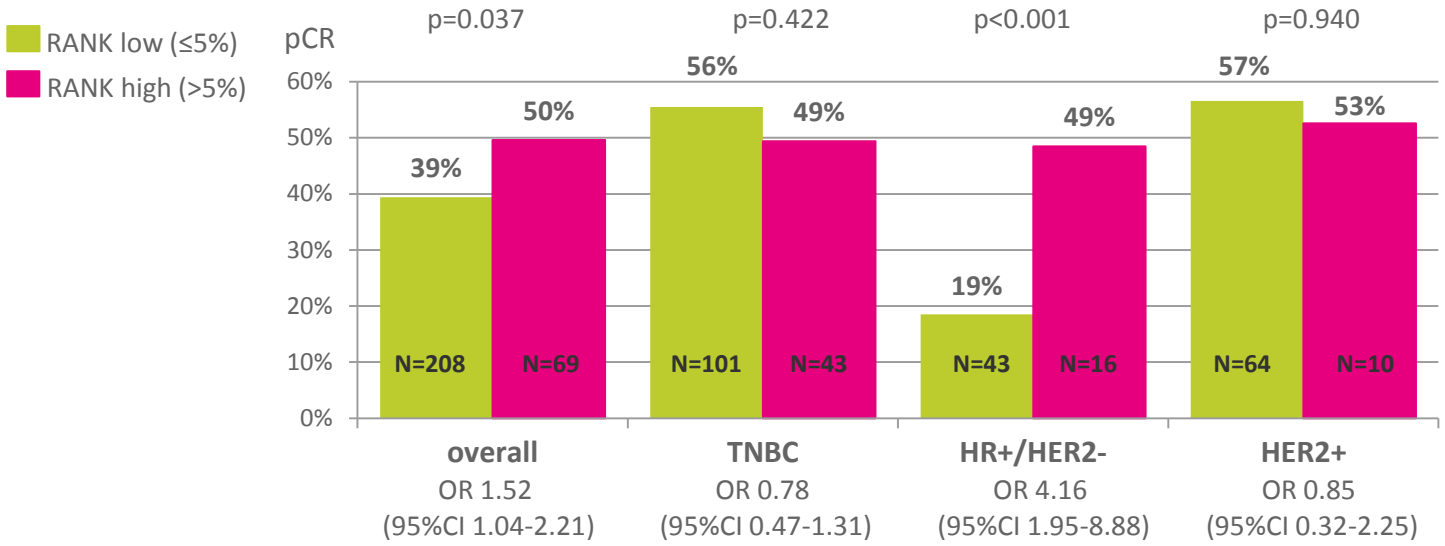
Denosumab as add-on to different regimen of nab-paclitaxel-anthracycline based neoadjuvant chemotherapy in early breast cancer: Subgroup analyses by RANK expression and HR status

Theresa Link, Jens-Uwe Blohmer, Marianne Just, Michael Untch, Oliver Stötzer, Peter A. Fasching, Andreas Schneeweiss, Pauline Wimberger, Sabine Seiler, Jens Huober, Wolfgang D. Schmitt, Christian Jackisch, Kerstin Rhiem, Claus Hanusch, Carsten Denkert, Bruno Sinn, Knut Engels, Valentina Nekljudova, Sibylle Loibl

-This is a joint study by GBG and AGO-B-

AGO-B
BREAST STUDY GROUP

pCR Rates by RANK and Subtype



Interaction Test RANK*subtype
(%, high vs low) p=0.0012

- Overall, RANK expression did not add additional predictive value (OR=1.05 [95%CI 0.69-1.60], p=0.823) when adjusted for BC subtype and the continuous variables age, Ki-67 and sTILs in multivariate model.
- In HR+/HER2- RANK expression was an independent significant predictor of pCR (OR=2.98 [95%CI 1.30-6.79], p=0.010) when adjusted for the continuous variables age, Ki-67 and sTILs.

Summary and Conclusion

- A high RANK expression was detected in 20.8% of the patients.
- A high RANK expression was associated with significantly higher pCR rates (49.6% vs. 39.4%; p=0.037).
- This effect was driven by patients with HR+/HER2- BC.
- However, a clinical benefit of denosumab in relation to RANK expression could not be shown. Further explorative analyses are still ongoing.

Germline mutation status and therapy response in patients with homologous recombination deficient, HER2-negative early breast cancer: Results of the GeparOLA study (NCT02789332). Jan Hauke[1], Corinna Ernst[1], Peter A. Fasching[2], Christian Jackisch[3], Fenja Seither[4], Peter Klare[5], Kerstin Rhiem[1], Sabine Schmatloch[6], Jens Huober[7], Andrea Stefek[8], Sabine Seiler[4], Christoph Uleer[9], Gabriele Doering[10], Andreas Schneeweiß[11], Carsten Denkert[12], Michael Untch[13], Jens-Uwe Blohmer[14], Rita K. Schmutzler[1], Sibylle Loibl[4], Eric Hahnen[1]

Figure 3: *gBRCA1/2* mutation status and pCR rates overall and in subgroups by hormone receptor status

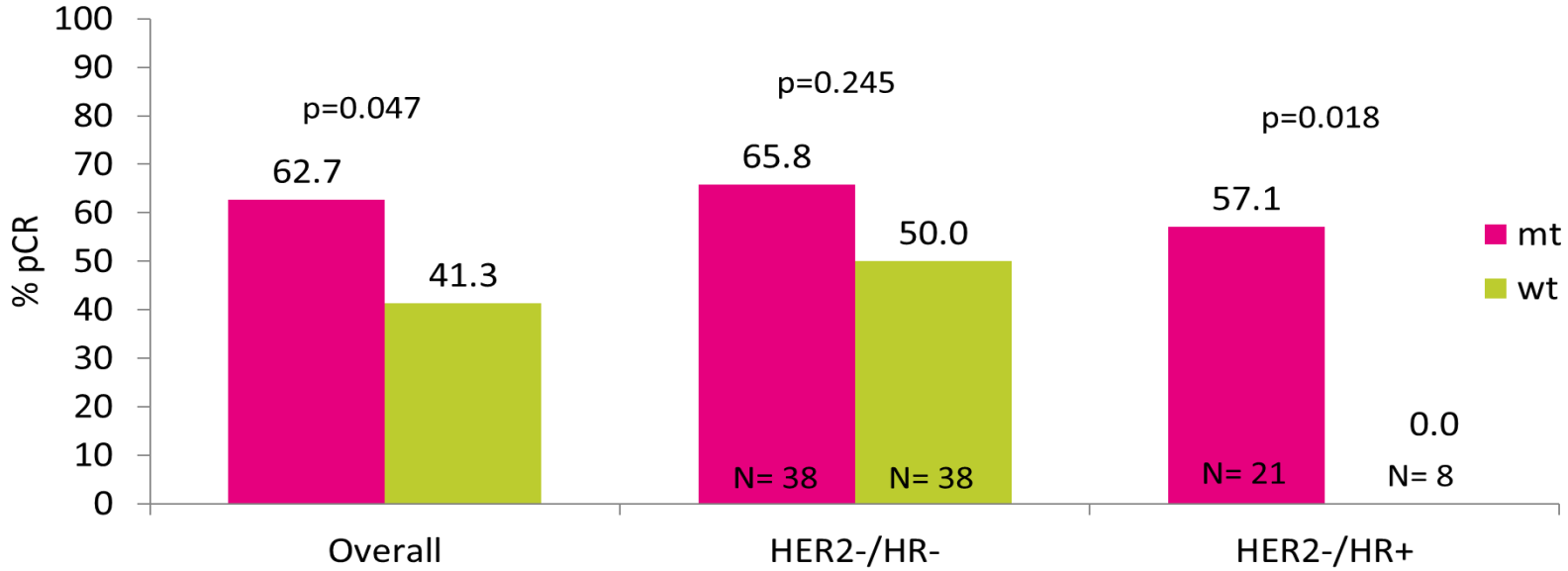
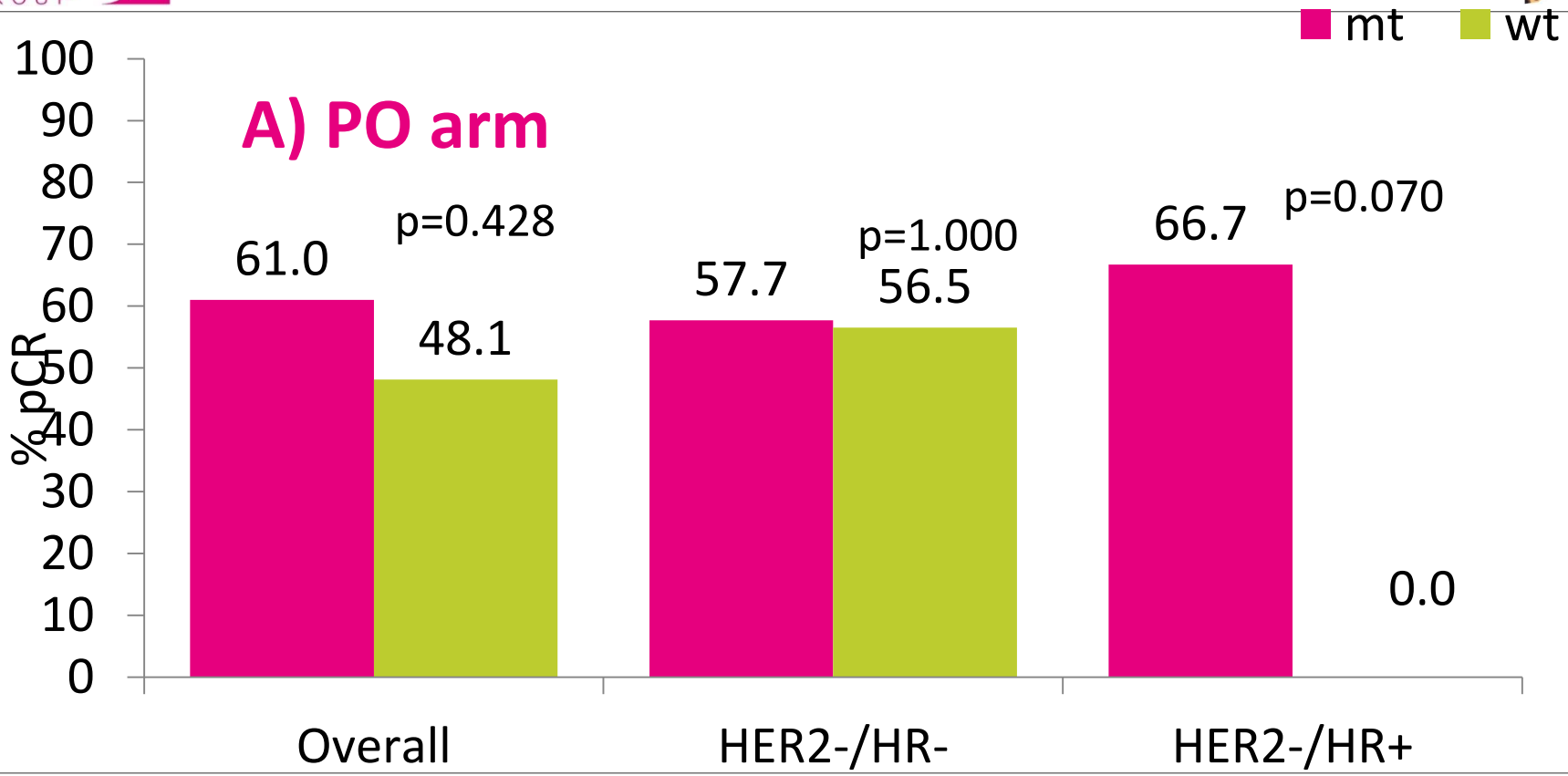


Figure 4: *gBRCA1/2* mutation status and pCR rates overall and in subgroups of HR- and HR+ breast cancer per treatment arm



HERZLICHEN DANK!

- **Wenn man den Standard ändern will, muss man die Erkenntnisse von fast 30 Jahren AGO B/ GBG Studien berücksichtigen und sich damit vergleichen**
- **Das gilt insbesondere für sog „Deeskalations“ strategien**

Fragen

- Kann man die Radikalität des axillären Eingriffes nach NACT reduzieren ?
- Wie kann man TDM 1 postneoadjuvant toppen ?
- Ist dosisdicht bei HR positiven Patientinnen genau so wirksam wie bei HR negativen ?
- Wird Olaparib bei HR pos und TNBC der neue Standard bei BRCA Mautationen und wenn ja, kann man auf die Chemo verzichten ?
- Ist das Kapitel CDK 4 /6 postneoadjuvant geschlossen ?

Diagnostik und Therapie früher und fortgeschrittener Mammakarzinome

in der DGGG e.V.
sowie
in der DKG e.V.

Guidelines Breast
Version 2021.1D

Save the Date:

Update virtuell am 27. Februar 2021

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