original reports

Adjuvant Palbociclib for Early Breast Cancer: The PALLAS Trial Results (ABCSG-42/AFT-05/BIG-14-03)

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abstract

PURPOSE Palbociclib is a cyclin-dependent kinase 4 and 6 inhibitor approved for advanced breast cancer. In the adjuvant setting, the potential value of adding palbociclib to endocrine therapy for hormone receptor–positive breast cancer has not been confirmed.

PATIENTS AND METHODS In the prospective, randomized, phase III PALLAS trial, patients with hormone receptor–positive, human epidermal growth factor receptor 2–negative early breast cancer were randomly assigned to receive 2 years of palbociclib (125 mg orally once daily, days 1-21 of a 28-day cycle) with adjuvant endocrine therapy or adjuvant endocrine therapy alone (for at least 5 years). The primary end point of the study was invasive disease-free survival (iDFS); secondary end points were invasive breast cancer–free survival, distant recurrence-free survival, locoregional cancer-free survival, and overall survival.

RESULTS Among 5,796 patients enrolled at 406 centers in 21 countries worldwide over 3 years, 5,761 were included in the intention-to-treat population. At the final protocol-defined analysis, at a median follow-up of 31 months, iDFS events occurred in 253 of 2,884 (8.8%) patients who received palbociclib plus endocrine therapy and in 263 of 2,877 (9.1%) patients who received endocrine therapy alone, with similar results between the two treatment groups (iDFS at 4 years: 84.2% *v* 84.5%; hazard ratio, 0.96; CI, 0.81 to 1.14; $P = .65$). No significant differences were observed for secondary time-to-event end points, and subgroup analyses did not show any differences by subgroup. There were no new safety signals for palbociclib in this trial.

CONCLUSION At this final analysis of the PALLAS trial, the addition of adjuvant palbociclib to standard endocrine therapy did not improve outcomes over endocrine therapy alone in patients with early hormone receptor–positive breast cancer.

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ASSOCIATED CONTENT

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Appendix

Data Supplement

Protocol

Author affiliations and support information (if applicable) appear at the end of this article.

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INTRODUCTION

Breast cancer is the most frequent malignancy in women worldwide and is curable in about three of four patients with early-stage, nonmetastatic disease.[1,2] The most prevalent subtype of early breast cancer is hormone receptor–positive,[3] and—after surgery, and radiotherapy and chemotherapy if indicated—adjuvant endocrine treatment (ET) for at least 5 years constitutes the standard of care.[4] Despite outcome improvements over the years, a sizable proportion of patients still experience disease recurrence. Thus, novel agents targeting new pathways, aimed at overcoming resistance to endocrine therapy, are being investigated.[5]

Cyclin-dependent kinases 4 and 6 (CDK4/6) trigger the phosphorylation of the retinoblastoma protein involved in cancer cell S-phase entry, and their blockade by specific inhibitors (CDK4/6i) can arrest cell cycle progression through G1 phase, thus promoting transient cell cycle withdrawal into a quiescent state and eventually permanent senescence, either of which can prohibit tumor progression.[6] Clinically, CDK4/6i have improved outcomes in patients with advanced breast cancer.[7-9] Palbociclib is a first-in-class oral CDK4/6i that, in combination with endocrine therapy, provides significant increases in objective response rates and progression-free survival in patients with advanced breast cancer, established in three randomized trials

CONTEXT

Key Objective

The addition of cyclin-dependent kinase 4 and 6 inhibitors (CDK4/6i) such as palbociclib to endocrine treatment (ET) has improved outcomes for patients with metastatic hormone receptor-positive human epidermal growth factor receptor 2–negative breast cancer. Large clinical trials are conducted to assess the usefulness of CDK4/6i in the curative early disease setting. PALLAS investigates the efficacy and safety of the addition of two years of adjuvant palbociclib to ET in patients with HR+ human epidermal growth factor receptor 2 early breast cancer.

Knowledge Generated

Two years of adjuvant palbociclib added to ET did not improve invasive disease-free survival or any other efficacy end point (4-year invasive disease-free survival 84.2% *v* 84.5%; hazard ratio 0.96). 44.9% of patients did not complete two years of palbociclib treatment, mainly because of protocol-defined reasons (neutropenia).

Relevance

PALLAS is the largest adjuvant CDK4/6i trial in the curative breast cancer setting. The results of this final protocol-defined analysis do not support the addition of palbociclib to ET. Translational research on the basis of the sizable trans-PALLAS program will be needed to identify reasons for the observed palbociclib efficacy difference compared with the metastatic setting.

(PALOMA-1-3).[7,10,11] All these studies met their primary end point by markedly prolonging progression-free survival versus ET alone, with overall survival (OS) improvements in some settings.[12]

The addition of palbociclib to ET has been proven to be clinically safe in these trials,[13] which is a precondition for using a drug in the early—curative—breast cancer setting. Typically, reversible neutropenia without associated infection is the most common side effect, and the feasibility of using this drug with its well-defined toxicity profile in the adjuvant setting has been previously established.[14] Experimental data suggest that palbociclib not only is active against proliferating tumor cells but also can exert anticancer stem-cell activity.[15]

Here, we report the final results of the global phase III Palbociclib CoLlaborative Adjuvant Study (PALLAS) that was designed to determine whether the addition of palbociclib to standard adjuvant endocrine therapy improves outcomes compared with endocrine therapy alone in patients with early hormone receptor–positive breast cancer.

PATIENTS AND METHODS

Trial Design and Oversight

This prospective, multicenter, randomized open-label phase III trial was conducted in 406 centers in 21 countries on five continents worldwide (listed in the Data Supplement [online only] available together with the Protocol [online only] and the statistical analysis plan). The trial was cosponsored and led by the academic groups Austrian Breast and Colorectal Cancer Study Group (ABCSG) and the Alliance Foundation Trials (AFT), in collaboration with PrECOG LLC, the NSABP Foundation, the Breast International Group, and the German Breast Group and in agreement with Pfizer, Inc, which provided funding and drug for the study. A global steering committee oversaw the trial design and conduct, and an international Independent Data Monitoring Committee monitored the trial regularly.

Data collection and monitoring were controlled by the study sponsors. Separate but harmonized databases were held for sites inside and outside the United States, with the data being merged on a monthly basis. Data quality was ensured by reviews following respective policies, and all data analyses were performed by ABCSG's and AFT's statistical teams. The funder had no role in data collection, data analysis, or data interpretation.

All analyzed patients provided written informed consent, and the trial was performed in strict accordance with ICH-GCP guidelines (ClinicalTrials.gov identifier: NCT02513394, EudraCT 2014-005181-30). The trial was approved by institutional review boards and ethics committees. The first author wrote the first draft of the article, with input from the other authors. All the authors contributed to the interpretation of the data and to revisions in the article and made the decision to submit the article for publication. All the authors vouch for the integrity, accuracy, and completeness of the data and for the fidelity of the trial to the Protocol and analysis plans.

Trial Participants and Random Assignment

We enrolled patients with histologically confirmed stage II or III hormone receptor–positive breast cancer and age 18 years or older. Before random assignment, patients had completed definitive breast surgery (and (neo)adjuvant chemotherapy and/or radiotherapy, if indicated). Trial inclusion was possible irrespective of eventual neoadjuvant treatment response. Standard adjuvant endocrine therapy commenced within 12 months of the histologic diagnosis,

and enrollment into the study had to occur within 6 months of starting endocrine therapy.[16]

A permuted block design with random block size (4 or 6) was used to randomly assign the patients 1:1 to receive 2 years of palbociclib in addition to ongoing standard adjuvant endocrine therapy or ongoing standard adjuvant endocrine therapy alone, stratified by anatomic stage (IIA *v* IIB or III), previous adjuvant or neoadjuvant chemotherapy (yes *v* no), age (≤ 50 years *v* > 50 years), and geographical region (United States *v* Europe *v* others). PALLAS statistical staff at the Mayo Clinic (Rochester, MN) provided the random assignment schedule created using SAS software (version 9.4) to Oracle Corporation (Redwood City, CA) who designed the telephone-based and web-based interactive response technology. Enrollment of patients with stage IIA disease was capped at 1,000 patients.

Trial Procedures

Lack of metastatic disease had to be proven per institutional practice before random assignment (Data Supplement). Also, the receipt of a tumor tissue block at a central biorepository was mandatory before random assignment.

Patients randomly assigned to arm A received palbociclib at a starting dose of 125 mg orally once daily, days 1-21, followed by 7 days off, in a 28-day cycle for a total duration of 2 years, in addition to standard adjuvant endocrine therapy (tamoxifen and aromatase inhibitor, with or without ovarian function suppression) for a duration of at least 5 years. The Protocol allowed for palbociclib dose reductions (to 100 mg and 75 mg, once daily, respectively) and interruptions, with discontinuation required for repeated severe neutropenia (grade 3 or higher). Patients randomly assigned to arm B received endocrine therapy alone for a duration of at least 5 years. Patients in both arms were evaluated by physical examination and laboratory testing at least quarterly for the first 2 years, followed by every 6-month intervals until year 5 and annually until year 10. Any imaging was symptom-directed, as per international guidelines. Follow-up methodology and intensity were similar between study arms, and necessary adaptations occurred during the COVID-19 pandemic.

Trial End Points

All time-to-event end points comply with the original Standardized Definitions for Efficacy End Points (STEEP) criteria,[17] except for the secondary end point invasive breast cancer–free survival, which is defined in the updated STEEP criteria,[18] and for locoregional recurrence-free survival (for details, see the Data Supplement). The primary end point was invasive disease-free survival (iDFS) defined as the time from random assignment to the date of first event: local or regional invasive ipsilateral recurrence, contralateral invasive breast cancer, distant recurrence, second primary invasive cancer of nonbreast origin, or death from any cause.

Statistical Analysis

Sample size was estimated for the primary end point of iDFS on the basis of a hazard ratio (HR) of 0.75 as the target effect size of palbociclib plus endocrine therapy versus endocrine therapy alone. Originally, the required sample size was estimated to be 4,600 patients, but was increased in 2018 to 5,600 because of lower event rates observed in comparable clinical trials as anticipated for this trial. Using a group sequential design, 469 events had to occur to achieve a power of 85% in the final analysis. The design

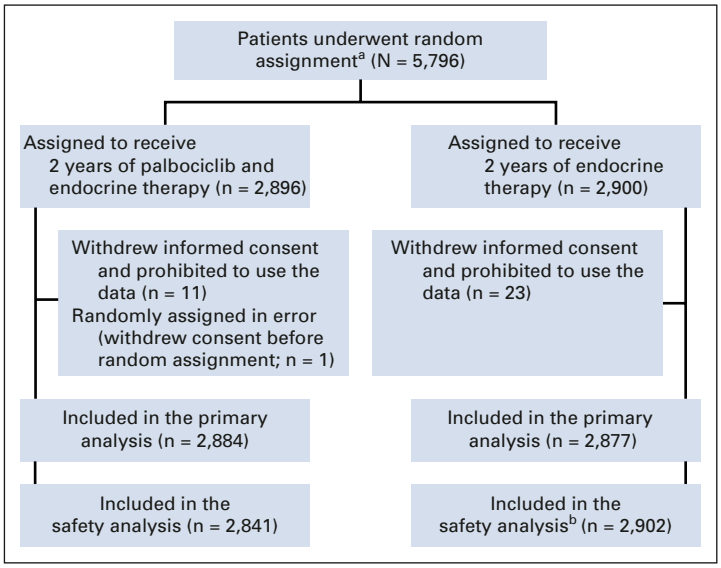

FIG 1. CONSORT diagram. [a]Of 6,688 patients who were screened for eligibility, 892 were not randomly assigned because of the following reasons: not meeting inclusion criteria (n = 466), declined to participate (n = 259), and other reasons (n = 167), leading to 5,796 randomly assigned patients. [b]Includes 36 patients from the palbociclib plus endocrine therapy group who received endocrine therapy only.

included two interim analyses (IA) for nonbinding futility (IA1 and IA2) and for binding superiority (IA2 only) using O'Brien-Fleming boundaries on the basis of Lan-DeMets spending functions to control the overall one-sided type I error rate at 0.025. They were scheduled to occur when 33% and 67% of the 469 events were observed. At the second interim analysis (IA2), the test statistic crossed the predefined futility boundary and palbociclib was discontinued in the approximately 350 patients who still were on active palbociclib treatment on May 29, 2020.[16]

According to the intention-to-treat principle, all randomly assigned patients were included in the final analyses. Only patients who withdrew their informed consent and explicitly prohibited the use of any collected data were excluded. Stratified log-rank tests with stratification factors of (neo)adjuvant chemotherapy (yes *v* no) and age (≤ 50 *v* > 50) at random assignment were used for the comparisons of time-to-event end points between the two treatment groups. Results were summarized using Kaplan-Meier curves with yearly estimates of the survival rates. HRs with two-sided 95% CIs

TABLE 1. Baseline Characteristics of all Patients in the Intention-to-Treat Population

Parameter	Palbociclib Plus Endocrine Therapy (n = 2,884), No. (%)	Endocrine Therapy Alone (n = 2,877), No. (%)	Total (N = 5,761), No. (%)
Anatomic stage			
I or IIA	513 (17.8)	519 (18.0)	1,032 (17.9)
IIB or III	2,370 (82.2)	2,358 (82.0)	4,728 (82.1)
Unknown	1 (0.0)	0	1 (0.0)
T-stage[a]			
T0, T1, Tis or TX	558 (19.3)	501 (17.4)	1,059 (18.4)
T2	1,603 (55.6)	1,636 (56.9)	3,239 (56.2)
T3 or T4	722 (25.0)	740 (25.7)	1,462 (25.4)
Unknown	1 (0.0)	0	1 (0.0)
N-stage[a]			
N0	365 (12.7)	385 (13.4)	750 (13.0)
N1	1,431 (49.6)	1,411 (49.0)	2,842 (49.3)
N2	700 (24.3)	709 (24.6)	1,409 (24.5)
N3	386 (13.4)	372 (12.9)	758 (13.2)
NX	1 (0.0)	0	1 (0.0)
Unknown	1 (0.0)	0	1 (0.0)
Tumor grade			
G1 or G2	1,926 (66.8)	1,971 (68.5)	3,897 (67.6)
G3	836 (29.0)	769 (26.7)	1,605 (27.9)
GX	118 (4.1)	137 (4.8)	255 (4.4)
Unknown	4 (0.1)	0	4 (0.1)
Neoadjuvant or adjuvant chemotherapy			
No	499 (17.3)	507 (17.6)	1,006 (17.5)
Yes	2,384 (82.7)	2,370 (82.4)	4,754 (82.5)
Unknown	1 (0.0)	0	1 (0.0)
Menopausal status			
Postmenopausal	1,562 (54.2)	1,534 (53.3)	3,096 (53.7)
Premenopausal (including perimenopausal)	1,303 (45.2)	1,323 (46.0)	2,626 (45.6)
Not applicable (male patient)	17 (0.6)	19 (0.7)	36 (0.6)
Unknown	2 (0.1)	1 (0.0)	3 (0.1)
Sex (at birth)			
Female	2,867 (99.4)	2,858 (99.3)	5,725 (99.4)
Male	17 (0.6)	19 (0.7)	36 (0.6)

[a]Assessed by pathologic staging or by clinical staging if preoperative therapy was given with the higher stage presented in this table.

were calculated via stratified Cox proportional hazards regression models. For post hoc comparisons between treatment arms within subgroups on the basis of patient characteristics and clinicopathologic factors, unstratified Cox models were used. Further post hoc analyses investigated treatment effect heterogeneity and the possible impact of drug exposure in relation to iDFS, as well as palbociclib dose reductions and early discontinuations over time (for details, see the Data Supplement).

Safety analyses were performed in all randomly assigned patients excluding those who did not start palbociclib or ET (safety population), according to actual treatment received. Incidences of treatment-emergent toxicities were reported per treatment arm and maximum grade within each adverse event term.

Analyses were carried out using SAS software (version 9.4). Two-sided P values $< .05$ were considered statistically significant. All data obtained through November 20, 2020, the date when 469 events were documented in the clinical database, were included in statistical analysis.

RESULTS

Patients and Follow-Up

Of the 5,796 patients randomly assigned between September 1, 2015, and November 30, 2018, 35 withdrew consent for use of all data, resulting in 5,761 patients included in the intention-to-treat population (Fig 1). Among these, 2,884 were randomly assigned to receive palbociclib plus endocrine therapy and 2,877 to receive endocrine therapy alone. Treatment arms in the trial were well balanced (Table 1, Data Supplement): the median age was 52 years (interquartile range, 45-61 years), and about half of the 5,761 patients were postmenopausal. One third had stage IIB disease, and half of the patients had stage III disease. Neoadjuvant chemotherapy was given to 1,939 (33.7%) patients and 2,875 (49.9%) received adjuvant chemotherapy before random assignment. An aromatase inhibitor was initiated in 3,872 (67.2%) patients and tamoxifen in 1,872 (32.5%) patients; 1,243 (21.6%) patients received a concurrent luteinizing hormone releasing-hormone agonist for ovarian function suppression. The median follow-up for this final analysis was 31 months (interquartile range, 24.5-37.3 months).

TABLE 2. Events Contributing to the Primary End Point

Event Category	Palbociclib Plus Endocrine Therapy (n = 2,884), No.	Endocrine Therapy Alone (n = 2,877), No.	Total (N = 5,761), No.
iDFS event	253	263	516
Distant recurrence	182	174	356
Second primary invasive cancer of nonbreast origin	30	37	67
Local recurrence	21	26	47
Regional recurrence	13	12	25
Contralateral invasive breast cancer	7	12	19
Death without recurrence	9	9	18

NOTE. Shown are data for all the patients in the intention-to-treat group who were included in the primary analysis. All first iDFS events are included. Hence, if a patient experienced several iDFS events on the same day, all these events are included. There are 14 patients with multiple iDFS events detected at the same time—two with local and regional recurrence, four with local and distant recurrence, six with regional and distant recurrence, and two with local, regional, and distant recurrence.

Abbreviation: iDFS, invasive disease-free survival.

Efficacy

Primary end point events occurred in 516 (9.0%) patients, 253 (8.8%) in patients treated with palbociclib plus endocrine therapy and 263 (9.1%) in patients receiving endocrine therapy alone. Distant metastasis was the first event in 356 (6.2%) patients, and second primary invasive cancer of nonbreast origin in 67 (1.2%) patients. Local or regional recurrences, contralateral invasive breast cancers, and deaths without prior cancer recurrence were first events in $< 1\%$ of patients (Table 2). One hundred seventy-six (3.1%) patients died during the observational period, of whom, 100 (3.5%) patients were treated with palbociclib plus endocrine therapy, and 76 (2.6%) patients were treated with endocrine therapy alone (Data Supplement).

The primary end point of iDFS was not significantly different in patients receiving palbociclib and endocrine therapy versus those receiving endocrine therapy alone, with a HR of 0.96 (CI, 0.81 to 1.14; $P = .65$) and iDFS rates at year 4 of 84.2% versus 84.5% (Fig 2A). The two treatment groups also did not differ with regard to secondary end points: 4-year survival rates for invasive breast cancer–free survival: 85.4% versus 86.0%; distant recurrence-free survival: 86.2% versus 87.8%; locoregional recurrence-free survival: 96.8% versus 95.4%; and OS of 93.8% versus 95.2%, respectively (Figs 2B-2E). Similar results were obtained for iDFS within subgroups of patients (Fig 3).

Treatment effect heterogeneity analysis to detect a relationship between a higher baseline risk and the HR effect size showed no significant differential palbociclib effect trend from low- to high-risk patients with regard to iDFS (Data Supplement).

Disease Recurrences

The majority of first distant recurrences in both arms occurred in nonvisceral locations (n = 256, 67.7% of patients with distant recurrences), particularly in bone (Data Supplement). Characteristic of the enrolled hormone receptor–positive breast cancer population, visceral metastases were less frequent, and if occurring, predominantly in liver and

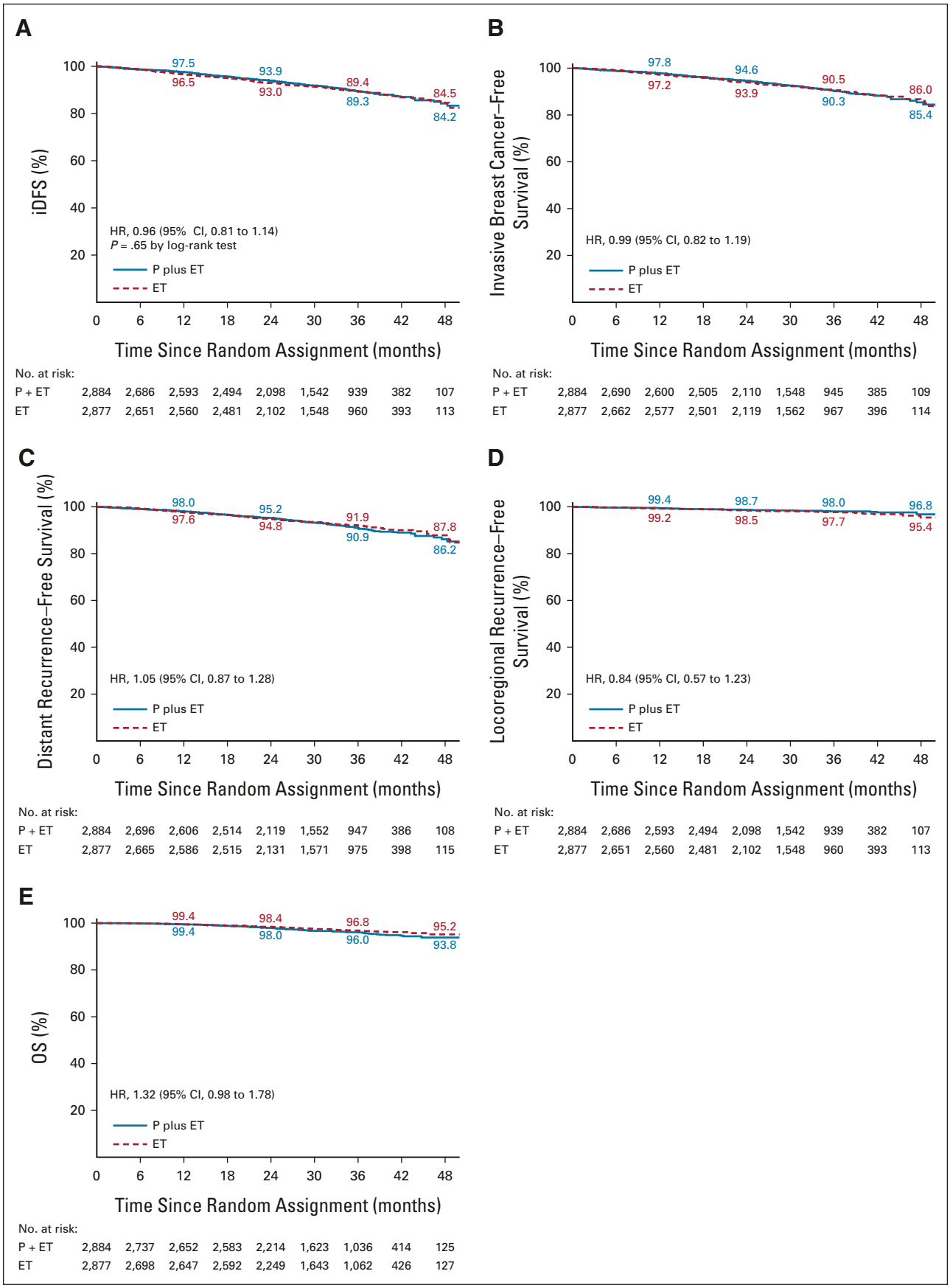

FIG 2. (continued on following page)

FIG 2. (Continued). Kaplan-Meier estimates of survival for the primary end point of (A) iDFS and for the secondary end points of (B) invasive breast cancer–free survival, (C) distant recurrence-free survival, (D) locoregional recurrence-free survival, and (E) OS are shown for women with stage II-III histologically confirmed hormone receptor–positive, HER2-negative breast cancer. The HRs with 95% CIs are given for each end point. In addition, the *P* value of a stratified log-rank test is shown for the primary end point. The numbers along the curves indicate the event-free rates in yearly intervals. ET, endocrine treatment; HER2, human epidermal growth factor receptor 2; HR, hazard ratio; iDFS, invasive disease-free survival; OS, overall survival; P, palbociclib.

lung. Disease recurrence in the central nervous system was rare (n = 19, 5.0%).

Treatment Exposure

Over the 2-year treatment period shown, a total of 55.2% (95% CI, 53.3 to 57.0) and 33.4% (31.7 to 35.1) of patients required reductions to a 100 mg and to a 75 mg daily dose, respectively (Data Supplement). Furthermore, cumulative incidence of early palbociclib discontinuations was 44.9% (CI, 43.1 to 46.7, Data Supplement), but landmark analysis did not show significant iDFS benefit for patients who remained on palbociclib for a longer duration (Data Supplement): the greatest difference was observed at the 24-month landmark comparing patients who did receive the full preplanned palbociclib treatment versus those who discontinued early (unadjusted HR = 0.89, 95% CI, 0.58 to 1.34; adjusted HR = 0.79, 95% CI, 0.52 to 1.20).

Safety and Side Effects

Of 5,761 patients, 5,743 (2,841 in the palbociclib plus endocrine therapy group and 2,902 in the endocrine therapy–alone group) initiated treatment and were included in the safety population. There were no new safety signals with respect to palbociclib treatment: overall, 2,826 (99.5%) patients receiving palbociclib and endocrine therapy and 2,604 (89.7%) patients receiving endocrine therapy alone experienced at least one adverse event. The respective frequencies of serious adverse events are 369 (13.0%) for the palbociclib and endocrine therapy group and 229 (7.9%) for the group of patients receiving endocrine therapy alone.

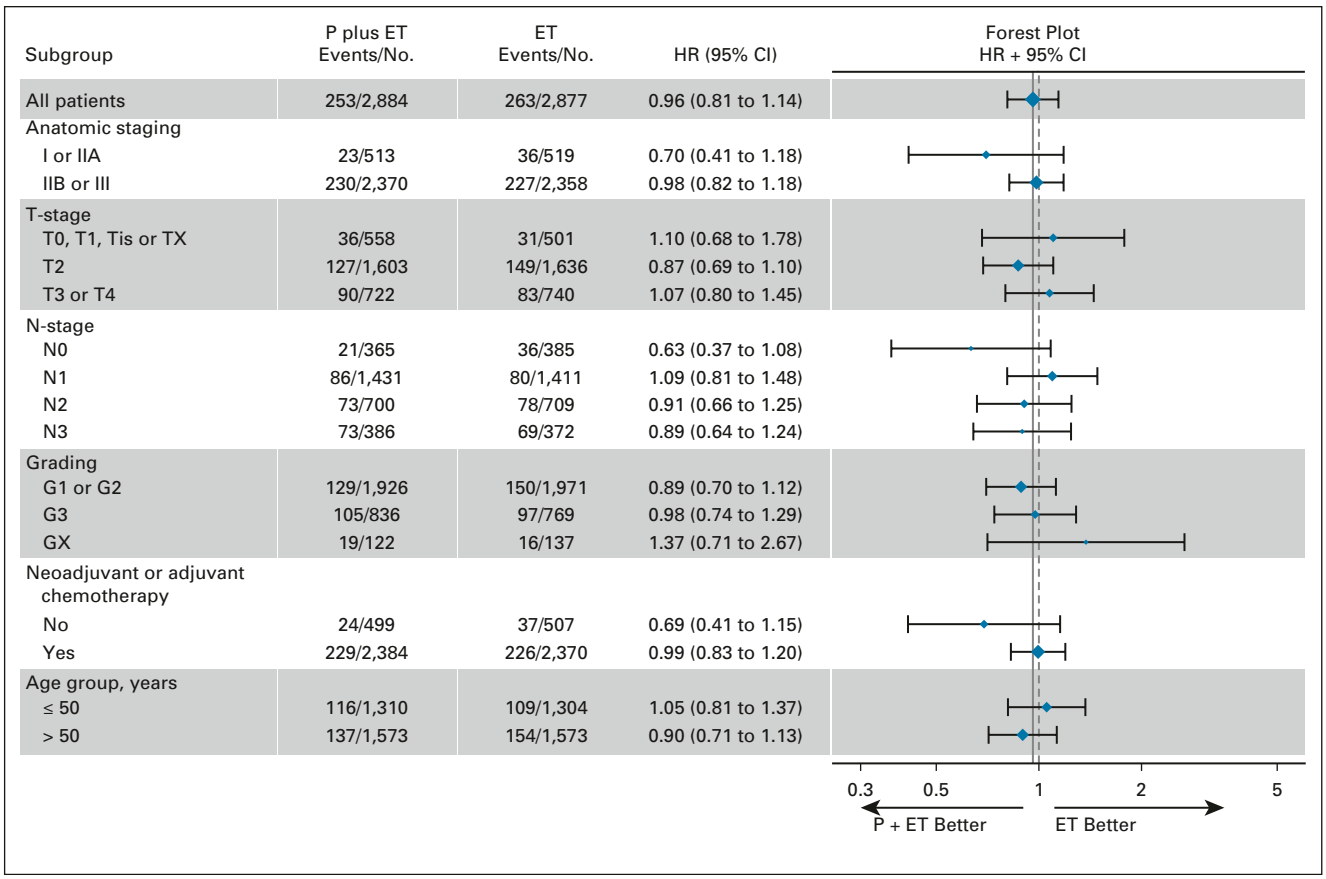

FIG 3. The forest plot shows the HRs (diamonds) and 95% CIs (horizontal lines) with regard to invasive disease-free survival within subgroups according to anatomic stage, tumor stage (T-stage), nodal status (N-stage), histologic grade, prior neoadjuvant or adjuvant chemotherapy, and age group. The solid vertical line indicates the overall HR estimate, and the dashed vertical line indicates a HR of 1.00. No significant interactions between subgroups and treatment groups were observed. ET, endocrine treatment; HR, hazard ratio; P, palbociclib.

TABLE 3. Adverse Events per Grade[a]

	Palbociclib Plus Endocrine Therapy (n = 2,841), No. (%)					Endocrine Therapy Alone (n = 2,902), No. (%)				
Adverse Event	Grade 1-2	Grade 3	Grade 4	Grade 5	Grade Unknown	Grade 1-2	Grade 3	Grade 4	Grade 5	Grade Unknown
Any adverse event	732 (25.8)	1,917 (67.5)	163 (5.7)	14 (0.5)	0	2,153 (74.2)	417 (14.4)	24 (0.8)	10 (0.3)	0
Neutropenia	611 (21.5)	1,635 (57.6)	124 (4.4)	0	1 (0.0)	132 (4.5)	11 (0.4)	0	0	1 (0.0)
Leukopenia	702 (24.7)	850 (29.9)	14 (0.5)	0	0	215 (7.4)	3 (0.1)	0	0	1 (0.0)
Fatigue	1,104 (38.9)	60 (2.1)	0	0	0	550 (19.0)	10 (0.3)	0	0	0
Arthralgia	1,055 (37.1)	32 (1.1)	0	0	0	1,270 (43.8)	35 (1.2)	0	0	0
Upper respiratory tract infection	807 (28.4)	32 (1.1)	0	0	0	477 (16.4)	4 (0.1)	0	0	0
Hot flush	695 (24.5)	7 (0.2)	0	0	2 (0.1)	842 (29.0)	7 (0.2)	0	0	0
Anemia	655 (23.1)	14 (0.5)	0	0	0	155 (5.3)	4 (0.1)	0	0	0
Thrombocytopenia	594 (20.9)	24 (0.8)	1 (0.0)	0	0	49 (1.7)	1 (0.0)	0	0	0
Nausea	545 (19.2)	7 (0.2)	0	0	0	238 (8.2)	4 (0.1)	0	0	0
Alopecia	510 (18.0)	0	0	0	1 (0.0)	149 (5.1)	0	0	0	0
Diarrhea	454 (16.0)	21 (0.7)	0	0	0	145 (5.0)	5 (0.2)	0	0	0
Headache	438 (15.4)	8 (0.3)	0	0	0	331 (11.4)	7 (0.2)	0	0	0
Cough	415 (14.6)	1 (0.0)	0	0	0	222 (7.6)	0	0	0	0
Constipation	395 (13.9)	0	0	0	0	171 (5.9)	0	1 (0.0)	0	0
Insomnia	376 (13.2)	7 (0.2)	0	0	0	353 (12.2)	4 (0.1)	0	0	0
Lymphopenia	266 (9.4)	98 (3.4)	5 (0.2)	0	0	113 (3.9)	8 (0.3)	1 (0.0)	0	0
Rash	333 (11.7)	5 (0.2)	0	0	0	148 (5.1)	3 (0.1)	0	0	0
Lymphoedema	332 (11.7)	4 (0.1)	0	0	1 (0.0)	267 (9.2)	1 (0.0)	0	0	0
Back pain	302 (10.6)	10 (0.4)	0	0	0	284 (9.8)	3 (0.1)	0	0	0
Hypertension	159 (5.6)	46 (1.6)	0	0	0	167 (5.8)	60 (2.1)	0	0	0
Tissue infection	69 (2.4)	53 (1.9)	2 (0.1)	0	0	76 (2.6)	31 (1.1)	0	0	0

[a]Adverse events shown are regardless of attribution; the table summarizes all grade 1-2 events occurring in 10% or more patients, all grade 3 events occurring in 1% or more patients, all grade 4 events occurring in 1% or more patients, and all grade 5 events occurring in 1% or more patients. No deaths were attributed to Protocol therapy.

Table 3 summarizes all-grade toxicities in ≥ 10% of patients for grade 1-2 and ≥ 1% of patients for grade 3, 4, and 5; the Data Supplement shows serious adverse events per grade. The most common adverse events in patients who received palbociclib and endocrine therapy were neutropenia (83.5%), leukopenia (55.1%), and fatigue (41.0%), which were less common in patients who received endocrine therapy alone (5%, 7.5%, and 19.3%, respectively). Other adverse events more common in patients who received palbociclib and endocrine therapy compared with those receiving endocrine therapy alone were upper respiratory tract infection (29.5% *v* 16.6%), anemia (23.5% *v* 5.5%), thrombocytopenia (21.8% *v* 1.7%), and alopecia (18.0% *v* 5.1%). None of the 176 deaths in the trial were considered related to study treatment.

DISCUSSION

This final Protocol-defined analysis of the PALLAS trial, with 5,796 recruited patients and a 31-month median follow-up and exceeding the predefined number of events, did not show significant improvements in survival end points for the addition of palbociclib to adjuvant endocrine therapy. These definitive findings from the PALLAS trial, already indicated by an interim analysis,[16] are surprising given the established efficacy of palbociclib and other CDK4/6i in advanced breast cancer. The combination of CDK4/6i with endocrine therapy became the approved standard of care for hormone receptor–positive breast cancer in the metastatic setting on the basis of large phase III studies: five studies evaluated CDK4/6i in first-line metastatic patients and showed consistent improvement in progression-free survival[8,10,19-21] and partly in OS[22,23] across studies. Three trials evaluated CDK4/6i in the pretreated metastatic setting and showed significant improvements in progression-free survival and OS,[24,25] with the OS benefit in PALOMA-3 confined to patients who had documented sensitivity to previous endocrine therapy.[12]

Overall, CDK4/6i are considered safe with manageable toxicity.[13,26] There were no new safety signals in this large

adjuvant trial, with the majority of early discontinuations resulting from neutropenia (Protocol-mandated) and certain demographic factors associated with early discontinuation (unpublished data).[27] However, landmark analyses did not reveal suboptimal drug exposure as a reason for the observed lack of palbociclib efficacy.

A smaller trial of 1 year of adjuvant palbociclib in the specific situation of high-risk disease after limited response to neoadjuvant chemotherapy, PENELOPE-B, also showed no significant iDFS benefit.[28] By contrast, the monarchE trial investigating 2 years of adjuvant abemaciclib in high-risk patients reported an interim result, suggesting a significant iDFS benefit for CDK4/6i,[29] and an updated analysis confirmed a relative 30% hazard rate reduction at a median follow-up of 27 months (HR = 0.70, $P < .0001$).[30] Ribociclib is currently being studied in the adjuvant setting in the NATALEE study (NCT03701334).

There are several possible explanations for the observed outcome differences seen in adjuvant CDK4/6i studies, including differences in study populations and procedures, drug regimens, follow-up durations, or efficacy differences between the drugs. The latter is unlikely given the almost identical magnitude of benefits in advanced breast cancer trials.[31] Preclinically, palbociclib has similar potency against cyclin D1-CDK4 and cyclin D2-CDK6 complexes, whereas ribociclib and abemaciclib have greater potency against CDK4 than CDK6.[32,33] Subtle differences have been reported from CDK4/6i trials in the metastatic setting: although palbociclib appears to be more effective in patients with bone-only disease,[34] abemaciclib appears to be most effective in patients with aggressive and poor prognosis disease,[35] which is in line with the reported benefit of adjuvant abemaciclib in the monarchE study of high-risk patients. A sizable fraction of higher risk patients enrolled in PALLAS and, in line with PENELOPE-B, did not derive greater benefit from palbociclib than the general study population.

It was demonstrated in the neoadjuvant setting that palbociclib may preferentially work in the most luminal tumors,[36] and it might be that any antiproliferative effect of adjuvant palbociclib can only be shown in the absence of cytotoxic chemotherapy.[37] In the same study, tumor cell proliferation recovered notably between the end of neoadjuvant palbociclib and surgery, indicating that continuous CDK4/6i treatment (as with abemaciclib in the monarchE study) may provide the advantage of uninterrupted cell cycle inhibition, which could better promote tumor cell senescence[38] than intermittent therapy.[39] Of several described resistance mechanisms against CDK4/6i, reactive resistance by clonal evolution or adaptation is an unlikely reason for palbociclib's inefficiency in the adjuvant setting.[40,41] Also, the lack of benefit of palbociclib in the early disease setting may simply reflect the lack of an available sensitive target: successful cessation of the cell cycle requires proliferating cancer cells, and breast cancer stem cells that emerge from dormancy in a stochastic manner over time—the putative target of adjuvant therapy—might not be affected by the CDK4/6i.[39] By contrast, in the neoadjuvant setting, with proliferating target cells as in advanced disease, the addition of palbociclib to anastrozole led to higher cell cycle arrest than anastrozole alone[36] and abemaciclib led to inhibition of cell cycle progression measured by Ki67 expression.[42]

The lack of adjuvant palbociclib efficacy does not preclude further integration of CDK4/6i into the breast cancer treatment algorithm. In addition to new combinations being currently investigated in various breast cancer subtypes,[43] translational science will help to better understand unique tissue and/or serum biomarkers[44] that may predict individual benefit or resistance[45] for each of the approved CDK4/6 inhibitors to guide optimal patient selection and treatment combinations.[46] The sizable trans-PALLAS biorepository containing both tumor tissue and serial plasma specimens together with the planned clinical long-term follow-up of patients will serve as an excellent resource to support such important research.

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Please see our Appendix (online only) for a full list of the PALLAS groups and investigators and their affiliations.

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Austrian Breast & Colorectal Cancer Study Group (ABCSG)

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SOLTI—Breast Cancer Research Group

GBG Forschungs GmbH

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