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- Stand *November*

Real-world Efficacy of Ribociclib + Aromatase Inhibitor/Fulvestrant or Endocrine Monotherapy or Chemotherapy as First-line Treatment in Women With HR–Positive, HER2–Negative Locally Advanced or Metastatic Breast Cancer: Third Interim Analysis From the RIBANNA Study

PS10-16

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Introduction

- Ribociclib (RIB), an orally bioavailable selective cyclin-dependent kinase 4/6 (CDK4/6) inhibitor, in combination with letrozole, an aromatase inhibitor (AI) significantly prolonged progression-free survival (PFS) in treatment-naive patients with hormone receptor–positive (HR+), human epidermal growth factor receptor-2–negative (HER2–) advanced breast cancer (ABC).[1] Based on these results from MONALEESA 2, RIB + AI was approved in 2017 by the European Medical Agency as an initial endocrine therapy (ET) for the treatment of postmenopausal women with HR+, HER2– advanced or metastatic breast cancer[2]
- In December 2018, the European commission expanded the indication for RIB, approving the use of RIB in combination with an AI or fulvestrant (FUL) for the treatment of women with HR+, HER2– locally advanced or metastatic breast cancer as initial ET or in women who have received prior ET. For premenopausal or perimenopausal women, RIB + ET in combination with a luteinizing hormone-releasing hormone agonist was approved[3]
- The data from MONALEESA-3 (RIB + FUL) and MONALEESA-7 (RIB + non-steroidal AI/tamoxifen + goserelin) showed a significant improvement in PFS and the overall survival outcome in patients receiving RIB + ET compare with those receiving ET alone, irrespective of the menopausal status line of therapy, and combination partner[4-7]
- Real-world evidence on the effectiveness, safety, and tolerability of RIB + AI/FUL in patients with HR+, HER2– ABC is helpful to gain insights into routine clinical practice
- The non interventional RIBANNA study (CLEE011ADE03) was planned to evaluate RIB + AI/FUL in a routine clinical setting among patients with ABC (October 2017 - October 2024). Data will be collected on treatment decisions for first-line therapy (including established standard first-line therapies such as ET and chemotherapy [CT] in three different cohorts) on descriptive comparison. In addition, data on further lines of therapy will be collected to gain insight into the efficacy upon different therapy sequencing
- The study results of the first and second interim analyses of the RIBANNA study were presented in SABCS 2018 and 2019. In this poster, the third interim analysis data from this study are presented

Objectives

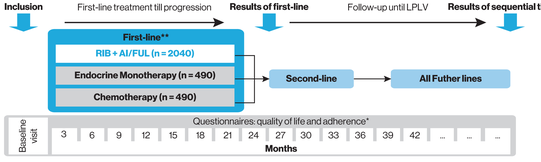
- To provide updated data on demographic characteristics
- To provide data on safety and dose modifications in the first-line setting

Methods

Study Design and Patient Population

- RIBANNA is a prospective, non interventional study ongoing in Germany since October 2017 in premenopausal, perimenopausal, and postmenopausal women (planned, N = 3020) planned to be administered either frontline treatment with RIB + AI/FUL (n = 2040), ET (n = 490), or CT (n = 490) for HR+, HER2– ABC (**Figure 1**), prescribed in accordance with the respective German treatment guidelines
- Key eligibility criteria included adult women of any menopausal status with a histologically confirmed HR+, HER2– advanced or metastatic breast cancer of any histology, no previous systemic therapy for advanced or metastatic breast cancer, no contraindications, and no involvement in an interventional or non-interventional clinical study
- Patient data from clinical practice in all three cohorts (RIB + AI/FUL, ET, and CT) was collected to assess efficacy, safety, and tolerability
- In all three cohorts, further lines of treatment are being documented to gain insight into the outcomes of sequential therapy, for which the patients are being observed across treatment lines for up to 7 years

Figure 1. The RIBANNA Study Design



* Adherence questionnaires were only collected for the RIB + AI/FUL cohort.
** Planned enrolment size.
AI, aromatase inhibitor; FUL, fulvestrant; LPLV, last patient last visit; RIB, ribociclib.

Results

Patient Characteristics and Disposition

- Overall, 2356 patients were enrolled in the study by the data cutoff date of October 15, 2020 (RIB + AI/FUL, n = 1976; ET, n = 209; CT, n = 171)
- Of 2214 treated patients, a total of 1860 (84%) patients received RIB + AI/FUL therapy in the first-line setting (**Table 1**)

Table 1. Patient Disposition

Patients	Total (N = 2356), n (%)	RIB + AI/FUL (n = 1976), n (%)	ET (n = 209), n (%)	CT (n = 171), n (%)
Treated	2214 (94.0)	1860 (94.1)	193 (92.3)	161 (94.2)
First-line therapy	2214 (94.0)	1860 (94.1)	193 (92.3)	161 (94.2)
Second-line therapy	263 (11.2)	198 (10.0)	32 (15.3)	33 (19.3)
Third-line therapy	56 (2.4)	42 (2.1)	7 (3.3)	7 (4.1)
Fourth-line therapy	1 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)
Discontinued study	551 (23.4)	427 (21.6)	56 (26.8)	68 (39.8)
Death	235 (10.0)	177 (9.0)	24 (11.5)	34 (19.9)
Lost to Follow-Up	100 (4.2)	78 (3.9)	8 (3.8)	14 (8.2)
Other reason	80 (3.4)	61 (3.1)	11 (5.3)	8 (4.7)
Withdrawal of informed consent	72 (3.1)	60 (3.0)	7 (3.3)	5 (2.9)
Physician's decision	43 (1.8)	38 (1.9)	3 (1.4)	2 (1.2)

AI, aromatase inhibitor; CT, chemotherapy; ET, endocrine therapy; FUL, fulvestrant; RIB, ribociclib.

- The safety analysis set (N = 2214) included all patients who received at least one dose of study medication, i.e., at least one documented treatment with a dose > 0 on the therapy form, comprising 1860 (91.9%), 193 (89.4%), and 161 (87.0%) patients from the RIB + AI/FUL (n = 2024), ET (n = 216), and CT (n = 185) cohorts, respectively. The full analysis set (N = 1905), which included all patients, except screening failures and locked patients, who received at least one dose of study medication (safety analysis set) and for whom at least one post-baseline evaluation was recorded, comprised 1619 (80.0%), 158 (73.1%), and 128 (69.2%) patients from the RIB + AI/FUL, ET, and CT cohorts, respectively
- In the RIB + AI/FUL and CT cohorts, 45.2% and 58.6% of patients, respectively, were aged < 65 years. Approximately 36.8% of patients in the RIB + AI/FUL cohort and 58.2% of patients in the ET cohort were aged > 70 years (**Table 2**)

Table 2. Demographic and Baseline Characteristics (Full Analysis set)

Demographic variable	Total (N = 1905)	RIB + AI/FUL (n = 1619)	ET (n = 158)	CT (n = 128)	P value (difference RIB + AI/FUL vs ET)	P value (difference RIB + AI/FUL vs CT)
Mean age, years (SD)	65.6 (11.6)	65.4 (11.5)	71.0 (11.6)	61.8 (11.5)	< 0.001	0.001
Age (years), n (%)						
< 65	854 (44.8)	732 (45.2)	47 (29.7)	75 (58.6)	< 0.001	0.007
65 - 70	333 (17.5)	292 (18.0)	19 (12.0)	22 (17.2)	-	-
> 70	718 (37.7)	595 (36.8)	92 (58.2)	31 (24.2)	-	-
Menopausal status, n (%)						
Postmenopausal	1697 (89.1)	1439 (88.9)	146 (92.4)	112 (87.5)	0.127	0.754
Premenopausal/perimenopausal	188 (9.9)	164 (10.1)	10 (6.3)	14 (10.9)	-	-
ECOG performance status, n (%)						
0	818 (42.9)	708 (43.7)	54 (34.2)	56 (43.8)	< 0.001	0.272
1	670 (35.2)	569 (35.1)	57 (36.1)	44 (34.4)	-	-
≥ 2	161 (8.5)	120 (7.4)	26 (16.5)	15 (11.7)	-	-
Mean time since initial diagnosis, years (SD)	5.9 (7.3)	5.9 (7.3)	6.8 (8.5)	4.7 (6.3)	0.154	0.051
T stage at start of study*, n (%)						
TX	582 (30.6)	496 (30.8)	54 (34.2)	32 (25.0)	0.596	0.027
T0 + T1	395 (20.8)	345 (21.4)	31 (19.6)	19 (14.8)	-	-
T2-T4	911 (48.0)	765 (47.4)	70 (44.3)	76 (59.4)	-	-
N stage at start of study*, n (%)						
NX	635 (33.4)	534 (33.1)	59 (37.3)	42 (32.8)	0.068	0.980
N0 + N1	948 (49.9)	804 (49.8)	81 (51.3)	63 (49.2)	-	-
N2 + N3	304 (16.0)	267 (16.6)	15 (9.5)	22 (17.2)	-	-
M stage at start of study*, n (%)						
M0	48 (2.5)	42 (2.6)	2 (1.3)	4 (3.1)	0.425	0.772
M1	1829 (96.3)	1551 (96.2)	155 (98.1)	123 (96.1)	-	-
Grading at initial diagnosis*, n (%)						
G1	106 (5.6)	99 (6.1)	5 (3.2)	2 (1.6)	0.063	0.002
G2	1122 (59.0)	955 (59.1)	102 (64.6)	65 (50.8)	-	-
G3	488 (25.7)	411 (25.4)	29 (18.4)	48 (37.5)	-	-
Hormone receptor status at initial diagnosis*, n (%)						
ER+/PR+	1531 (80.7)	1315 (81.5)	125 (79.6)	91 (71.1)	0.577	0.016
ER+/PR–	225 (11.9)	186 (11.5)	18 (11.5)	21 (16.4)	-	-
ER–/PR+	9 (0.5)	7 (0.4)	0 (0.0)	2 (1.6)	-	-
ER–/PR–	133 (7.0)	105 (6.5)	14 (8.9)	14 (10.9)	-	-
Metastases at start of study*, n (%)						
CNS, liver, lung	768 (42.0)	649 (41.9)	39 (25.2)	80 (65.0)	< 0.001	< 0.001
Bone only	580 (31.7)	488 (31.5)	75 (48.4)	17 (13.8)	-	-
Skin, lymph nodes, other	434 (23.8)	377 (24.3)	37 (23.9)	20 (16.3)	-	-

*Remaining cases are missing.
AI, aromatase inhibitor; CNS, central nervous system; CT, chemotherapy; ECOG, Eastern Cooperative Oncology Group; ER, estrogen receptor; ET, endocrine therapy; FUL, fulvestrant; PR, progesterone receptor; RIB, ribociclib; SD, standard deviation.

Prior Adjuvant Chemotherapy and ET (Full Analysis Set)

- In all cohorts, nonsteroidal AIs were the most frequently received prior ET (225 [13.9%], 21 [13.3%], and 13 [10.2%] patients from the RIB + AI/FUL, ET, and CT cohorts, respectively) and anthracycline-based combination therapy was the most frequently received prior CT in the adjuvant setting (218 [13.5%], 16 [10.1%], and 17 [13.3%] patients from the RIB + AI/FUL, ET, and CT cohorts, respectively)
- The prior antineoplastic treatments received by patients in the adjuvant setting are listed in **Table 3**

Table 3. Prior Antineoplastic Treatment in the Adjuvant Setting (Full Analysis Set)

	Total (N = 1905)	RIB + AI/FUL (n = 1619)	ET (n = 158)	CT (n = 128)	P value (difference RIB + AI/FUL vs ET)	P value (difference RIB + AI/FUL vs CT)
No prior adjuvant disease*	914 (48.0)	772 (47.7)	75 (47.5)	67 (52.3)	0.449	0.592
Prior adjuvant disease	974 (51.1)	831 (51.3)	83 (52.5)	60 (46.9)	-	-
Adjuvant ET only	230 (23.6)	195 (23.5)	23 (27.7)	12 (20.0)	0.219	0.381
Adjuvant CT only	262 (26.9)	231 (27.8)	15 (18.1)	16 (26.7)	-	-
Adjuvant ET + CT	285 (29.3)	252 (30.3)	23 (27.7)	10 (16.7)	-	-
Missing information regarding adjuvant therapy**	197 (20.2)	153 (18.4)	22 (26.5)	22 (36.7)	-	-
Missing information regarding prior adjuvant disease	17 (0.9)	16 (1.0)	0 (0.0)	1 (0.8)	-	-

*M stage (MX, M1) or locally advanced at initial diagnosis.
**Patients with prior adjuvant disease but without documentation of prior antineoplastic medication.
AI, aromatase inhibitor; CT, chemotherapy; ET, endocrine therapy; FAS, final analysis set; FUL, fulvestrant; RIB, ribociclib.

Ribociclib Dosing in the First-line Setting

- In the safety population, RIB (n = 1860) was mainly prescribed in combination with letrozole (68.2%), FUL (20.7%), anastrozole (6.2%), and exemestane (4.7%) in the first-line setting
- The starting dose of RIB in the first-line setting was 600 mg in most (87.1%) patients in the RIB + AI/FUL cohort
- In patients who received RIB + AI/FUL in the first-line setting, the mean daily dose of RIB was 413.1 mg/day including dose interruptions and 532.9 mg/day excluding dose interruptions
- In the RIB + AI/FUL cohort, dose interruptions for RIB were required in 33.0% of patients in the first-line setting, mainly due to adverse events (AEs) in 23.2% of patients

Safety

- As of October 15, 2020, the mean (standard deviation) duration of drug exposure was 322.7 (247.4) days for patients receiving RIB + AI/FUL, 313.0 (187.6) days for those receiving ET, and 285.9 (272.1) days for those receiving CT
- The frequencies of treatment-emergent AEs (> 5% in any treatment cohort) to date in each treatment cohort are shown in **Table 4**
- The most frequent AEs in all treatment cohorts were nausea, neutropenia, fatigue, and leucopenia
- In patients who received RIB + AI/FUL in the first-line setting, 3.2% had QT prolongation in the electrocardiogram (ECG)

Table 4. Incidence of Treatment-Emergent Adverse Events (> 5% in Any Treatment Cohort) During First-line Therapy (Safety Analysis Set)

Adverse event, n (%)	RIB + AI/FUL (n = 1860)		ET (n = 193)		CT (n = 161)	
	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4
Any adverse event	1515 (81.5)	703 (37.8)	121 (62.7)	62 (32.1)	136 (84.5)	74 (46)
Nausea	411 (22.1)	22 (1.2)	27 (14)	1 (0.5)	24 (14.9)	2 (1.2)
Neutropenia	367 (19.7)	229 (12.3)	13 (6.7)	11 (5.7)	23 (14.3)	12 (7.5)
Fatigue	357 (19.2)	16 (0.9)	19 (9.8)	3 (1.6)	28 (17.4)	1 (0.6)
Leukopenia	290 (15.6)	92 (5.0)	16 (8.3)	12 (6.2)	20 (12.4)	10 (6.2)
Alopecia	222 (11.9)	2 (0.1)	10 (5.2)	-	19 (11.8)	1 (0.6)
Diarrhea	178 (9.6)	13 (0.7)	10 (5.2)	1 (0.5)	22 (13.7)	3 (1.9)
Dyspnea	132 (7.1)	30 (1.6)	6 (3.1)	2 (1.0)	17 (10.6)	5 (3.1)
Vomiting	128 (6.9)	22 (1.2)	8 (4.2)	2 (1.0)	14 (8.7)	2 (1.2)
Constipation	124 (6.7)	4 (0.2)	7 (3.6)	-	18 (11.2)	1 (0.6)
Anemia	115 (6.2)	35 (1.9)	7 (3.6)	4 (2.1)	12 (7.5)	3 (1.9)
Bone pain	111 (6.0)	4 (0.2)	12 (6.2)	1 (0.5)	11 (6.8)	3 (1.9)
Dizziness	111 (6.0)	2 (0.1)	10 (5.2)	1 (0.5)	4 (2.5)	-
Arthralgia	109 (5.9)	2 (0.1)	17 (8.8)	3 (1.6)	6 (3.7)	1 (0.6)
Rash	107 (5.8)	4 (0.2)	2 (1.0)	1 (0.5)	15 (9.3)	-
Hot flush	107 (5.8)	1 (0.1)	7 (3.6)	-	3 (1.9)	-
Pruritus	102 (5.5)	1 (0.1)	3 (1.6)	-	2 (1.2)	-
Deterioration in physical health	101 (5.4)	41 (2.2)	10 (5.2)	6 (3.1)	20 (12.4)	12 (7.5)
Decreased appetite	92 (5.0)	3 (0.2)	8 (4.2)	1 (0.5)	12 (7.5)	1 (0.6)
Headache	92 (5.0)	2 (0.1)	4 (2.1)	-	9 (5.6)	-
Back pain	85 (4.6)	7 (0.4)	11 (5.7)	1 (0.5)	8 (5.0)	2 (1.2)
Thrombocytopenia	79 (4.3)	19 (1.0)	6 (3.1)	2 (1.0)	8 (5.0)	2 (1.2)
Malignant neoplasm progression	80 (4.3)	58 (3.1)	9 (4.7)	4 (2.1)	9 (5.6)	7 (4.4)
Hypertension	66 (3.6)	19 (1.0)	6 (3.1)	1 (0.5)	10 (6.2)	4 (2.5)
Polyneuropathy	21 (1.1)	-	3 (1.6)	-	15 (9.3)	-
Palmar-plantar erythrodysaesthesia syndrome	19 (1.0)	2 (0.1)	-	-	9 (5.6)	1 (0.6)

AI, aromatase inhibitor; CT, chemotherapy; ET, endocrine therapy; F, fulvestrant; RIB, ribociclib.

- In the RIB + AI/FUL cohort, approximately 85% of patients had at least one ECG measurement during RIB treatment, of which 41.4% patients received three or more ECG measurements using the cardiac health application and 29.3% patients received using conventional ECG monitoring (**Table 5**)

Table 5. Number of ECG Measurements in the First Three Visits* (Full Analysis Set)

	RIB + AI/FUL (n = 1619)	RIB + AI/FUL conventional ECG (n = 967)	RIB + AI/FUL Cardiac health application (n = 116)
Mean (SD)	1.7 (1.0)	2.0 (0.8)	2.2 (0.8)
Number of ECG measurements, n (%)			
No ECG measurement	244 (15.1)	-	-
At least one ECG measurement	1375 (84.9)	967 (100.0)	116 (100.0)
At least two ECG measurements	933 (57.6)	639 (66.1)	89 (76.7)
Three ECG measurements	429 (26.5)	283 (29.3)	48 (41.4)

*Only baseline visit, Visit 1, and Visit 2 are included.
AI, aromatase inhibitor; ECG, electrocardiogram; FUL, fulvestrant; RIB, ribociclib; SD, standard deviation.

Conclusions

- The RIBANNA study demonstrated diverse population characteristics among patients receiving RIB treatment in a real-world setting. Based on the baseline demographic data, treatment with RIB (CDK4/6 inhibitor) was observed to be very well accepted by patients (premenopausal and postmenopausal) with HR+, HER2– ABC
- In this study, 61.7% of patients were therapy naive for ET. These findings are in line with data previously reported in the MONALEESA studies[4,5,8]
- The most common AEs observed in patients from the RIB + AI/FUL cohort were nausea, neutropenia, fatigue, and leucopenia, which were similar to those observed in the other cohorts
- Efficacy data will be reported during fourth and fifth interim analyses in 2021 and 2022

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