BALVERSA® (erdafitinib)
BALVERSA - RAGNAR study (CAN2002)

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Overview[1]

RAGNAR (NCT04083976) is a phase 2, open-label, single-arm, global, multicenter study evaluating the efficacy and safety of BALVERSA in adult and pediatric patients (children aged ≥6 years) with unresectable, locally advanced, or metastatic solid tumor malignancies (tumor agnostic), *FGFR* mutations or fusions, and documented disease progression.

RAGNAR is an ongoing study that is currently not recruiting.

Key eligibility criteria[1,2]

- Age ≥6 years.
- Histologically confirmed, unresectable, locally advanced or metastatic solid tumor with *FGFR* mutation/gene fusion.
- Patient must have received ≥1 prior line of systemic therapy for metastatic disease or must be a child/adolescent with a newly diagnosed solid tumor and no acceptable standard therapies.
- Documented disease progression (any progression requiring a change in treatment prior to full-study screening).

Study design[1-3]

Screening phase
Molecular eligibility and full-study screening

↓

Treatment phase
BALVERSA oral tablet (planned N=336)

↓

End of treatment visit
Occurs 30 days after the last BALVERSA dose

↓

Follow-up phase
Follow-up until death, consent withdrawal, loss to follow-up, or end of study

Molecular screening[4]

- Preliminary results of molecular screening for *FGFR* alterations in 110 patients were reported.
  - CCA was the most common malignancy (n=30; 27%). Overall, 80% of patients with CCA had *FGFR2* fusion, with the most common *FGFR* variant being *FGFR2-BICC1*.
  - High-grade glioma was the second most common malignancy (n=21; 19%). Overall, 95% of patients with high-grade glioma had *FGFR3* fusion, with the most common *FGFR* variant being *FGFR3-TACC3*.

Efficacy results[2,5-12]

- After a median follow-up of 17.9 months, in the primary cohort of patients with 16 solid tumor types (n=217)[2,5]:
  - ORR per IRC: 30% (95% CI, 24-36)
  - Investigator-assessed ORR: 25% (95% CI, 20-32)
  - DCR: 74% (95% CI, 67-80)
  - Median DOR: 6.9 months (95% CI, 4.4-7.1)
  - Investigator-assessed median DOR: 7 months (95% CI, 5.5-8.5)
  - CBR: 46% (95% CI, 39-53)
  - Median PFS: 4.2 months (95% CI, 4.1-5.5)
  - Median OS: 10.7 months (95% CI, 8.7-12.1)
- Additional efficacy results for other patient populations have been presented and/or published.[6-12]

Safety results[2,5-12]

- After a median follow-up of 17.9 months, in the primary cohort of patients with 16 solid tumor types (n=217)[2,5]:
  - Grade ≥3 TEAEs: 46%
  - Most common grade ≥3 BALVERSA-related TEAEs: stomatitis (12%), palmar-plantar erythrodysesthesia syndrome (6%), and hyperphosphatemia (5%)
  - Serious TEAEs: 39%
  - Most common serious grade ≥3 TRAEs: stomatitis (2%) and diarrhea (1%)
  - Most common TRAEs that led to treatment discontinuation: palmar-plantar erythrodysesthesia syndrome (2%) and stomatitis (2%)
  - Central serous retinopathy events: 14%
  - Treatment-related deaths: none
- Additional safety results for other patient populations have been presented and/or published.[6-12]

Note: CBR, clinical benefit rate; CCA, cholangiocarcinoma; CI, confidence interval; DCR, disease control rate; DOR, duration of response; FGFR, fibroblast growth factor receptor; IRC, independent review committee; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; TEAE, treatment-emergent adverse event; TRAE, treatment-emergent adverse event.

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RAGNAR (NCT04083976) is a phase 2, open-label, single-arm, global, multicenter study evaluating the efficacy and safety of BALVERSA in adult and pediatric patients (children aged ≥6 years) with unresectable, locally advanced, or metastatic solid tumor malignancies (tumor agnostic), *FGFR* mutations or fusions, and documented disease progression.[1]

RAGNAR is an ongoing study that is currently not recruiting.[1]

RAGNAR study design[1-3]

Key inclusion criteria

- Age ≥6 years.
- Histologically confirmed, unresectable, locally advanced or metastatic solid tumor with *FGFR* mutation/gene fusion.
- Patient must have received ≥1 prior line of systemic therapy for metastatic disease or must be a child/adolescent with a newly diagnosed solid tumor and no acceptable standard therapies.
- Documented disease progression (any progression requiring a change in treatment prior to full-study screening).

Key exclusion criteria

- Prior chemotherapy, targeted therapy, or treatment with an investigational anticancer agent <30 days or ≤5 drug half-lives (whichever is longer) before the first dose of BALVERSA.
- Presence of *FGFR* gatekeeper and resistance mutations.
- Histologically confirmed transitional cell carcinoma of the urothelium (ie, bladder cancer) or hematologic malignancy (ie, myeloid and lymphoid neoplasms).
- Active malignancies other than for disease requiring therapy.
- For patients with NSCLC only: pathogenic somatic mutations or gene fusions in *EGFR, ALK, ROS1, NTRK*, and *BRAF* V600E.

Screening phase

Molecular eligibility and full-study screening

Treatment phase

BALVERSA[a] oral tablet

Planned N=336

End of treatment visit

Occurs 30 days after the last dose of BALVERSA

Follow-up phase

Follow-up until death, consent withdrawal, loss to follow-up, or end of study

Primary endpoint

- ORR per IRC, assessed by CT or MRI per RECIST v1.1 or RANO criteria

Secondary endpoints

- Investigator-assessed ORR
- Safety
- DCR
- DOR
- PFS
- PK
- CBR
- OS
- HRQoL

[a]Treatment until disease progression, intolerable toxicity, consent withdrawal, or investigator's decision to discontinue treatment.

Please visit ClinicalTrials.gov for complete study details.

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Primary endpoint[1]

- ORR per IRC

Secondary endpoints[2]

- Investigator-assessed ORR
- DOR
- DCR
- CBR
- PFS
- OS
- Safety
- HRQoL
- PK

Primary analysis methods[2]

- The primary cohort included patients of age ≥12 years with unresectable, locally advanced, or metastatic solid tumors (except urothelial carcinoma), predefined *FGFR1-4* alterations (mutations/fusions), and documented disease progression. Patients had ≥1 prior line of systemic therapy and no alternative standard therapy. Patients received BALVERSA PO once daily on a 21-day cycle until disease progression or intolerable toxicity.
  - Adult and adolescent patients (aged ≥15 to <18 years) were initiated with BALVERSA 8 mg with possible uptitration to 9 mg based on cycle 1 day 14 serum phosphate levels.
  - Adolescent patients (aged ≥12 to <15 years) were initiated with BALVERSA 5 mg with possible uptitration to 6 mg or further to 8 mg based on cycle 1 day 14 and cycle 2 day 7 serum phosphate levels.
  - Efficacy for patients with non-CNS tumors was assessed using RECIST v1.1 by CT or MRI of the chest, abdomen, and pelvis every 6 weeks for 12 months, and every 12 weeks thereafter.
  - Efficacy for patients with primary brain tumors was assessed using RANO by brain MRI at baseline, every 6 weeks for the first 12 months, and every 12 weeks thereafter.

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RAGNAR primary analysis: baseline demographics and disease characteristics[2]

Characteristic	**N=217**
Age, median (range), years	57 (48-64)
Sex	
Male	120 (55)
Female	97 (45)
Region	
Europe	94 (43)
Asia	53 (24)
North America	48 (22)
Rest of world	22 (10)
Race	
White	112 (52)
Asian	57 (26)
Black or African American	6 (3)
Other or not reported	42 (19)
ECOG PS (n=215)[a]	
0	65 (30)
1	149 (69)
2[b]	1 (<1)
Time from progression/relapse on the last line of treatment to first dose, months (n=214)[c]	1.25 (0.82-2.14)
Metastatic sites	
Presence of metastases sites	179 (82)
Lymph node	119 (55)
Liver	99 (46)
Lung	94 (43)
Bone	49 (23)
Adrenal gland	17 (8)
Brain	12 (6)
Spinal cord	5 (2)
Other	68 (31)

Data are presented as n (%) unless otherwise specified.

[a]ECOG PS is only applicable to adults.

[b]One patient was enrolled with an ECOG PS score of 2, which did not meet protocol eligibility criteria.

[c]Applicable only to patients with nonmissing values for progression/relapse date of last line of treatment.

RAGNAR primary analysis: additional baseline demographics and disease characteristics

RAGNAR primary analysis: additional baseline demographics and disease characteristics[2]

Characteristic	N=217
Number of body sites with metastatic disease (n=179)[a]	
Median (IQR)	2 (2-3)
1	40 (22)
2	50 (28)
≥3	89 (50)
Prior systemic therapy in advanced/metastatic setting	
Chemotherapy	215 (99)
Immunotherapy	67 (31)
Other systemic therapy	91 (42)
Number of prior lines of anticancer therapies	
Median (IQR)	2 (2-4)
1	50 (23)
2	67 (31)
≥3	100 (46)
Tumor types	
CCA	31 (14)
High-grade glioma	30 (14)
Pancreatic cancer	18 (8)
Breast cancer	16 (7)
Squamous cell head and neck cancers	15 (7)
Squamous NSCLC	14 (6)
Non-squamous NSCLC	9 (4)
Carcinoma of unknown primary	8 (4)
Colorectal cancer	8 (4)
Endometrial cancer	8 (4)
Esophageal cancer	8 (4)
Gastric cancer	8 (4)
Ovarian cancer	8 (4)
Low-grade glioma	7 (3)
Cervical cancer	6 (3)
Salivary gland cancer	5 (2)
Soft tissue sarcoma	3 (1)
Prostate cancer	2 (1)
Others	13 (6)

Data are presented as n (%) unless otherwise specified.
[a]Metastatic site with other will be considered as 1 body site.

CCA, cholangiocarcinoma; IQR, interquartile range; NSCLC, non-small cell lung carcinoma.

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- Preliminary results of molecular screening for *FGFR* alterations in 110 patients were reported.[4]

RAGNAR molecular screening for *FGFR* alterations[4]

Malignancy	**n (%)**	**Predominant eligible *FGFR* alteration (%)**	**Most frequent *FGFR* variant(s)**
CCA	30 (27)	*FGFR2* fusion (80)	*FGFR2-BICC1* fusion
Glioma, high-grade	21 (19)	*FGFR3* fusion (95)	*FGFR3-TACC3* fusion
Pancreatic	9 (8)	*FGFR2* fusion (78)	*FGFR1* and *FGFR2* fusions
NSCLC	8 (7)	*FGFR3* fusion (63)	*FGFR3-TACC3* fusion
Breast	5 (5)	*FGFR2* mutation (40) and fusion (40)	*FGFR1* and *FGFR2* mutations/fusions
Colorectal	5 (5)	*FGFR3* mutation (40) and fusion (40)	*FGFR3-TACC3* fusion
Endometrial	4 (4)	*FGFR2* mutation (100)	*FGFR2-C382R* mutation
Gastric	4 (4)	*FGFR3* mutation (50)	*FGFR3* mutations
Ovarian	4 (4)	*FGFR2* fusion (50)	*FGFR1-3* mutations/fusions
Cancer of unknown primary	4 (4)	*FGFR2* fusion (50)	*FGFR2* and *FGFR3* mutations/fusions
Cervical	3 (3)	*FGFR3* mutation (100)	*FGFR3-S249C* mutation
Head and neck, squamous cell	3 (3)	*FGFR3* fusion (67)	*FGFR3-TACC3* fusion
Esophageal	2 (2)	*FGFR3* mutation (50) and fusion (50)	*FGFR3* mutations/fusions
Glioma, low-grade	2 (2)	*FGFR1* mutation (100)	*FGFR1-K656E* mutation
Prostate	2 (2)	*FGFR3* mutation (50) and fusion (50)	*FGFR3* mutations/fusions
Salivary gland	2 (2)	*FGFR2* mutation (50)	*FGFR1* and *FGFR2* mutations/fusions
Basal cell	1 (1)	*FGFR2* mutation (100)	*FGFR2* mutation
Thymic	1 (1)	*FGFR1* fusion (100)	*FGFR1* fusion

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- The median follow-up for efficacy was 17.9 months (IQR, 13.6-23.9), median treatment duration was 4.3 months (IQR, 2.1-9.2), and ORR per IRC assessment was 64 (30%; 95% CI, 24-36) of 217 patients.[2]
  - Responses were observed in 16 distinct tumor types. No responses were observed for cervical cancer, soft-tissue sarcoma, and prostate cancer. Other tumor types with response included duodenal cancer and thyroid carcinoma.
  - Among the 64 responding patients, 6 (3%) had a CR and 58 (27%) had a PR.
  - ORR was 25% (95% CI, 16-37) in patients with *FGFR 1-3* mutations and 33% (95% CI, 25-41) in patients with *FGFR 1-3* fusions.
- Median time to response was 1.4 months (IQR, 1.4-2.7) after initiation of BALVERSA treatment.[2]
- Investigator-assessed ORR was 25% (95% CI, 20-32), median DOR was 6.9 (95% CI, 4.4-7.1) months (investigator-assessed median DOR was 7 [95% CI, 5.5-8.5] months), DCR was 74% (95% CI, 67-80), CBR was 46% (95% CI, 39-53), median PFS was 4.2 (95% CI, 4.1-5.5) months (there were 160 PFS events), and median OS was 10.7 (95% CI, 8.7-12.1) months.[2]

RAGNAR primary cohort analysis: confirmed response rates by tumor type[2,5]

Tumor type	N (treated)	ORR (%)	DCR (%)
Total	217	30	74
Salivary	5	100	100
Pancreatic	18	56	94
CCA	31	52	97
Endometrial	8	50	75
Non-squamous NSCLC	9	33	56
Squamous head and neck	15	33	87
Breast	16	31	69
Low-grade glioma	7	29	71
Cancer of unknown primary	8	25	88
Ovarian	8	25	63
Squamous NSCLC	14	21	86
Other[a]	13	15	77
Gastric	8	13	63
Esophageal	8	13	38
High-grade glioma	30	10	57

[a]Duodenal cancer and thyroid carcinoma (n=1 confirmed ORR, each).

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- At a median treatment exposure of 4.3 (IQR, 2.1-9.2) months, 216 (99.5%) patients experienced ≥1 TEAEs.[2]
- BALVERSA-related grade ≥3 TEAEs occurred in 100 (46%) patients.[2]
  - The most frequent BALVERSA-related grade ≥3 TEAEs were stomatitis (12%), palmar-plantar erythrodysesthesia (6%), and hyperphosphatemia (5%).
- Serious TEAEs occurred in 85 (39%) patients. The most common serious grade ≥3 TRAEs were stomatitis in 4 (2%) patients and diarrhea in 2 (1%) patients. The most common TRAEs that led to treatment discontinuation were palmar-plantar erythrodysesthesia syndrome in 3 (2%) patients and stomatitis in 3 (2%) patients.[2]
- Central serous retinopathy events occurred in 31 (14%) patients.[2]
  - Grade 1-2: Chorioretinopathy occurred in 8 (4%) patients, detachment of retinal pigment epithelium in 7 (3%) patients, and retinal detachment in 6 (3%) patients.
  - Grade 3: Retinal edema (<1%).
- TEAEs led to death in 8 (4%) patients (multiple organ dysfunction syndrome, pyrexia, COVID-19, sepsis, pulmonary embolism, respiratory failure, cardiac arrest, and subdural hematoma); all were considered unrelated to BALVERSA by investigator assessment.[2]

RAGNAR primary cohort analysis: TEAEs by grade (≥20% in any grade group)[2]

TEAEs by worst toxicity grade (≥20% in any grade group), n (%)	N=217			
	Grade 1-2	Grade 3	Grade 4	Grade 5
All TEAEs	64 (29)	124 (57)	20 (9)	8 (4)
Hyperphosphatemia	143 (66)	11 (5)	0	0
Diarrhea	119 (55)	9 (4)	0	0
Stomatitis	95 (44)	25 (12)	0	0
Dry mouth	105 (48)	1 (<1)	0	0
Dry skin	73 (34)	4 (2)	0	0
Palmar-plantar erythrodysesthesia syndrome	61 (28)	12 (6)	0	0
Constipation	64 (29)	2 (1)	0	0
Fatigue	56 (26)	7 (3)	0	0
Alanine aminotransferase increased	51 (24)	11 (5)	0	0
Aspartate aminotransferase increased	53 (24)	5 (2)	0	0
Decreased appetite	55 (25)	3 (1)	0	0
Anemia	39 (18)	18 (8)	0	0
Dry eye	48 (22)	0	0	0
Alopecia	44 (20)	0	0	0

RAGNAR primary cohort analysis: TEAEs by grade (<20% in all grade groups)

RAGNAR primary analysis: TEAEs by grade (<20% in all grade groups)[2]

TEAE by worst toxicity grade (<20% in all grade groups), n (%)	N=217			
	Grade 1-2	Grade 3	Grade 4	Grade 5
Nausea	41 (19)	2 (1)	0	0
Paronychia	37 (17)	6 (3)	0	0
Nail disorder	36 (17)	4 (2)	0	0
Onycholysis	34 (16)	6 (3)	0	0
Arthralgia	36 (17)	3 (1)	0	0
Epistaxis	38 (18)	0	0	0
Vomiting	33 (15)	5 (2)	0	0
Dysgeusia	37 (17)	0	0	0
Abdominal pain	24 (11)	10 (5)	0	0
Blood alkaline phosphatase increased	32 (15)	2 (1)	0	0
Nail discoloration	32 (15)	0	0	0
Weight decreased	26 (12)	3 (1)	0	0
Asthenia	21 (10)	7 (3)	0	0
Vision blurred	25 (12)	2 (1)	0	0
Pyrexia	23 (11)	2 (1)	0	1 (<1)
Hyponatremia	17 (8)	6 (3)	2 (<1)	0
Pain in extremity	24 (11)	1 (<1)	0	0
Nail dystrophy	20 (9)	3 (1)	0	0
Back pain	20 (9)	2 (1)	0	0
Headache	20 (9)	2 (1)	0	0
Myalgia	22 (10)	0	0	0
Thrombocytopenia	19 (9)	3 (1)	0	0

TEAE, treatment-emergent adverse event.

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CBR	Clinical benefit rate	**IQR**	Interquartile range
CCA	Cholangiocarcinoma	**MRI**	Magnetic resonance imaging
CI	Confidence interval	**NSCLC**	Non-small cell lung cancer
CNS	Central nervous system	**ORR**	Objective response rate
COVID-19	Coronavirus disease 2019	**OS**	Overall survival
CR	Complete response	**PFS**	Progression-free survival
CT	Computed tomography	**PK**	Pharmacokinetics
DCR	Disease control rate	**PO**	Orally
DOR	Duration of response	**PR**	Partial response
ECOG PS	Eastern Cooperative Oncology Group performance status	**RANO**	Response Assessment in Neuro-Oncology
FGFR	Fibroblast growth factor receptor	**RECIST**	Response Evaluation Criteria in Solid Tumours
HRQoL	Health-related quality of life	**TEAE**	Treatment-emergent adverse event
IRC	Independent review committee	**TRAE**	Treatment-related adverse event

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A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 13 April 2026.

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2. Pant S, Schuler M, Iyer G, et al. Erdafitinib in patients with advanced solid tumours with FGFR alterations (RAGNAR): an international, single-arm, phase 2 study. *Lancet Oncol.* 2023;24(8):925-935.
3. Schuler M, Tabernero J, Massard C, et al. Phase 2 open-label study of erdafitinib in adult and adolescent patients with advanced solid tumors harboring fibroblast growth factor receptor gene alterations. Poster presented at: European Society of Medical Oncology (ESMO) Congress; September 18-22, 2020; Virtual.
4. Massard C, Pant S, Iyer G, et al. Preliminary results of molecular screening for FGFR alterations in the RAGNAR histology-agnostic study with the FGFR inhibitor (FGFRi) erdafitinib. Poster presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; June 4-8, 2021; Virtual.
5. Pant S, Schuler M, Iver G. Efficacy and safety of erdafitinib in adults with cholangiocarcinoma (CCA) with prespecified fibroblast growth factor receptor alterations (FGFRalt) in the phase 2 open-label, single-arm RAGNAR trial: expansion cohort results. Poster presented at: American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium; January 19-21, 2023; San Francisco, CA and Virtual.
6. Pant S, Schuler M, Iver G, et al. Tumor agnostic efficacy and safety of erdafitinib (erda) in patients (pts) with advanced solid tumors with prespecified FGFR alterations (FGFRalt): RAGNAR primary analysis. Poster presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, IL and Virtual.
7. Pant S, Arnold D, Tabernero J, et al. Efficacy and safety of erdafitinib in adults with pancreatic cancer and prespecified fibroblast growth factor receptor alterations (*FGFRalt*) in the phase 2 open-label, single-arm RAGNAR trial. Poster presented at: European Society of Medical Oncology (ESMO) Congress; October 20-24, 2023; Madrid, Spain.
8. Carranza O, Schuler M, Tabernero J, et al. Efficacy and safety of erdafitinib in adults with breast cancer and prespecified fibroblast growth factor receptor alterations in the phase 2 open-label, single-arm RAGNAR trial. Poster presented at: American Society for Clinical Oncology (ASCO) Congress; May 31-June 4, 2024; Chicago, IL.
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11. Schuler M, Tabernero J, Carranza O, et al. Efficacy and safety of erdafitinib in adults with NSCLC and prespecified fibroblast growth factor receptor alterations in the phase 2 open-label, single-arm RAGNAR trial. Oral Presentation at: American Society for Clinical Oncology (ASCO) Congress; May 31-June 4, 2024; Chicago, IL.
12. Pant S, Park JO, Su W-C, et al. Efficacy and safety of erdafitinib in patients with advanced or metastatic cholangiocarcinoma and FGFR alterations: pooled analysis of RAGNAR and LUC2001 studies. Poster presented at: American Society for Clinical Oncology (ASCO) Congress; May 31-June 4, 2024; Chicago, IL.

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