1. Overview ovarian cancer trials

REFRACTAIR (progression during platinum)	RESISTANT AFTER 1 LINE (< 6 mths after platinum)
Low grade serous: BGOG-ov60/VS-6766 BGOG-GYN2/BOUQUET REGN4018 **BRCA +:** REGN4018 **Clear cell:** BGOG-GYN2/BOUQUET REGN4018 **Endometrioid** REGN4018 **High grade serous:** BGOG-ov66/Aravive AMG650 (temporary closed) REGN4018 **All histological types allowed:** REGN4018	**Low grade serous:** BGOG-ov60/VS-6766 BGOG-GYN2/BOUQUET REGN4018 **BRCA +:** REGN4018 **Clear cell:** BGOG-GYN2/BOUQUET REGN4018 **Endometrioid:** REGN4018 **High grade serous:** BGOG-ov55/MIRASOL BGOG-ov66/Aravive BGOG-ov61/EPIK-O AMG650 (temporary closed) REGN4018 **All histological types allowed:** REGN4018
non-high grade serous, non-high-grade endometrioid epithelial ovarian, fallopian tube or primary peritoneal cancer (i.e. LGSOC, clear cell carcinoma, mucinous carcinoma, carcinosarcoma, undifferentiated carcinoma, seromucinous carcinoma, malignant Brenner tumours, Grades 1 or 2 endometrioid carcinoma, or SCCOHT)	
BGOG-GYN2/BOUQUET (not primary refractory)	

RESISTANT AFTER 2 LINES (<6 mths after platinum)	RESISTANT AFTER 3 LINES (<6 mths after platinum)
Low grade serous: BGOG-ov60/VS-6766 BGOG-GYN2/BOUQUET REGN4018 **BRCA +:** REGN4018 **Clear cell:** BGOG-GYN2/BOUQUET REGN4018 **Endometrioid:** REGN4018 **High grade serous:** BGOG-ov55/MIRASOL BGOG-ov66/Aravive BGOG-ov61/EPIK-O AMG650 (temporary closed) REGN4018 **All histological types allowed:** REGN4018	**Low grade serous:** BGOG-ov60/VS-6766 BGOG-GYN2/BOUQUET REGN4018 **BRCA +:** REGN4018 **Clear cell:** BGOG-GYN2/BOUQUET REGN4018 **Endometrioid:** REGN4018 **High grade serous:** BGOG-ov55/MIRASOL BGOG-ov66/Aravive BGOG-ov61/EPIK-O AMG650 (temporary closed) REGN4018 **All histological types allowed:** REGN4018
non-high grade serous, non-high-grade endometrioid epithelial ovarian, fallopian tube or primary peritoneal cancer (i.e. LGSOC, clear cell carcinoma, mucinous carcinoma, carcinosarcoma, undifferentiated carcinoma, seromucinous carcinoma, malignant Brenner tumours, Grades 1 or 2 endometrioid carcinoma, or SCCOHT)	
BGOG-GYN2/BOUQUET	

RESISTANT AFTER 4 LINES (< 6 mths after platinum)	RESISTANT AFTER >4 LINES (< 6 mths after platinum)
Low grade serous: BGOG-ov60/VS-6766 BGOG-GYN2/BOUQUET REGN4018 **BRCA +:** REGN4018 **Clear cell:** BGOG-GYN2/BOUQUET REGN4018 **Endometrioid:** REGN4018 **High grade serous:** AMG650 (temporary closed) REGN4018 **All histological types allowed:** REGN4018	**Low grade serous:** BGOG-ov60/VS-6766 BGOG-GYN2/BOUQUET REGN4018 **BRCA +:** REGN4018 **Clear cell:** REGN4018 **Endometrioid:** REGN4018 **High grade serous:** AMG650 (temporary closed) REGN4018 **All histological types allowed:** REGN4018
non-high grade serous, non-high-grade endometrioid epithelial ovarian, fallopian tube or primary peritoneal cancer (i.e. LGSOC, clear cell carcinoma, mucinous carcinoma, carcinosarcoma, undifferentiated carcinoma, seromucinous carcinoma, malignant Brenner tumours, Grades 1 or 2 endometrioid carcinoma, or SCCOHT)	
BGOG-GYN2/BOUQUET	

SENSITIVE AFTER 1 LINE	SENSITIVE AFTER 2 LINES
Low grade serous: BGOG-ov60/VS-6766 REGN4018 **Clear cell:** REGN4018 **Endometrioid:** REGN4018 **High grade serous:** REGN4018 PICCOLO (in case of platinum allergy) **All histological types allowed:** REGN4018	**Low grade serous:** BGOG-ov60/VS-6766 REGN4018 **Clear cell:** REGN4018 **Endometrioid:** REGN4018 **High grade serous:** REGN4018 PICCOLO (in case of platinum allergy) **All histological types allowed:** REGN4018

SENSITIVE AFTER 3 LINES	SENSITIVE AFTER 4 LINES
Low grade serous: BGOG-ov60/VS-6766 REGN4018 **Clear cell:** REGN4018 **High grade serous:** REGN4018 PICCOLO (in case of platinum allergy) **All histological types allowed:** REGN4018	**Low grade serous:** BGOG-ov60/VS-6766 REGN4018 **Clear cell:** REGN4018 **High grade serous:** REGN4018 PICCOLO (in case of platinum allergy) **All histological types allowed:** REGN4018

BGOG-GYN2/BOUQUET: A phase II, open-label, multicenter, platform study evaluating the efficacy and safety of biomarker-driven therapies in patients with persistent or recurrent rare epithelial ovarian tumors.

Treatment:

Treatment assignment based on Biomarker profile
- Ipatasertib + paclitaxel
- Trastuzumab emtansine

Main inclusion criteria:

- Histologically confirmed non-high grade serous, non-high-grade endometrioid epithelial ovarian, fallopian tube or primary peritoneal cancer (i.e. LGSOC, clear cell carcinoma, mucinous carcinoma, carcinosarcoma, undifferentiated carcinoma, seromucinous carcinoma, malignant Brenner tumours, Grades 1 or 2 endometrioid carcinoma, or SCCOHT
- Platinum resistant
- Previous treatment with one to four lines of therapy, at least one of which was platinum-based Hormonal therapy does not count as a line of therapy
- Measurable disease according to RECIST 1.1

More information can be found on clinicaltrials.gov: NCT04931342

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-ov60/VS-6766: A Phase 2 Study of VS-6766 (Dual RAF/MEK Inhibitor) Alone and In Combination with Defactinib (FAK Inhibitor) in Recurrent Low-Grade Serous Ovarian Cancer (RAMP 201)

Treatment:
Randomization 1:1
VS-6766
VS-6766 + defactinib

Main inclusion criteria:

-Histologically proven LGSOC (ovarian, peritoneal)

- Tumor with KRAS mutation

-Adequate archival tumor tissue less than 5 years old or fresh biopsy tissue samples (as defined in the lab manual) must be available for central confirmation prior to treatment assignment.

-Progression (radiographic or clinical) or recurrence of LGSOC after at least one prior systemic therapy for metastatic disease. Below are additional prior treatments that are allowed once the requirement of prior platinum therapy is satisfied.

-Only one prior line of MEK/RAF inhibitor therapy is allowed. No grade 4 toxicity on previous MEK inhibitor exposure.

-Measurable disease according to RECIST 1.1

More information can be found on clinicaltrials.gov: NCT04625270

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

AMG650: A Phase 1, Multicenter, Open-label, Dose-Exploration and Dose-Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 650 in Subjects With Advanced Solid Tumors

Treatment:
AMG 650 (PO)

Main inclusion criteria:

- Platinum-Resistant High Grade Serous Ovarian Cancer, primary peritoneal cancer and/or fallopian-tube cancer subjects only: Subject must have histologically or cytologically confirmed diagnosis of metastatic or unresectable high grade serous ovarian cancer
- Progressed on no more than 5 prior systemic treatments for locally advanced or metastatic disease
- History of bowel obstruction, abdominal fistula, gastrointestinal perforation or intra-abdominal abscess within 6 months of study entry
- Measurable disease

More information can be found on clinicaltrials.gov: NCT04293094

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-ov61/EPIK-O: A Phase III, multi-center, randomized (1:1), open-label, active-controlled study to assess the efficacy and safety of alpelisib (BYL719) in combination with olaparib as compared to single agent cytotoxic chemotherapy, in participants with no germline BRCA mutation detected, platinum-resistant or refractory, high-grade serous ovarian cancer

Treatment:
Arm 1: Alpelisib + Olaparib
Arm 2: Paclitaxel or PLD
Randomisation 1:1

Main inclusion criteria:

- histologically confirmed diagnosis of high-grade serous or high-grade endometrioid ovarian cancer, fallopian tube cancer or primary peritoneal cancer
- Measurable disease or presence of disease by CA-125
- No germline BRCA1/2 mutation (can be tested centrally)
- received prior bevacizumab or is not eligible to receive bevacizumab
- Platinum-resistant or platinum refractory (except primary platinum refractory)
- No more than 3 prior lines

More information can be found on clinicaltrials.gov: NCT04729387

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

REGN4018: a Phase ½ Study of REGN4018 (a MUC16xCD3 Bispecific Antibody) administered Alone or in Combination with Cemiplimab in Patients with Recurrent Ovarian Cancer

Treatment:
REGN4018 monotherapie or REGN4018 + cemiplimab

Main inclusion criteria:

- Patients with histologically or cytologically confirmed diagnosis of advanced epithelial ovarian cancer (except carcinosarcoma), primary peritoneal, or fallopian tube cancer who have all of the following:
  - serum CA-125 level ≥2x ULN (in screening)
  - has received at least 1 line of platinum-containing therapy or must be platinumintolerant
  - documented relapse or progression on or after the most recent line of therapy
  - no standard therapy options likely to convey clinical benefit
- Prior treatment with anti-PD-1/PD-L1 therapy if the following:

  a. Monotherapy cohorts: Excluded if given within 5 half-lives of first dose

  b. Combination therapy cohorts:

  - Excluded if previously discontinued anti-PD-1/PD-L1 therapy due to toxicity.
  - Excluded if prior anti-PD-1/PD-L1 therapy was given within 3 weeks of first dose of study therapy, regardless of half-life or approval status of the drug.

More information can be found on clinicaltrials.gov: NCT03564340

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-ov66: A Phase 3, Randomized, Double-Blind, Adaptive, Placebo/Paclitaxel-Controlled Study of AVB-S6-500 in Combination with Paclitaxel in Patients with Platinum-Resistant Recurrent Ovarian Cancer (AXLerate-OC).

Treatment:
Arm 1: Paclitaxel + AVB-S6-500
Arm 2: Paclitaxel + Placebo
Randomisation 1:1

Main inclusion criteria:

- Histologically confirmed and documented recurrent ovarian, fallopian tube, or peritoneal cancer. Only patients with high-grade serous adenocarcinoma
- Platinum resistant, max 4 prior lines. Primary platinum-refractory not allowed
- Measurable disease
- received prior bevacizumab or is not eligible to receive bevacizumab

More information can be found on clinicaltrials.gov: NCT04729608

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-ov55/MIRASOL: A Randomized, Open-label, Phase 3 study of Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression.

Treatment:
Arm 1: Mirvetuximab Soravtansine
Arm 2: investigators choice chemo (paclitaxel weekly, PLD, topotecan weekly, topotecan day 1-5)
Randomisatie 1 :1

Main inclusion criteria:

- Patients must have a confirmed diagnosis of high-grade serous EOC, primary peritoneal cancer, or fallopian tube cancer
- positive for FRα expression
- Primary refractory (defined as having progressed within 3 months after last dose of carbo) is not allowed
- Patients must have received at least 1 but no more than 3 prior systemic lines of anticancer therapy, and for whom single-agent therapy is appropriate as the next line of treatment:
    a) Adjuvant ± neoadjuvant considered one line of therapy
    b) Maintenance therapy (eg, bevacizumab, PARP inhibitors) will be considered as part of the preceding line of therapy (ie, not counted independently)
    c) Therapy changed due to toxicity in the absence of progression will be considered as part of the same line (ie, not counted independently)
    d) Hormonal therapy will be counted as a separate line of therapy unless it was given as maintenance
- Measurable disease

More information can be found on clinicaltrials.gov: NCT04209855

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

PICCOLO: A Phase 2, Single Arm Study of Mirvetuximab soravtansine in Recurrent Platinum-Sensitive, High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression

Treatment:
Mirvetuximab Soravtansine

Main inclusion criteria:

- confirmed diagnosis of high-grade serous EOC, primary peritoneal cancer, or fallopian tube cancer

- platinum-sensitive disease

- Prior anticancer therapy
    a. Patients must have received at least 2 prior systemic lines of platinum therapy and be considered by the investigator as appropriate for single-agent non-platinum therapy (documentation required – eg, high risk of hypersensitivity reaction; risk of further cumulative toxicity with additional platinum, including but not limited to myelosuppression, neuropathy, renal insufficiency or other)

    Note: Patients who have had had a documented platinum allergy may have had only 1 prior line of platinum

    b. Patients may have received up to but no more than 1 prior independent non-platinum cytotoxic therapy

    c. Patients must have had testing for BRCA mutation (tumor or germline) and, if positive, must have received a prior PARP inhibitor as either treatment or maintenance therapy

    d. Neoadjuvant ± adjuvant therapies are considered 1 line of therapy

- measurable disease (RECIST 1.1)

- positive for FRα expression

More information can be found on clinicaltrials.gov: NCT05041257

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

2. Overview cervical cancer trials

Early Stage Cervical Cancer	
RACC: randomised non-inferiority trial of robot-assisted laparoscopic surgery versus laparotomy in women with early stage cervical cancer	
PRIMARY ADVANCED	**FIRST RECURRENCE**
BGOG-cx11	BGOG-cx12 R2810-ONC-ISA-1981
SECOND LINE CHEMO METASTATIC	**THIRD LINE METASTATIC OR MORE**
BGOG-cx12 R2810-ONC-ISA-1981 DESTINY-02	R2810-ONC-ISA-1981 DESTINY-02

R2810-ONC-ISA-1981: A phase 2 study of cemiplimab, an anti –PD-1 monoclonal antibody, and ISA101B vaccine in patients with recurrent/metastatic HPV16 cervical cancer who have experienced disease progression after first line chemotherapy

Treatment:
Cemiplimab + ISA101b vaccine

Main inclusion criteria:

- recurrent or metastatic HPV16 positive squamous cell cervical cancer, who have experienced disease progression after treatment with platinum containing therapy (must have been used to treat metastatic, persistent, or recurrent cervical cancer)
- HPV16 genotype positive (determined centrally)
- Prior treatment with a PD-(L)-1 inhibitor not allowed
- Measurable disease

More information can be found on clinicaltrials.gov: NCT04646005

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

DESTINY-PanTumor02: A Phase II, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Trastuzumab Deruxtecan (T-DXd, DS-8201a) for the Treatment of Selected HER2-expressing Tumors

Treatment:
Trastuzumab Deruxtecan

Main inclusion criteria:

- Metastatic or advanced cervical carcinoma
- Patients must have HER2-overexpression (IHC 3+ or IHC 2+) as determined by local or central assessment
- FFPE tumor sample at the time of diagnosis of metastatic or locally advanced unresectable disease
- Measurable disease

More information can be found on clinicaltrials.gov: NCT04482309

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-cx11: A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer

Treatment:
Radiochemo +/- pembrolizumab

Main inclusion criteria:

- Has histologically-confirmed squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma of the cervix

- Has high-risk LACC (a or b below):
a. FIGO 2014 Stage IB2-IIB (with node-positive disease) – must meet criteria below for positive pelvic lymph node OR para-aortic lymph node involvement
  - pelvic lymph node involvement as assessed by one of the following criteria:
    - o Histopathologic, biopsy-proven pelvic node involvement, or
    - o 2 or more positive pelvic nodes by MRI or CT (≥1.5 cm shortest dimension), or
    - o 2 or more positive pelvic nodes by PET / CT with SUV ≥2.5
  - Para-aortic lymph node involvement as assessed by one of the following criteria:
    - o Histopathologic, biopsy-proven para-aortic node involvement, or
    - o 1 or more positive para-aortic nodes by MRI or CT (≥1.5 cm shortest dimension), or
    - o 1 or more positive para-aortic nodes by PET / CT with SUV ≥2.5
b. FIGO 2014 Stages III-IVA (either node-positive or node-negative disease)

- Biopsy required

More information can be found on clinicaltrials.gov: NCT04221945

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-cx12: Randomized, Open-Label, Phase 3 Trial of Tisotumab Vedotin vs Investigator's Choice Chemotherapy in Second- or Third-Line Recurrent or Metastatic Cervical Cancer

Treatment:
Randomisation 1:1
Tisotumab Vedotin
Vs SOC choice: Topotecan, vinorelbine, gemcitabine of pemetrexed

Main inclusion criteria:

- Has recurrent or metastatic cervical cancer with squamous cell, adenocarcinoma, or adenosquamous histology, and:
  a. Has experienced disease progression during or after treatment with a standard of care systemic chemotherapy doublet, or platinum-based therapy (if eligible), defined as either:
     - paclitaxel+cisplatin+bevacizumab, **or**
     - paclitaxel+carboplatin+bevacizumab, **or**
     - paclitaxel+topotecan/nogitecan+bevacizumab

  NOTE: only in cases where bevacizumab is not a standard of care therapy or the participant is ineligible for bevacizumab treatment according to local standards, prior treatment with bevacizumab is not required.

  b. Has received 1 or 2 prior systemic therapy regimens for recurrent and/or metastatic cervical cancer. Chemotherapy administered in the adjuvant or neoadjuvant setting, or in combination with radiation therapy, should not be counted as a systemic therapy regimen. Single agent therapy with pembrolizumab for r/mCC should be counted.
  c. Is not a candidate for curative therapy, including but not limited to radiotherapy or exenterative surgery.

- Measurable disease

More information can be found on clinicaltrials.gov: NCT04697628

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

3. Overview endometrial cancer trials

PRIMARY ADVANCED	FIRST RECURRENCE
BGOG-EN11	BGOG-EN12/POD1UM
SECOND LINE CHEMO METASTATIC	**THIRD LINE METASTATIC OR MORE**
BGOG-EN12/POD1UM JZLA	BGOG-EN12/POD1UM JZLA

BGOG-EN11: A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Adjuvant Chemotherapy With or Without Radiotherapy for the Treatment of Newly Diagnosed High-Risk Endometrial Cancer After Surgery With Curative Intent

Treatment:
TC + pembro followed by pembro +/- radiochemo
TC + placebo followed by placebo +/- radiochemo
Randomisation 1:1:

Main inclusion criteria:

-Has a histologically confirmed new diagnosis of Endometrial Carcinoma or Carcinosarcoma (Mixed Mullerian Tumor) and:

a) has undergone curative intent surgery that included hysterectomy and bilateral salpingo-oophorectomy. Pelvic lymph node sampling, para-aortic lymph node sampling, including sentinel lymph node, and lymph node dissection are optional

Note: If prior oophorectomy for reasons other than endometrial cancer, participants may still be eligible for study

b) is at high risk for recurrence following treatment with curative intent surgery, ie. one of the following:

- FIGO (2009) surgical stage I/II with myometrial invasion of non-endometrioid histology including serous adenocarcinoma, clear cell carcinoma, mucinous carcinoma, mixed epithelial carcinoma, dedifferentiated/undifferentiated carcinoma, squamous cell carcinoma, or carcinosarcoma
- FIGO (2009) surgical stage I/II with myometrial invasion of any histology with known aberrant p53 expression or p53 mutation
- FIGO (2009) surgical stage III of IVa of any histology

-No Neoadjuvant therapy received

-Disease-free after surgery

More information can be found on clinicaltrials.gov: NCT04634877

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

BGOG-EN12/POD1UM: An Umbrella Study of INCMGA00012 Alone and in Combination With Other Therapies in Participants With Advanced or Metastatic Endometrial Cancer Who Have Progressed on or After Platinum-Based Chemotherapy

Treatment:
Group A: MSI-H (INCMGA000012)
Group B: dMMR or POLE mutations (INCMGA000012)
Group D: FGFR mutations (INCMGA00012 + pemigatinib)
Group E: PD-L1: INCGMA00012+ Epacadostat

Main inclusion criteria:

advanced or metastatic endometrial cancer with disease progression on or after treatment with at least 1 platinum-containing regimen for advanced or metastatic disease

Groups A and B: Have not been previously treated with a PD-(L)1 inhibitor

Group A only: Tumor tissue centrally tested as MSI-H.

Group B only: Tumor tissue centrally tested as dMMR or locally tested as an ultra-mutated POLE tumor

Group D only: Tumor tissue tested locally based as having an FGFR mutation or alteration

Group E only: Tumor tissue centrally tested as PD-L1 positive

	A	B	D	E
Previous IO permitted	No	No	Yes	No
Biomarker	MSI-H	dMMR POLE	FGFR	PD-L1
Number of previous lines	≥ 1 plat. based	≥ 1 plat. based	≥ 1 plat. based	MAX. 1 line

Measurable disease

More information can be found on clinicaltrials.gov: NCT04463771

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

JZLA: A Phase 1a/1b Study of LY3484356 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with ER+ Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers

Treatment:
Arm 1: LY3484356 (oral SERD)
Arm 2: LY3484356 (oral SERD) + abemaciclib
Randomisation 1:1

Main inclusion criteria:

- Endometrioid endometrium carcinoma, ER+

- patients must have progressed after platinum-containing chemotherapy, be deemed inappropriate for or declined
- platinum-containing chemotherapy, and must not have had prior fulvestrant or AI therapy.

- Measurable disease as defined by RECIST 1.1

More information can be found on clinicaltrials.gov: NCT04188548

In case of questions, please contact **016/34 74 19 (joke.deroover@uzleuven.be)**.

4. Kanker en zwangerschap

Graag willen we advies geven of op de hoogte zijn wanneer kanker wordt vastgesteld tijdens de zwangerschap. Iedere vorm van kanker is van toepassing. Ook als er geen therapie tijdens de zwangerschap toegediend wordt zijn we geïnteresseerd.

Als chemotherapie of radiotherapie toegediend wordt tijdens de zwangerschap kunnen we het kind kosteloos na de geboorte in Leuven opvolgen. Wanneer chemotherapie toegediend wordt kunnen onze onderzoekers helpen bij het nemen van bloedstalen voor een farmacokinetische studie. Dit luik is optioneel.

Meer info vindt u op onze website www.cancerinpregnancy.org

Bij vragen kan U ons contacteren via telefoonnummer **016/34 42 52 (frederic.amant@uzleuven.be)**.

Info

5. Info

Verantwoordelijke uitgever
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