An Industry Supported Symposium at the IGCS 2024 Annual Global Meeting

EMERGING GLOBAL THERAPIES IN CLINICAL TRIALS IN PROGRESS FOR ENDOMETRIAL AND OVARIAN CANCERS, UNDERSTANDING THE LANDSCAPE AND OPTIMIZING STRATEGIES

Dublin, Ireland

Friday, October 18, 2024

12:45 - 14:15 IST

This session is not included in the main event CME/CPD credit

TRIALS IN PROGRESS COURSE FACULTY

Bradley Monk, MD
Florida Cancer Specialists & Research Institute
West Palm Beach, FL, USA

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University Milano-Bicocca Oncology
Milan, Italy

ENGOT
European Network of Gynaecological Oncological Trial groups

Graziela Dal Molin, MD
Beneficencia Portuguesa de Sao Paulo Brazil

eva Brazilian Gynecologic Oncology Group
LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP

Keiichi Fujiwara, MD, PhD
Global Oncology Trials Japan
Japan

GOTJ
Global Oncology Trials Japan

Jae-Hoon Kim, MD, PhD
Gangnam Severance Hospital Seoul South Korea
Republic of Korea

KGOG
Korean Gynecologic Oncology Group

Stephanie Lheureux, MD, PhD
Princess Margaret Cancer Centre
Ontario, Canada

Canadian Cancer Trials Group
Groupe canadien des essais sur le cancer

THANK YOU

The GOG Foundation, Inc. is grateful to our commercial supporters for unrestricted educational grants associated with this Symposium.

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GENMAB
IMMUNOGEN
CORCEPT THERAPEUTICS
SUTRO BIOPHARMA

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Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer
ENGOT European Network of Gynaecological Oncological Trial groups
KGOG Korean Gynecologic Oncology Group
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LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP
GOTJ Global Oncology Trials Japan
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COURSE OBJECTIVES

Analyze

Analyze the key components of clinical trials in progress, including study design, participant recruitment, and data collection methods, to understand the fundamentals of ongoing research opportunities in ovarian and endometrial cancers.

Explore

Explore the dynamic competitive landscape of clinical trials in ovarian and endometrial cancers, analyzing emerging therapies, novel treatment modalities, and investigational agents to understand current trends and advancements shaping the field.

Assess

Assess and apply knowledge of the impact of the competitive trials landscape to optimize trial planning, execution, and enhance trial feasibility and success.

Understand

Understand the global reach of clinical trials in progress. And learn about the clinical trial networks that exist globally.

FACULTY DISCLOSURES

Name	Role in Activity	Disclosures
Bradley Monk, MD	Moderator	• **Honoraria/Expenses:** Acrivon, Adaptimmune, Agenus, Akeso Bio, Amgen, Biohaven, BMS, Corcept, Eli Lilly, Genmab/Seagen/Pfizer, Genelux, GOG Foundation, Gradalis, Zymeworks, GSK, Sutro, Verastem, Zentalis, Heng Rui, Regeneron, Roche/Genentech, ImmunoGen/AbbVie, Panavance, Karyopharm, Novocure, Onco4, Iovance, Mural/Alkermes, Novartis, Merck, Mersana, Myriad **Consultant/Advisory Board:** AstraZeneca, Eisai
Nicoletta Colombo, MD, PhD	Moderator	• **Consultant/Advisory Board:** Astra Zeneca, Clovis Oncology, EISAI, GSK, Immunogen, Mersana, MSD, Nuvation Bio, Onxerna, Pfizer, Pieris, Roche, Novocure
Graziela Dal Molin, MD	Speaker	• **Travel and accommodations:** AstraZeneca, GSK, MSD • **Consultancy or advisory board:** AbbVie, AstraZeneca, GSK, MSD • **Institutional grants for clinical trials (PI):** AstraZeneca, Pfizer • **Speaker fees:** AbbVie, AstraZeneca, GSK, ImmunoGen (now part of AbbVie), MSD
Keiichi Fujiwara, MD, PhD	Speaker	• **No declared conflicts of interest**
Jae-Hoon Kim, MD, PhD	Speaker	• **Honoraria/Expenses:** NSD, GSK, Takeda, Roche, AstraZeneca **Consultant/Advisory Board:** Biontec, Organoid Science, Zencellmed, Posvax, Jintz bio
Stephanie Lheureux, MD, PhD	Speaker	**Consultant/Advisory Board:** GSK, Roche, AbbVie, Astra-Zeneca, Schrodinger, Eisai, Repare, Zai lab, Merck, Gilead, Seagen

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

ENGOT European Network of Gynaecological Oncological Trial groups

KGOG Korean Gynecologic Oncology Group

eva Brazilian Gynecologic Oncology Group

LACOG Latin American Cooperative Oncology Group

GOTJ Global Oncology Trials Japan

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AGENDA

12:45 – 13:10: Welcome and Introductions

13:10 – 13:25: Endometrial Cancer Trials: Insights, New Opportunities and Navigating the Competitive Landscape

13:25 - 13:35: Discussion

13:35 – 13:50: Ovarian Cancer Trials: Insights, New Opportunities and Navigating the Competitive Landscape

13:50 – 14:00: Discussion

14:00 – 14:10: Global Clinical Trials, Managing Opportunities, and Engaging Important Relationships

14:10 - 14:15: Closing Remarks and Final Comments

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KGOG Korean Gynecologic Oncology Group

eva Grupo Brasileiro de Tumores Ginecológicos

LACOG Latin American Cooperative Oncology Group

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ENGOT INTRODUCTION

ENGOT
European Network of
Gynaecological Oncological Trial groups

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European Network of Gynaecological Oncological Trial groups (ENGOT)

ENGOT
European Network of Gynaecological Oncological Trial groups

AGO Study Group
ACO AUSTRIA
BGOG
cancer trials ireland
CEEGOG
DGOG The Dutch Gynaecological Oncology Group
EORTC The future of cancer therapy
GEICO Grupo Español de Investigación en Cáncer de Ovario
GINECO
HeCOG Hellenic Cooperative Oncology Group
ISGO The Israeli Gynecologic Oncology Trial group
MaNGO
MITO Multicenter Italian Trials in Ovarian cancer
NCRI National Cancer Research Institute
NOGGO e.V.
NSGO-CTU Nordic Society of Gynaecological Oncology - Clinical Trial Unit
POLISH GYNECOLOGIC ONCOLOGY GROUP PGOG
SAKK The Swiss Oncology Research Network
scottish gynaecological cancer trials group
Swiss GO Trial Group

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ENGOT
GROUPS

33
COUNTRIES

How do we run a trial in ENGOT?

ENGOT
European Network of
Gynaecological Oncological Trial groups

European Network of Gynaecological Oncological Trial Groups' Requirements for Trials Between Academic Groups and Industry Partners—First Update 2015

Andreas du Bois, MD, PhD, Alexander Reuss, Eric Pujade-Lauraine, MD, Sandro Pignata, MD, Jonathan Ledermann, MD, Antonio Casado, MD, Jalid Sehouli, MD, Mansoor Mirza, MD, Nicoletta Colombo, MD, Christian Marth, MD, Els Witteveen, MD, Jose Del Campo, MD, Paula Calvert, MD, Gerassimos Aravantinos, MD, Mehmet Ali Vardar, MD, Ate G.J. van der Zee, MD, Jacob Korach, MD, Cagatay Taskiran, MD, Mathias Fehr, MD, Ros Glasspool, MD, Jacobus Pfisterer, MD, David Cibula, MD, PhD, Ignace Vergote, MD, PhD, and On behalf of the member trial groups of the European Network of Gynaecological Oncological Trial Groups (ENGOT)

Abstract: The first version of ENGOT's Requirements for Trials Between Academic Groups and Industry Partners in Europe was published 2010. This first update integrates the experiences made by the ENGOT network and the cooperative group studies while performing, analyzing, and publishing -among others - three large phase III trials. Furthermore, progress in European legislation and its impact on clinical studies in Europe have been considered in this update process.

Key Words: Academic groups, ENGOT, Requirements, Trials

Received April 14, 2015, and in revised form Month DD, YYYY.
Accepted for publication April 15, 2015.

(*Int J Gynecol Cancer* 2015;00: 00–00)

Roadmap for the European Network of Gynaecological Trial Groups (ENGOT) Trials

Ignace Vergote, MD, PhD, Gabriele Elser, RN, Benedicte Votan, MSc, Laura Farrelly, BSc(hons), RN, Joke De Roover, PhD, Jane Bryce, RN, MSN, Andreas du Bois, MD, PhD, and On behalf of the member trial groups of the European Network of Gynaecological Trial groups (ENGOT)

Abstract: The European Network for Gynaecological Oncological Trial groups (ENGOT) is a research network of the European Society of Gynaecological Oncology and was founded in Berlin in October 2007. Earlier, we reported on the ENGOT minimal requirements for trials between academic groups and pharmaceutical companies. In this paper, we summarize the roadmap for performing trials in the ENGOT framework. In this roadmap, we define how an ENGOT trial should be set up and discuss the following items: What are the conditions to classify a study as an ENGOT trial? What is an ENGOT protocol? How are an ENGOT protocol, informed consent (ICF), and case report form (CRF) produced? How is the center selection and feasibility performed in ENGOT trials? How are regulatory and operational tasks handled? How should a confidentiality agreement between the industry and the whole ENGOT network be negotiated? How are contracts made between the industry and ENGOT and between ENGOT groups? How are funding, insurance, and communication flow arranged in ENGOT trials? What are the requirements for conducting substudies and what are the tasks for the leading group in an ENGOT trial? A template of a confidentiality agreement, a checklist of ENGOT criteria for new study proposals, and guidelines for authorship are also provided.

Key Words: ENGOT, Clinical trials, Gynecologic oncology, Trial, Management, Academic

(*Int J Gynecol Cancer* 2013;23: 1339–1343)

ENGOT partnership with industry

- Design of clinical trials
  - Patient oriented
  - Focus on unmet medical needs
  - Academic participation and “validation” of clinical trials design is a plus for credibility
  - Clinically-oriented translational research designs (Translational Research Group)
  - Opportunity of helping in the development of the pipeline from the beginning (from Phase I/II Group to phase III design)

ENGOT
European Network of Gynaecological Oncological Trial groups

ENGOT/GOG-F Liason Committee

Original Article

INTERNATIONAL JOURNAL OF GYNECOLOGICAL CANCER

Joint ENGOT and GOG Foundation requirements for trials with industry partners

Ignace Vergote,[1] Robert L Coleman,[2] Sandro Pignata,[3] Michael A Bookman,[4] Christian Marth,[5] Thomas J Herzog,[6] Antonio Gonzalez Martin,[7] Larry J Copeland,[8] On behalf of The European Network of Gynaecological Oncological Trial Groups (ENGOT) and The GOG Foundation, Inc

For numbered affiliations see end of article.

Correspondence to
Professor Ignace Vergote, Gynaecological Oncology,

Int J Gynecol Cancer: first published as 10.1136/ijgc-2(

HIGHLIGHTS

- The European Network of Gynaecological Oncological Trial Groups (ENGOT) and The GOG Foundation present for the first time the joint requirements for trials with industry.
- Guidelines are presented for sponsorship, trial steering committee, and development of a protocol, database, and statistical plan.
- A roadmap is presented for site selection, contracts, press releases, publications, and a communication plan.

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journal homepage: www.elsevier.com/locate/ygyno

Clinical commentary

Joint ENGOT and GOG Foundation requirements for trials with industry partners☆

Ignace Vergote [a,*,1], Robert L. Coleman [b,1], Sandro Pignata [c], Michael A. Bookman [d], Christian Marth [e], Thomas J. Herzog [f], Antonio Gonzalez-Martin [g,2], Larry J. Copeland [h,2], on behalf of the European Network of Gynaecological Oncological Trial Groups (ENGOT) and The GOG Foundation Inc.

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APGOT
Asia-Pacific Gynecologic Oncology Trials Group

LACOG
LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP

ENGOT
European Network of Gynaecological Oncological Trial groups

ENGOT achievements:

As of Sep 2024	
TRIALS PER TUMOUR	
Ovarian	92
Endometrial	29
Cervical	20
Vulvar	1
Gynae basket	10
TOTAL	152

As of Sep 2024	
TRIALS PER MODEL	
Model A	68
Model B	5
Model C	73
Model D	6

Published and presented trials as of 24 May 2023
55

ENGOT
European Network of Gynaecological Oncological Trial groups

Mission

- To bring the best treatment to gynaecological cancer patients through the best science and enabling every patient in every European country to access a clinical trial.

- Partnership with ENGOT can lead to a wise development of strategies and pipelines of different companies by supporting all in a fair manner

ENGOT
European Network of
Gynaecological Oncological Trial groups

Introducing KGOG:
Korean Gynecologic Oncology Group

Jae-Hoon Kim, MD, PhD
Korean Gynecologic Oncology Group (KGOG), Inc. President
Gangnam Severance Hospital
Seoul, South Korea
Republic of Korea

Mission & Vision

Advancing Research and Partnerships

1

Collaboration

Close collaboration with researchers and research organizations in Korea and worldwide.

2

Advancing Trials

Committed to advancing investigator-initiated trials based on national grants.

3

Strengthening Partnerships

Strengthening partnerships with research organizations, led by GOG-P, to expand sponsor-initiated studies.

4

Elevating Standards

Scientifically conducting clinical trials proposed by individual researchers or sponsors to elevate gynecologic cancer treatment standards.

KGOG's History & Present status

2002

Established
as an academic society

2005

Gynecologic Oncology Group (GOG)

2007

Gynecologic Cancer Intergroup (GCIG)

2020

Re-established in 2020

as **Non-profit Incorporated Association**

2022

20 Years History of KGOG

2024

78 member hospitals & 207 registered GYN specialists(in 50 million population)

22 member hospitals
December 2002

2025

Protocol

- KGOG Protocol Classification -

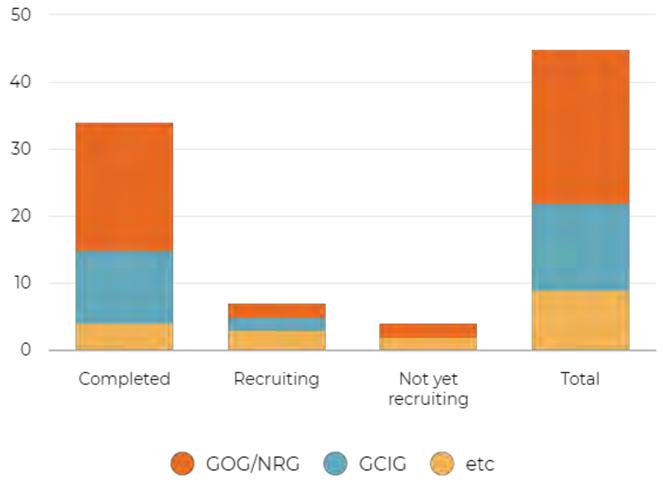
1. National-granted Project
2. IIT, SIT
3. KGOG-led or participated
4. Global Trials (NRG, GOG-P, GCIG)

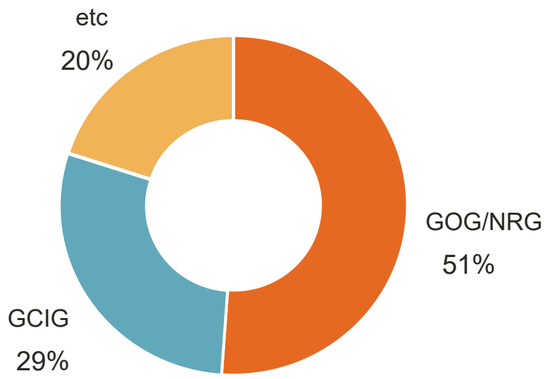
- Total # of clinical trials since 2002 -

1. Cervix: 1001-1049 (49)
2. Uterine corpus: 2001-2035 (35)
3. Ovary: 3001-3068 (68)
4. Others: 4001-4012 (12)

(As of June 2024)

Global Research Collaboration with NRG, GOG, GCIG & EAGOT (June 2024)





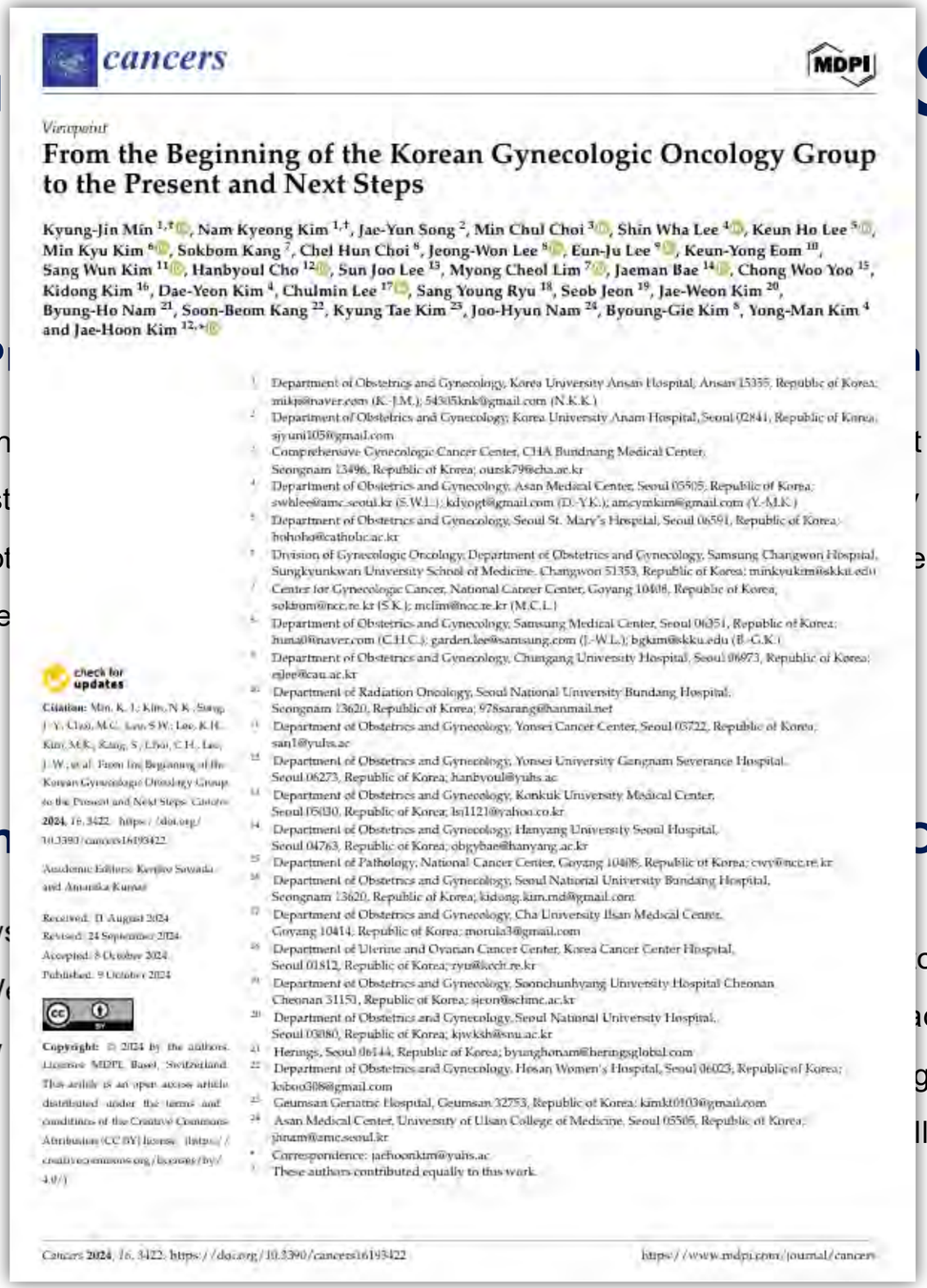
KGOG SIT

1 Consultation and P Assistance

KGOG offers expert consultation t guidance in selecting optimal trial sites to
robust and scientifically sound st execution.. We ensure each site is
ensures that each protocol is opt essary resources and specialized expertise.
specific clinical and regulatory re
execution.

3 Financial Managem Communication

Our financial management sys or meetings promote knowledge exchange
accuracy and promptness. W d the harmonization between sites, CROs,
while upholding transparency g clear communication for swift issue
financial aspect of our trials. llaboration, and smooth trial progression.



cancers

MDPI

Viewpoint

From the Beginning of the Korean Gynecologic Oncology Group to the Present and Next Steps

Kyung-Jin Min [1,†], Nam Kyeong Kim [1,†], Jae-Yun Song [2], Min Chul Choi [3], Shin Wha Lee [4], Keun Ho Lee [5], Min Kyu Kim [6], Sokbom Kang [7], Chel Hun Choi [8], Jeong-Won Lee [8], Eun-Ju Lee [9], Keun-Yong Eom [10], Sang Wun Kim [11], Hanbyoul Cho [12], Sun Joo Lee [13], Myong Cheol Lim [7], Jaeman Bae [14], Chong Woo Yoo [15], Kidong Kim [16], Dae-Yeon Kim [4], Chulmin Lee [17], Sang Young Ryu [18], Seob Jeon [19], Jae-Weon Kim [20], Byung-Ho Nam [21], Soon-Beom Kang [22], Kyung Tae Kim [23], Joo-Hyun Nam [24], Byoung-Gie Kim [8], Yong-Man Kim [4] and Jae-Hoon Kim [12,*]

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GOT-J INTRODUCTION

Global Oncology Trials Japan

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

ENGOT European Network of Gynaecological Oncological Trial groups

KGOG Korean Gynecologic Oncology Group

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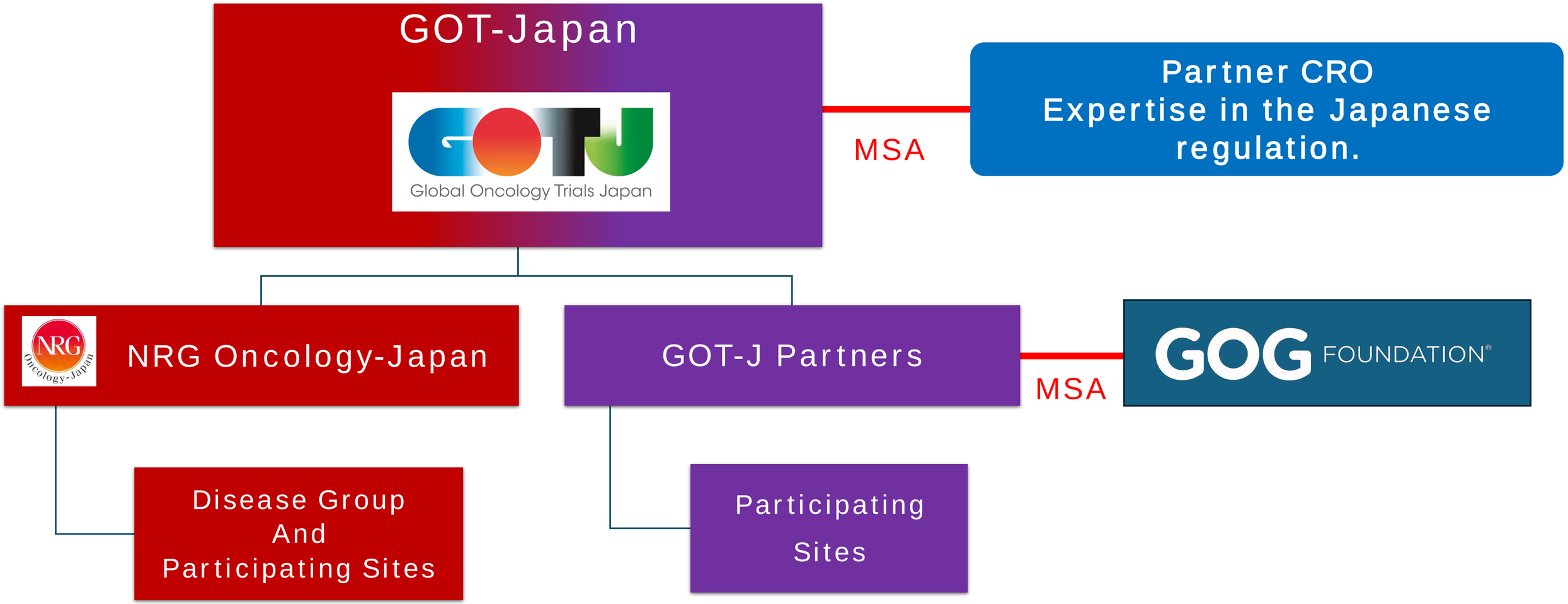
GOT-Japan

Global Oncology Trials Japan

Structure of GOTJ



Our Strengths

1. Strong partnership with GOG Foundation
2. Positive communication with regulatory authorities
3. Close collaboration with sites that have previously conducted clinical trials
4. Integrated partnership with Preferred CRO

Meaning of Logo

- Blue　Global Outlook
- Red　Passion
- Black　Resilience and toughness
- Green　Sustainability

Global Oncology Trials Japan

BRAZIL INTRODUCTION

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eva | Brazilian Gynecologic Oncology Group

Brazilian Gynecologic Oncology Group

Promote holistic control of gynecological cancer through education and research in prevention, treatment and patient support.

Education

Research

Collaboration

Advocacy

715 members

including medical oncologists, radiation oncologists, surgeons, pathologists, gynecologists, nurses, pharmacists

11,350 followers

including physicians and patients

Brazilian Gynecologic Oncology Group

Promote holistic control of gynecological cancer through education and research in prevention, treatment and patient support.

Education

National tumor boards, regional board reviews, National guideline book, Webinars, National Symposium

Research

8 ongoing studies
0123 ROCC Trial; **0223 ROSELLA; 0323 GLORIOSA;** 0623 eVOLVE-Cervical; 0124 DESTINY-Endometrial01

Collaboration

Bra: SBOC, SBCO, SBRT, FEBRASGO
Int.: GOG, GCIG,SGO

.

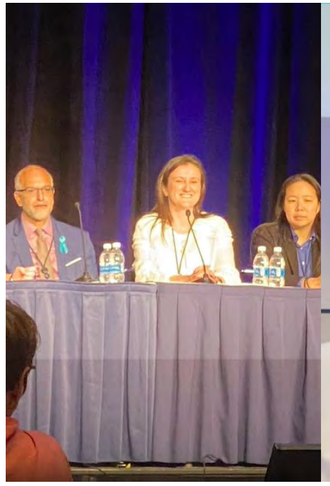
Advocacy

Movimento Brasil sem cancer do colo do útero **Partnership with WHO, PAHO**
Setembro em Flor Campaign: Partnership with **IPVS**

eva Brazilian Gynecologic Oncology Group

Education

Research



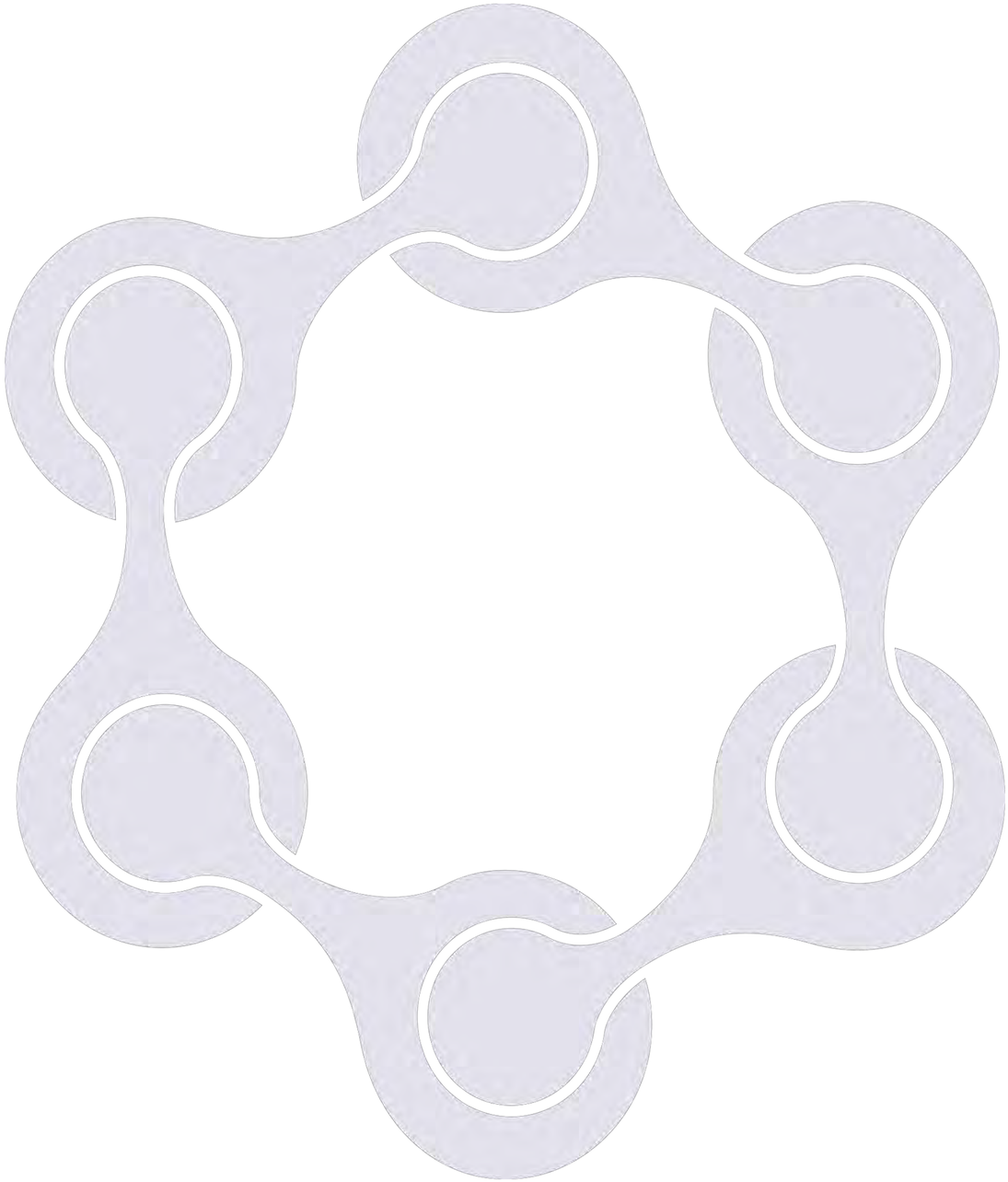
Collaboration

Advocacy

Thank You!

eva Brazilian Gynecologic Oncology Group

@gbtumoresginecologicos



LACOG

LATIN AMERICAN COOPERATIVE
ONCOLOGY GROUP

Infographic updated on 5/23/2024

LACOG MEMBERS

The **investigators** are an essential part of LACOG. We are **more than 600 members** from all over Latin America collaborating in observational studies and clinical trials. LACOG offers the possibility of Latin American investigators to develop new studies and participate in regional and international cancer trials.

ARGENTINA
38

BOLIVIA
04

BRAZIL
425

COLOMBIA
19

CHILE
12

COSTA RICA
06

CUBA
02

DOMINICAN REPUBLIC
02

ECUADOR
03

GUATEMALA
06

MEXICO
28

NICARAGUA
01

PARAGUAY
01

PERU
20

URUGUAY
04

VENEZUELA
03

TOTAL OF
620
INVESTIGATORS

LACOG INFOGRAPHIC

MEMBERS
620

COUNTRIES
17

Argentina, Brazil, Bolivia, Colombia, Chile, Costa Rica, Cuba, Dominican Republic, El Salvador, Ecuador, Guatemala, Mexico, Nicaragua, Panama, Peru, Uruguay and Venezuela

275
HOSPITALS AND RESEARCH SITES

MORE THAN 70
EPIDEMIOLOGICAL STUDIES AND CLINICAL TRIALS

MORE THAN 20.000
PATIENTS ENROLLED

MORE THAN 135
ABSTRACTS AND ARTICLES PUBLISHED

MORE THAN 30
EDUCATIONAL EVENTS PERFORMED

Infographic updated on 5/23/2024

2023 STUDY-RELATED ACTIVITIES

53
ONGOING STUDIES

119 sites
open for recruitment in 9 different Latin American countries

- **Argentina: 16**
- **Brazil: 89**
- **Colombia: 03**
- **Chile: 02**
- **Dom. Rep.: 01**
- **Guatemala: 01**
- **Mexico: 04**
- **Peru: 02**
- **Uruguay: 01**

eCRFs developed
6

SIV
62

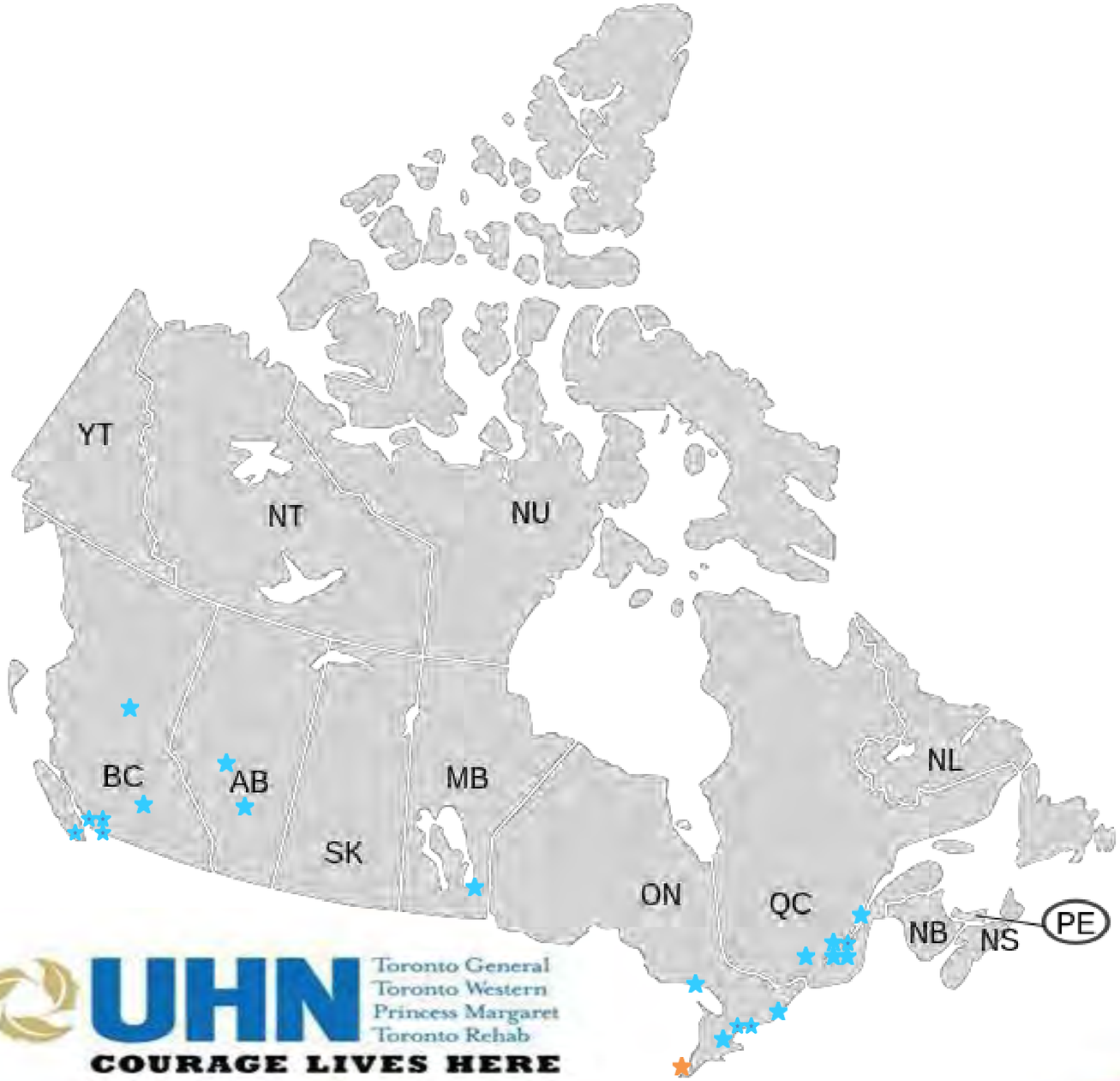
Monitoring visits
216

Signed contracts
94

Regulatory submissions
1271

CANADA INTRODUCTION

Princess Margaret Consortium Site Locations



UHN
Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
COURAGE LIVES HERE

Consortium Sites

- Lawson Health Research Institute
- Ottawa Hospital Research Institute
- Trillium Health Partners
- Kingston General Health Research Institute
- Sunnybrook's Odette Cancer Centre (Personalized Medicine Group)
- Sir Mortimer B. Davis Jewish General Hospital
- Centre Hospitalier de l'Universite de Montreal (CHUM Hospital)
- Chu De Quebec-Universite Laval (CHUQ Hospital)
- CancerCare Manitoba/ The University of Manitoba
- Tom Baker Cancer Centre
- Alberta Health Services/ The University Of Alberta
- BC Cancer Agency (BCCA) – 6 regional cancer centres
  - Abbotsford
  - Kelowna (Sindi Ahuwalia Hawkins Centre)
  - Prince George (Centre for the North)
  - Surrey
  - Vancouver
  - Victoria
- McGill University Health Centre
- Health Sciences North
- Hopital Maisonneuve-Rosemont
- Windsor Regional Hospital

Our Mission

Trials Network across Canada

International Collaboration

Development of pipeline options at the different timepoints of patient journey

Incorporation of robust translational endpoints to uncover underlying disease biology and agent mechanisms of action

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

ENGOT European Network of Gynaecological Oncological Trial groups

KGOG Korean Gynecologic Oncology Group

eva Grupo Brasileiro de Tumores Ginecológicos

LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP

GOTJ Global Oncology Trials Japan

GOG FOUNDATION® *Transforming the standard of care™*

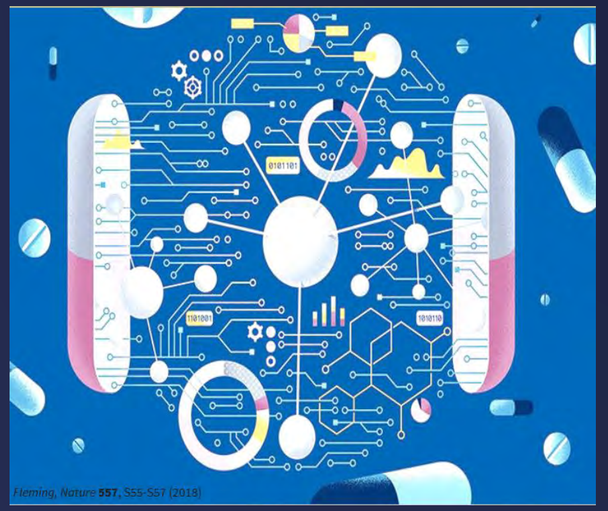
GOG PARTNERS

GOG network sites.

Trials Network

Oncology Expertise

- *Canada's largest* early phase drug academic development program
- Last decade, *>5800 patients enrolled* onto >300 clinical trials
- *Robust infrastructure* & *expertise* in multi-centre clinical trials
- Sponsor for *Investigator Initiated trials & Translational Research*



Support Canadian Oncology Research

- Ozmosis Research Inc. is an Ontario Corporation
- Ozmosis is a Canadian CRO investing profits into Cancer Research
- Affiliated with UHN

Importance of Collaboration

- GOG Network sites

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The GOG Foundation, Inc.
INTRODUCTION

GOG FOUNDATION®

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ENGOT European Network of Gynaecological Oncological Trial groups

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GOG PARTNERS

- Consulting/Strategy
- Clinical Trial Design
- Site Management
- Education

NRG ONCOLOGY
Advancing Research. Improving Lives.™

- CTEP and other core focused items

GOG FOUNDATION®
Transforming the standard of care

OUR MISSION

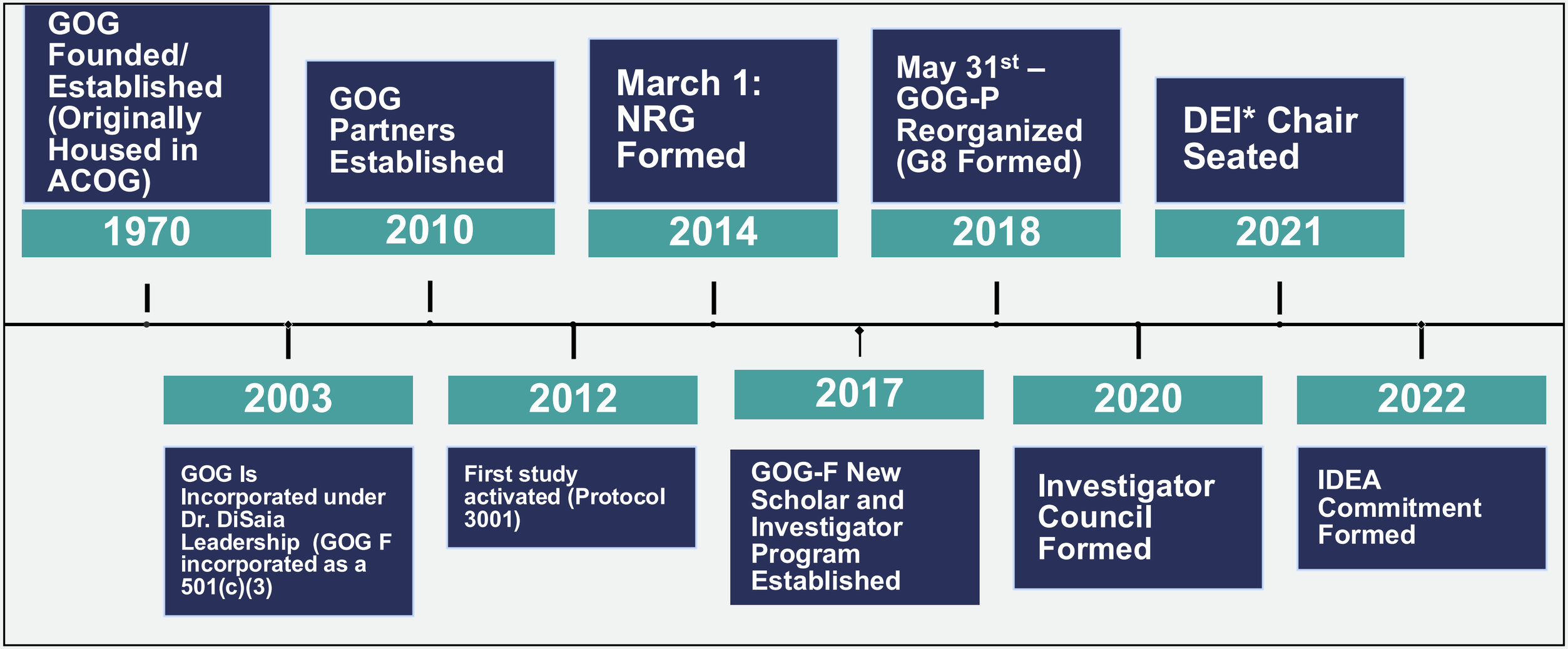
To conduct clinical and translational research that positively impacts patients through the prevention and treatment of gynecologic malignancies

OUR VISION

To be the premier collaborative network for transformative research in gynecologic malignancies

GOG PARTNERS
A GOG Foundation Program

Historical Context



*Diversity, Equity & Inclusion

GOG FOUNDATION®

Endometrial Cancer Trials: Insights, New Opportunities and Navigating the Competitive Landscape

Bradley Monk, MD

Florida Cancer Specialists & Research Institute

West Palm Beach, Florida, USA

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ENDOMETRIAL CANCER 2024

- ***Only gynecologic cancer with rising incidence and mortality***
- ***Has now exceeded ovarian cancer in annual estimated deaths***
- Corrected for hysterectomy rates, uterine cancer is ranked 15th for incident cases and 19th of the most lethal cancer* in the world

420,368 new cases* | **97,723 deaths***

~2/3 of these will be early stage and low grade with excellent prognosis

~1/3 will have high grade or advanced stage disease

Population of interest

Increasing Incidence

Increasing Mortality

Has surpassed ovarian cancer annual estimated mortality

*Gco.irac.who Corpus Uteri Fact Sheet: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://gco.iarc.who.int/media/globocan/factsheets/cancers/24-corpus-uteri-fact-sheet.pdf

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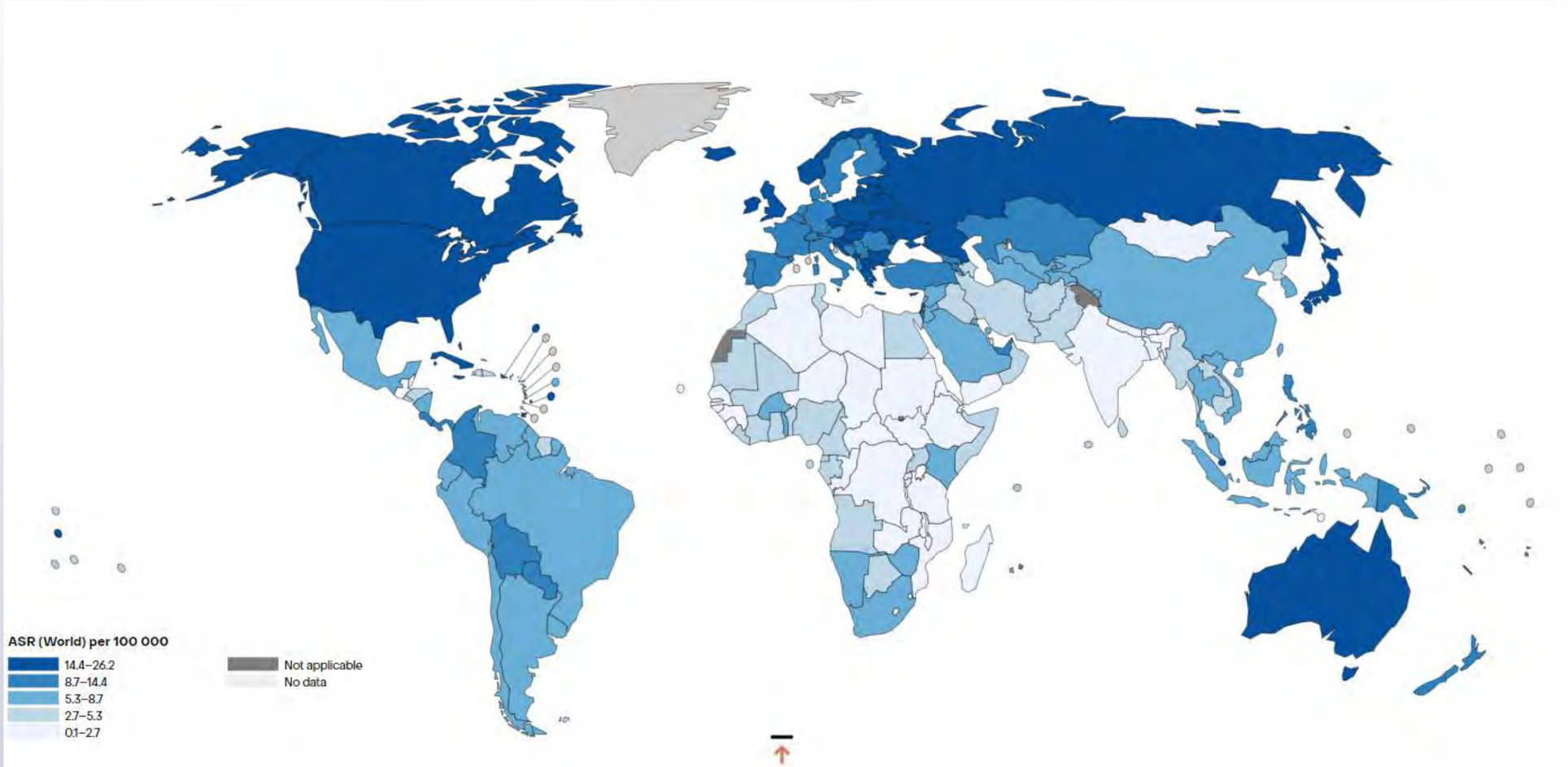
Age-Standardized Rate (World) per 100 000, Incidence, Females, in 2022
Corpus uteri



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Cancer TODAY | IARC
https://gco.iarc.who.int/today
Data version: Globocan 2022 (version 1.1) – 08.02.2024
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International Agency for Research on Cancer
World Health Organization

*Gco.irac.who Corpus Uteri Fact Sheet: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://gco.iarc.who.int/media/globocan/factsheets/cancers/24-corpus-uteri-fact-sheet.pdf

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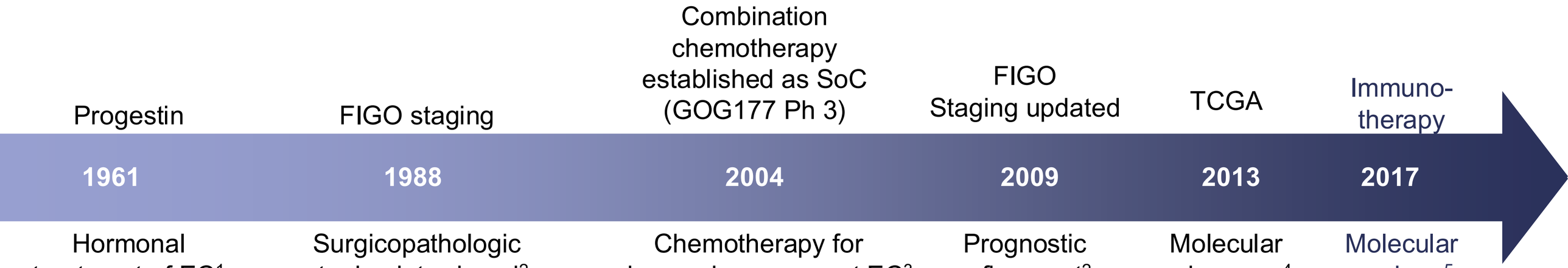
Immunotherapy Based On Molecular Characterization Is the Most Recent Therapeutic Breakthrough in EC Treatment



ESGO/ESTRO/ESP guidelines recommend molecular classification in all endometrial cancers, and considering pembrolizumab for second-line treatment of dMMR/MSI carcinomas[5]

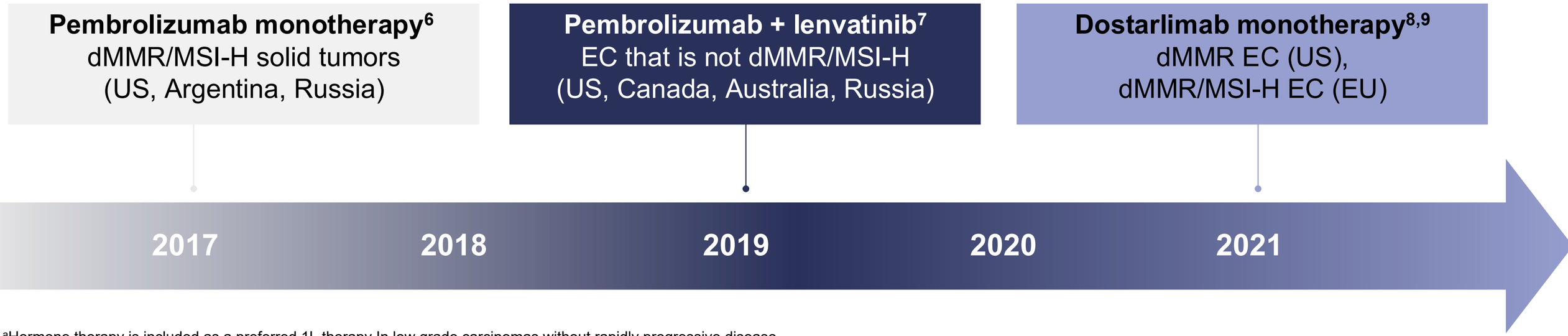
NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) recommend molecular analysis of endometrial cancers, including universal testing for MMR/MSI, and considering pembrolizumab[a] or dostarlimab[c] for first- or second-line treatment of dMMR/MSI-H tumors[6]

[a]For recurrent endometrial cancer, NCCN recommends MSI-H or dMMR testing if not previously done. Pembrolizumab is indicated for patients with MSI-H or dMMR tumors that have progressed following prior treatment.
[c]Dostarlimab-gxly is indicated for patients with dMMR recurrent or advanced EC that has progressed on or following prior treatment with a platinum-containing regimen. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms V.3.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed July 22, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. dMMR, mismatch repair deficient; EC, endometrial cancer; FIGO, International Federation of Gynecologists and Obstetricians; GOG, Gynecologic Oncology Group; MMR, mismatch repair; MSI, microsatellite instability; MSI-H, microsatellite instability-high; NCCN, National Comprehensive Cancer Network®; SoC, Standard of Care.

1. Yang S, et al. *Discov Med*. 2011;12:205-12. 2. Haltia U-M, et al. *J Gynecol Oncol*. 2014;25:30-35. 3. Fleming GF, et al. *J Clin Oncol.* 2004;22:2159-2166. 4. Cancer Genome Atlas Research Network, et al. *Nature*. 2013;497:67-73. 5. Concin N, et al. *Int J Gynecol Cancer.* 2021;31:12-39. 6. National Comprehensive Cancer Network (NCCN)® Clinical Practice Guidelines in Oncology. Uterine Neoplasms, Version 3.2021. Accessed July 22, 2021.

Current Treatment of Advanced/Recurrent or High-risk EC

- Treatment guidelines recommend platinum-based doublet (carboplatin + paclitaxel) alone or in combination as preferred first-line treatment of advanced/recurrent EC;[a,1,2] in second line, guidelines recommend PD-1 regimens based on biomarker (MMR/MSI) status[2]
- Guideline recommendations are based on recent approvals of PD-1 agents in the second-line or greater setting[3-5] and emerging datasets in first-line combinations without FDA approvals.



[a]Hormone therapy is included as a preferred 1L therapy In low grade carcinomas without rapidly progressive disease.
dMMR, mismatch repair deficient; EC, endometrial cancer; EU, European Union; MSI-H, microsatellite instability-high; PD-1, programmed death 1; US, United States.

1. Colombo N et al. *Ann Oncol*. 2016;27:16–41. 2. Concin N et al. *Int J Gynecol Cancer*. 2021;31:13–39. 3. Pembrolizumab [prescribing information]. Whitehouse Station. NJ: Merck Sharp & Dohme Corp.; 2021. 4. Dostarlimab (dostarlimab-gxly injection, for intravenous use) [prescribing information]. Research Triangle Park, NC, USA: GlaxoSmithKline LLC. 5. Jemperli Prescribing Information April 2022. 6. US FDA. Press Release. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-cancer-treatment-any-solid-tumor-specific-genetic-feature. Published: May 23, 2017. Accessed: May 14, 2021. 7. US FDA. Press Release. Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/simultaneous-review-decisions-pembrolizumab-plus-lenvatinib-australia-canada-and-us. Published: September 17, 2019. Accessed: May 14, 2021. 8. US FDA. Press Release. Available at: FDA Approves Immunotherapy for Endometrial Cancer with Specific Biomarker | FDA. Published: April 22, 2021. Accessed: June 7, 2021. 9. EMA: dostarlimab. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR. Accessed June 7, 2021.

2024 FDA Approvals in Endometrial Cancer

GY018
All Comers

NRG GY018

A Phase III Randomized, Placebo-controlled Study of Pembrolizumab (MK-3475, NSC #776864) in Addition to Paclitaxel and Carboplatin for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer

FDA Approval
June 2024

NEJM Publication
March 2023

DUO-E
dMMR

GOG 3041/ ENGOT-EN10/ D9311C000001

Durvalumab With or Without Olaparib as Maintenance Therapy After First-Line Treatment of Advanced and Recurrent Endometrial Cancer (DUO-E)

FDA Approval
June 2024

JCO Publication
October 2023

RUBY
All Comers

ENGOT –EN6/ GOG 3031/4010-03-001

A Study to Evaluate Dostarlimab Plus Carboplatin-paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Participants With Recurrent or Primary Advanced Endometrial Cancer (RUBY)

RUBY Part 1: March 2024

Annals of Oncology Publication
June 2024

Gynecologic Oncology Publication
July 2024

EVOLUTION OF MOLECULARLY DIRECTED THERAPY IN ENDOMETRIAL CANCER

What are the implications of prior IO treatment, and opportunities post-IO..?

TP53

- Predictor of response to anti angiogenic therapy.
- GOG-86P:
  - PFS HR 0.48 vs 0.87 in mutant TP53 vs. TP53wt
- Inhibition of nuclear export of wild type TP53:
  - Selinexor median PFS in TP53wt of 28.4 mo vs 5.2 months with placebo (Makker et al. ASCO 2024)

Anti-HER2 (+ other ADC's)

- Evolution of anti-HER2 treatments.
- DESTINY-Pan Tumor02:
  - ORR 57.5%; Median DOR: NR
- US FDA Accelerated Approval in HER2 3+
- Nishikawa et al. 2023: ORR 54.5% & 70%
- Other ADCs:
  - (TROP2, B7H4, FRalpha)

DNA Damage Repair

- Potential opportunity in the mutant TP53 population
- ADAGIO:
  - Adavosertib Median prior
  - LOT = 3
  - BICR ORR 26%
  - Median PFS 2.8mo
- Azenosertib (NCT04814108)
- PARPi
  - (UTOLA) – Joly F et al. ESMO 2023
  - Rucaparib – Corr et al. SGO 2024

Hormonal Therapies

- Possible role in the copy number low TP53wt population
- PALEO Study:
  - Letrozole vs Palbocilcib + letrozole
  - HR 0.56
  - Median PFS 8.3 vs 3 mo
- Letrozole + Abemaciclib:
  - ORR 30%

Aghajanian et al. J Clin Oncol. 2011; Leslie K. et al. Gyncol Oncol 2021; Nickles-Fader J Clin Oncol 2018; Nickles-Fader Clin Cancer Research 2020; Nishikawa et al. J Clin Oncol. 2023; Liu JF, et al. SGO 2023. Abstract 219; Mirza et al. ESMO 2020; P Konstantinopoulos et al. J Clin Oncol 2022; Funda Meric-Bernstam, MD et al. ASCO 2023. Vergote et al. J Clin Oncol 2023

MOVING IMMUNOTHERAPY EFFORTS INTO THE FRONTLINE AS CHEMOTHERAPY REPLACEMENT

GOG 3064/ENGOT-EN15/KN-C93

R → Pembrolizumab
R → Chemo

Primary endpoints:
PFS, OS

Key secondary endpoints:
ORR, DCR, DOR

Recruitment ongoing

dMMR patient population

ENGOT-en13 DOMENICA

R → Dostarlimab
R → Chemo

Primary endpoint:
PFS

Key secondary endpoints:
OS, PROs, ORR, DOR

Recruitment ongoing

dMMR patient population

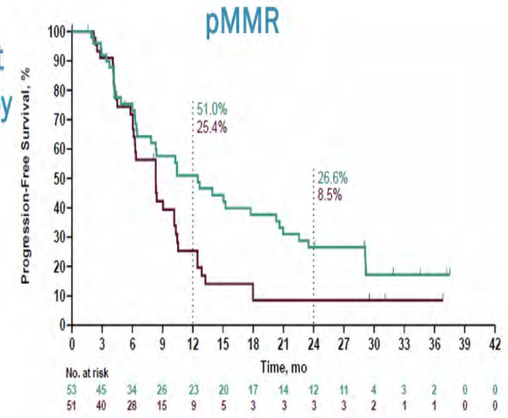
ENGOT-en9 LEAP-001

Pembrolizumab/Lenvatinib Miss OS, PFS in Endometrial Cancer

December 8, 2023

Sabrina Serani

PFS in Prior Neo/Adjuvant Chemotherapy Subgroup



dMMR and pMMR patient populations

Data cutoff date: October 2, 2023.

1. https://clinicaltrials.gov/study/NCT03884101. 2.Marth C et al. ESGO 2024. 3. Marth C et al. SGO 2024. 4.Pignata S et al ESMO-GYN 2024 Abstract 39O.

Nicoletta Colombo, MD, PhD

University Milano-Bicocca Oncology | Milan, Italy

Presenting:

- **ASCENT-GYN-01/GOG-3104/ENGOT-en26**
  A Randomized, Open-Label, Phase 3 Study of SG vs TPC in Participants With Endometrial Cancer Who Have Received Prior Platinum-Based Chemotherapy and Anti-PD-1/PD-L1 Immunotherapy

Keiichi Fujiwara, MD, PhD

Global Oncology Trials Japan | Japan

Presenting:

- **GOG-3095/MK-2870-005/ENGOT-en23**
  A Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice in Participants With Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Immunotherapy

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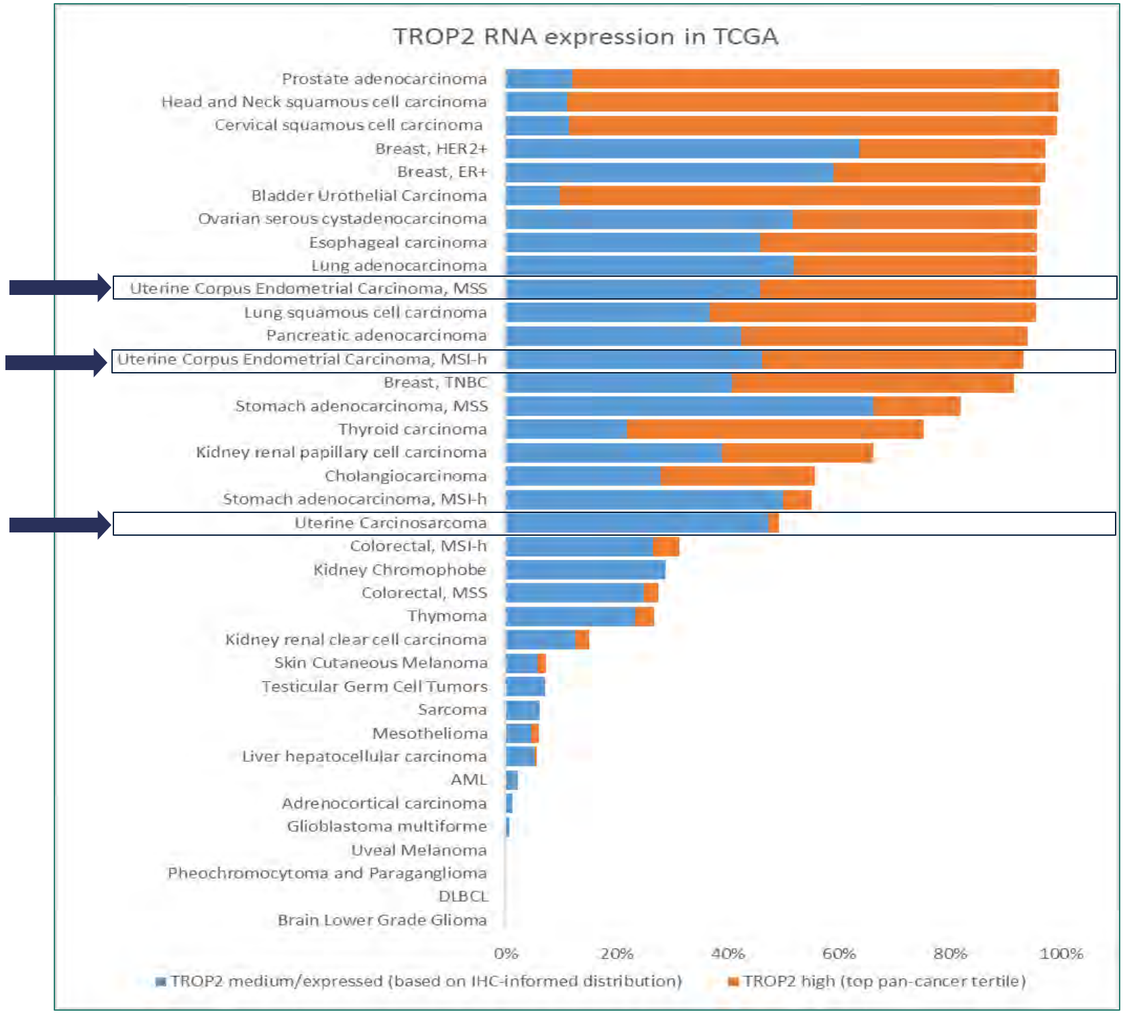
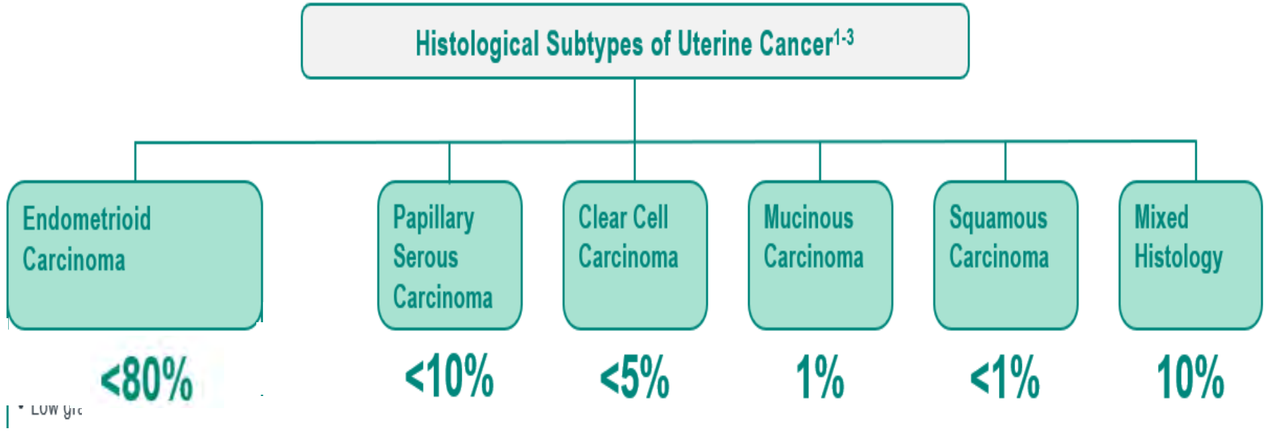
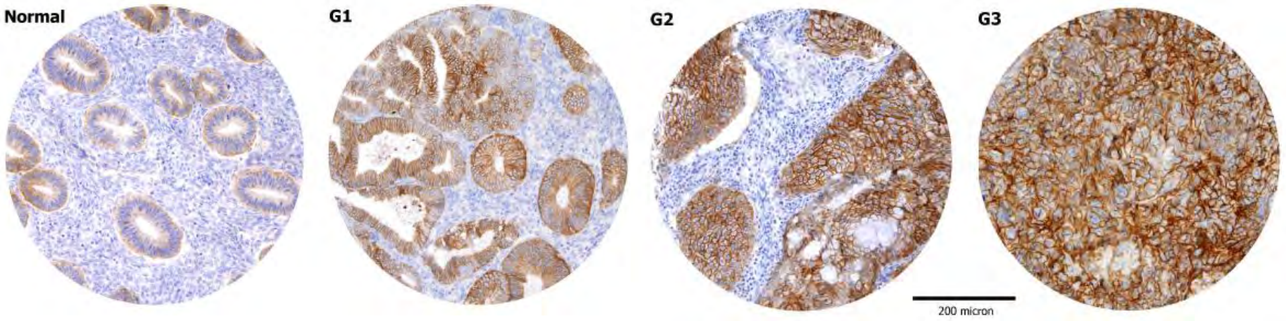
TROP2 is broadly expressed across EC Histologies







TROP2 Expression in Endometroid Histology is *inversely* correlated with differentiation.

[1]Morice, Lancet, 2016; [2]Gordon, Global Library of Women's Medicine, 2008; [3]Cerner Enviza, CancerMPact, Patient Metrics, Data Updated 25JAN2022. Bardia, et al., Ann Oncol 2021,32(6):746-756 & Bignotti et al. Int J Gynecol Cancer 2011. 21(9):1613-21.

CONFIDENTIAL

Sacituzumab Govitecan (SG): TROP-2-Directed ADC

Humanized Monoclonal Antibody (hRS7)

Selectively binds to Trop-2 (high antigen expression on multiple tumor types) with nanomolar affinity and is internalized.

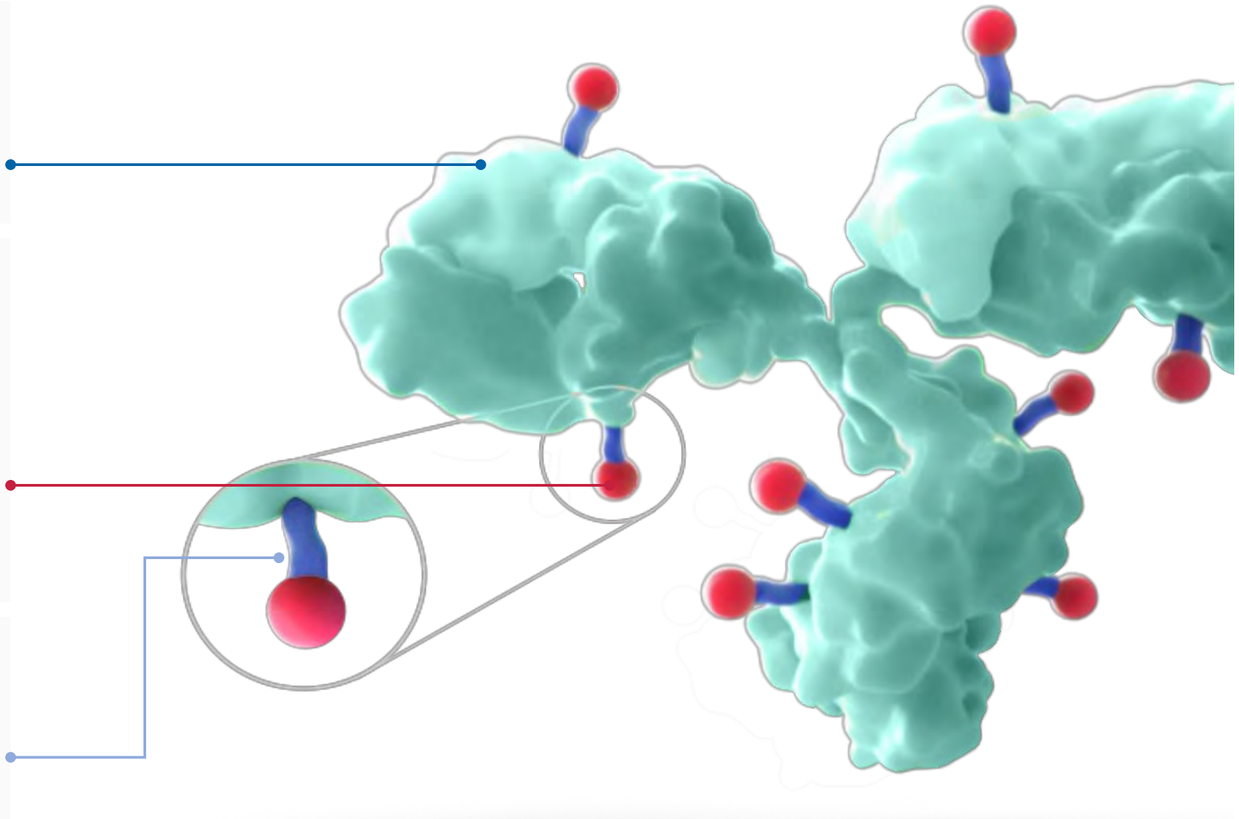
Cytotoxic Payload (SN-38)

SN-38 (active metabolite of irinotecan), a TOP1 inhibitor that blocks DNA replication)[1-3]

Has a high drug-to-antibody ratio of ~8:1

Hydrolysable Linker (CL2A)

Hydrolysis of the linker is thought to confer a unique drug-release profile, including a bystander effect



Trop-2-directed ADC consisting of a humanized anti-Trop-2 monoclonal antibody (hRS7) conjugated with the active metabolite of irinotecan (SN-38) by a hydrolysable linker (CL2A)[1-3]

ADC, antibody-drug conjugate; SG, sacituzumab govitecan.

1. Cardillo TM, et al. *Bioconjugate Chem*. 2015;26:919-931; 2. Rugo HS, et al. *Future Oncol*. 2020;16:705-715; 3. Kciuk M, et al. *Int J Mol Sci*. 2020;21:4919.

Confidential - External Use; Intended for HCP audiences

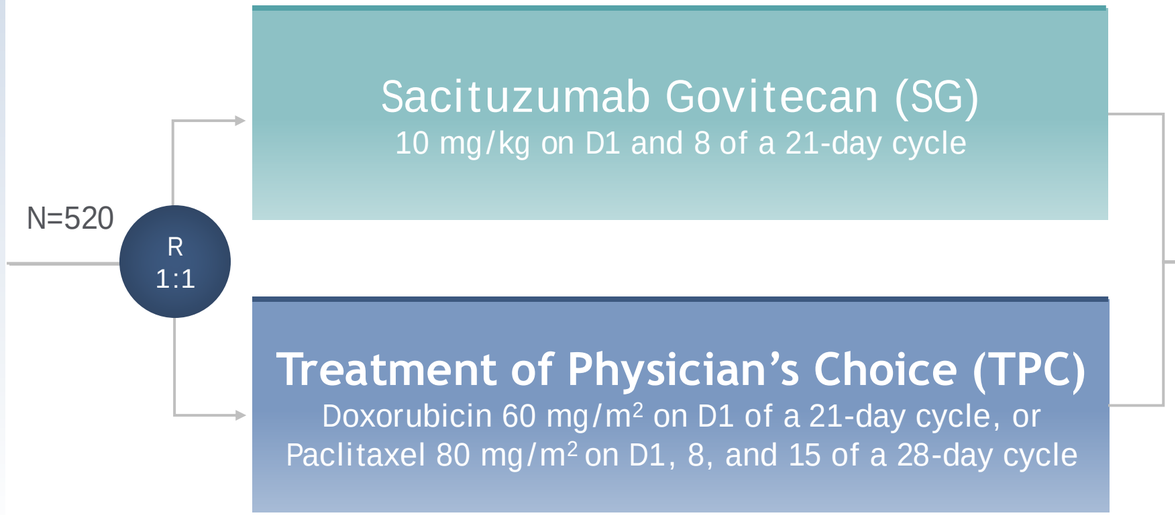
ASCENT-GYN-01/GOG-3104/ENGOT-en26

A Randomized, Open-Label, Phase 3 Study of SG vs TPC in Participants With Endometrial Cancer Who Have Received Prior Platinum-Based Chemotherapy and Anti-PD-1/PD-L1 Immunotherapy

ClinicalTrials.gov ID: NCT06486441

Key Eligibility Criteria

- Recurrent or persistent endometrial cancer (endometrial carcinoma or carcinosarcoma)
- Up to 3 prior lines of systemic therapy for endometrial cancer, including systemic platinum-based chemotherapy and anti-PD-1/PD-L1 therapy, either in combination or separately
- Radiologically evaluable disease (either measurable or nonmeasurable) per RECIST v1.1
- ECOG Performance Status of 0-1



Key Endpoints

Primary Endpoints

- PFS by BICR
- OS

Secondary Endpoints

- ORR, DOR, CBR
- PFS by INV
- Safety
- QOL

— Partnership with GOG-F and ENGOT —

— Now Recruiting —

BICR, blinded independent central review; CBR, clinical benefit rate; DOR, duration of response; ECOG, eastern cooperative oncology group; INV, investigator; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PD-1, programmed cell death protein 1; PD-L1, programmed cell death ligand 1; QOL, quality of life; RECIST, response evaluation criteria in solid tumors; SG, sacituzumab govitecan; TPC, treatment of physician's choice.

ascent-gyn-01

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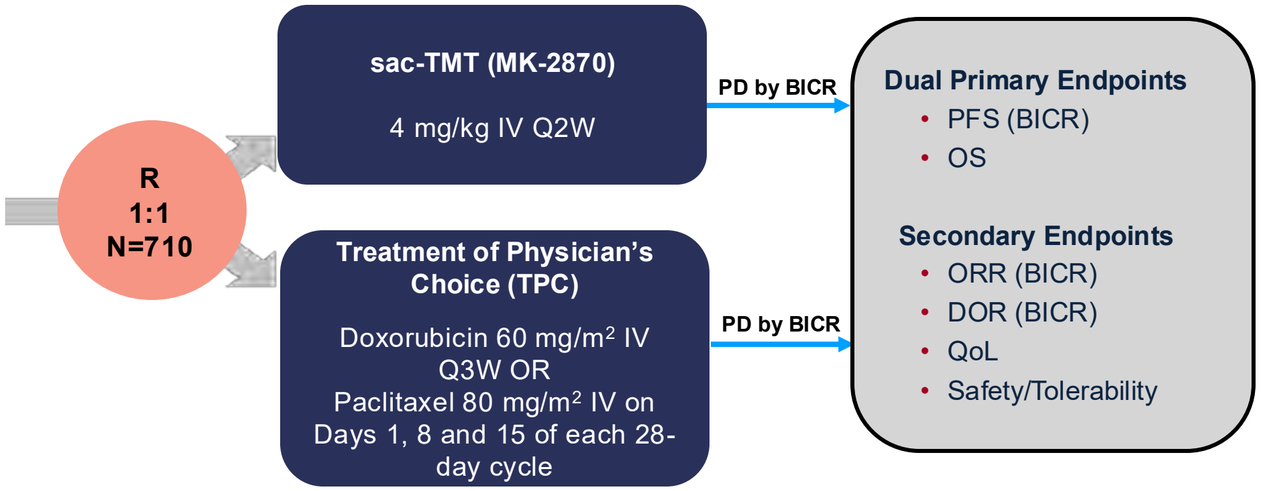
GOG-3095/MK-2870-005/ENGOT-en23/TroFuse-005

A Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice in Participants With Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Immunotherapy

(PI: Domenica Lorusso, MD)



Stratification:
- MMR (deficient MMR or proficient MMR)
- TROP2 expression (low vs. medium + high), per immunohistochemistry (IHC)
- Prior lines of therapy (≤ 2 or 3)
- Disease status at baseline per RECIST 1.1 as assessed by BICR (measurable vs non-measurable)

Key Inclusion
- Histologically-confirmed diagnosis of endometrial carcinoma or carcinosarcoma
- Radiologically apparent measurable or non-measurable disease
- Prior platinum exposure AND prior anti-PD-1/PD-L1 exposure (given separately or in combination), in any setting
- Recurrence of endometrial carcinoma or carcinosarcoma <12 months after completing platinum-based adjuvant therapy, OR received platinum in the metastatic setting, OR received an IO-based regimen in the recurrent setting after initial adjuvant platinum therapy regardless of platinum-free interval.

PLEASE ENROLL

BICR, blinded independent central review; dMMR, mismatch repair deficient; DOR, duration of response; ECOG, eastern cooperative oncology group; MMR, mismatch repair; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-1, programmed cell death receptor-1; PD-L1, programmed cell death-ligand 1; PFS, progression-free survival; pMMR, mismatch repair proficient; QoL, quality of life; TROP2, transmembrane glycoprotein encoded by the Tacstd2 gene. MK-2870 internal data

Protocol MK-2870-005 Am 02, published 02Feb2024. Merck 2023

NCT06132958

TroFuse-005 MSD Collaborations

Led by ENGOT and in collaboration with GOG Partners

Stephanie Lheureux, MD, PhD

Princess Margaret Cancer Centre | Ontario, Canada

Presenting:

- **XPORT-EC-042/GOG 3083/ENGOT-EN20**
  A Phase 3, Randomized, Placebo-controlled, Double-blind, Multicenter Trial of Selinexor in Maintenance Therapy After Systemic Therapy for Patients With p53 Wild-type, Advanced or Recurrent Endometrial Carcinoma

XPORT-EC-042: Trial Design

A Phase 3, Randomized, Placebo-controlled, Double-blind, Multicenter Trial of Selinexor in Maintenance Therapy After Systemic Therapy for Patients With **p53 Wild-type**, Advanced or Recurrent Endometrial Carcinoma (NCT05611931)[1,2]

Planned enrollment (N=220)

Patients ≥ 18 years with:

- Known *TP53*wt EC by central NGS
- Primary Stage IV disease or first recurrent EC
- Received ≥ 12 weeks of platinum-based chemotherapy **± immunotherapy**

Stratification

- Primary Stage IV vs recurrent
- PR vs CR

PR/CR per RECIST v1.1 following prior chemotherapy

R 1:1

Arm A
Selinexor 60 mg PO QW until PD, toxicity, or 3 years if in CR

n=110

Arm B
Placebo until PD, toxicity, or 3 years if in CR

n=110

Primary endpoint

- Investigator-assessed PFS

Key secondary endpoint:

- OS

Other secondary endpoints:

- Safety
- TFST
- PFS2
- TSST
- PFS by BICR
- QoL (EQ-5D-5L)

Exploratory endpoints:

- PFS per histology subtypes and other molecular features
- CR rate
- Duration of CR
- Tumor biomarkers
- PK exposure parameters and efficacy/safety endpoints

BICR, Blinded Independent Central Review; CR, complete response; EC, endometrial cancer; ECOG, Eastern Cooperative Oncology Group; EQ-5D-5L, EuroQol - 5 dimensions - 5 levels; NGS, next-generation sequencing; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS2, progression-free survival after consecutive treatment; PK, pharmacokinetic; PO, orally; PR, partial response; QoL, quality of life; QW, once weekly; R, randomization; RECIST, response evaluation criteria in solid tumors; TFST, time to first subsequent therapy; *TP53*, tumor protein 53 gene; TSST, time to second subsequent treatment; wt, wild-type.

1. Karyopharm Therapeutics Inc. Clinical Study Protocol Version 3.0. XPORT-EC-042. **2.** ClinicalTrials.gov. NCT05611931. https://www.clinicaltrials.gov/ct2/show/NCT05611931. Accessed February 1, 2024.

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Jae-Hoon Kim, MD, PhD

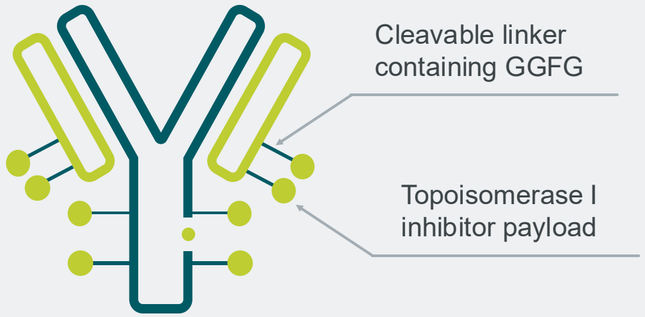
Gangnam Severance Hospital | Seoul, South Korea | Republic of Korea

Presenting:

- **BNT323-01/GOG 3105/ENGOT-EN25**
  A Phase III, Randomized, Multi-site, Open-label Trial of BNT323/DB-1303* Versus Investigator's Choice of Chemotherapy in Previously Treated Patients With HER2- Expressing Recurrent Endometrial Cancer

Trastuzumab Pamirtecan (BNT323/DB-1303)* HER2 ADC: Mechanism of Action[1-3]

Stable in circulation
Cleavable linker
Potent payload



Trastuzumab Pamirtecan (BNT323/DB-1303) is an investigational ADC comprised of a humanized anti-HER2 IgG1 monoclonal antibody, covalently linked to a proprietary DNA topoisomerase I inhibitor via a cleavable linker.

Designed to target cancer cells via selective binding to HER2

Trastuzumab Pamirtecan (BNT323/DB-1303) selectively binds to HER2 receptor on the surface of cancer cells.

Payload demonstrates DNA damage and apoptosis
Bystander killing

Upon endocytosis and cleavage by a lysosomal enzyme, the cytotoxic agent is released, resulting in DNA damage and apoptotic cell death.

*Partnered with DualityBio; ADC = antibody drug conjugate; DNA = deoxyribonucleic acid; GGFG = glycyl-glycyl-phenylalanyl-glycine; HER2 = human epidermal growth factor 2; IgG1 = immunoglobulin 1.

1. Investigator Protocol DB-1303-O-1001. DualityBio Inc. Published April 15, 2023. Approved July 18, 2023. 2. Moore S, et al. Oral Presentation. ESGO 2023 Congress. September 28-October 1, 2023; 3. Lin S, et al. DualityBio. 2022. (Poster).

BNT323/DB-1303 is an investigational product and are is not approved anywhere globally; its safety and efficacy have not been established. There is no guarantee that they will become commercially available.

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Trastuzumab Pamirtecan (BNT323/DB-1303)* Clinical Development Program

Multiple trials in multiple disease settings are ongoing

Trial	Phase	Indication(s)	Criteria	Treatment	Status
DB-1303-O-1001 (NCT05150691)**	I/IIa	Advanced or metastatic solid tumours	Dependent on arm and indication	• BNT323/DB-1303	Recruiting

DB-1303-O-3002 (NCT06018337)**	III	Hormone Receptor-positive (HR+), HER2-low metastatic breast cancer	Progressed on
			• At least 2 lines of endocrine therapy (ET)
			or
			• Within 6 months of first line ET + CDK4/6 inhibitor
			in the metastatic setting
				• BNT323/DB-1303
				• Investigator's choice single agent
				  • Capecitabine
				  • Paclitaxel
				  • Nab-paclitaxel
					Recruiting

BNT323-01/GOG-3105/ENGOT-EN25-NSGO-CTU†	III	Recurrent or Metastatic HER2 expressing Endometrial Cancer	At least one prior line of platinum-based therapy and exposure to immunotherapy	• BNT323/DB-1303
				• Investigator's choice
				  • Paclitaxel
				  • Doxorubicin
					Not yet recruiting

*Partnered with DualityBio. **Sponsored by Duality Bio † Sponsored by BioNTech; Received FDA Breakthrough Therapy Designation for EC
ET= Endocrine Therapy; HER2, Human epidermal growth factor receptor ; CDK= Cyclin dependant kinase
BNT323 / DB-1303 is an investigational product and are is not approved anywhere globally; its safety and efficacy have not been established. There is no guarantee that they will become commercially available

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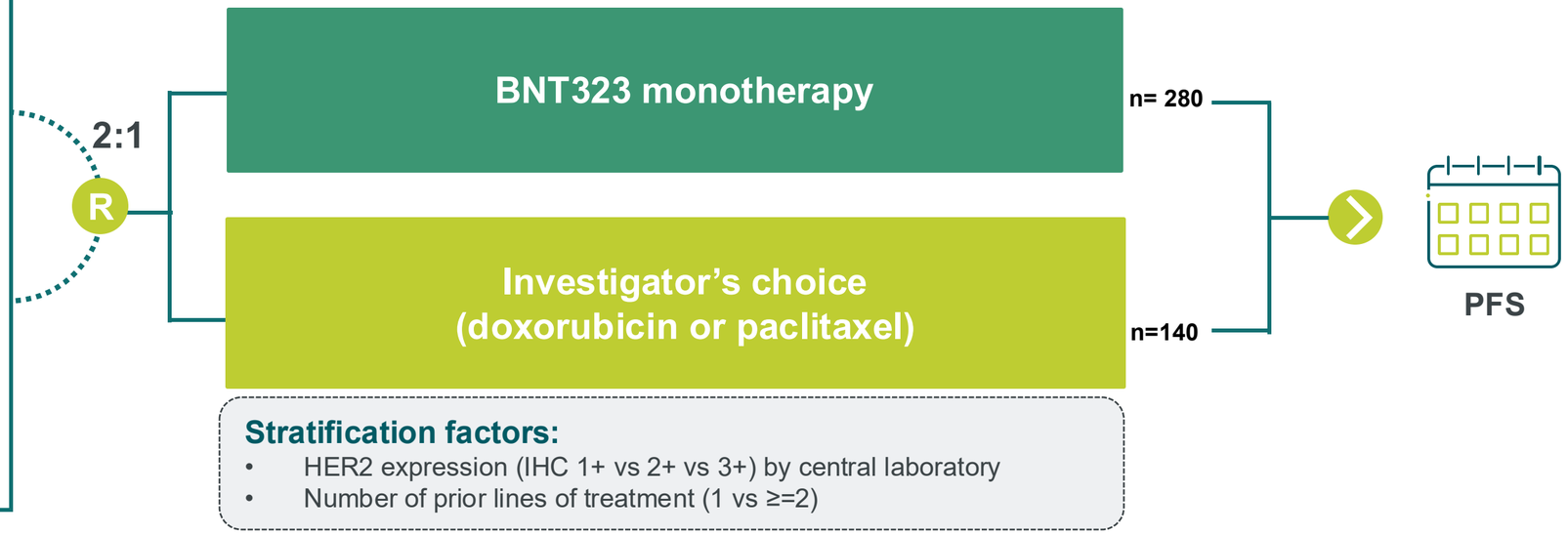
BNT323-01/GOG 3105/ENGOT-EN25: Trial Design

A Phase III, Randomized, Multi-site, Open-label Trial of BNT323/DB-1303* Versus Investigator's Choice of Chemotherapy in Previously Treated Patients With HER2- Expressing Recurrent Endometrial Cancer (NCT06340568)

PI: Dr. Floor Backes

KEY INCLUSION CRITERIA

- Recurrent, metastatic endometrial cancer (including HER2 1+, 2+, or 3+ score on IHC by central testing)
- At least 1 prior line of platinum-based therapy (in any setting) and prior immune checkpoint inhibitor (in any setting), up to three lines of prior therapy (excluding endocrine therapies)
- Measurable disease per RECIST v1.1
- ECOG PS 0 or 1



Stratification factors:

- HER2 expression (IHC 1+ vs 2+ vs 3+) by central laboratory
- Number of prior lines of treatment (1 vs ≥=2)

Primary Endpoints

- **PFS (BICR assessed)**

Secondary Endpoints

- **OS (Key)**
- PFS (Investigator assessed)
- ORR, DoR
- Safety

*Partnered with DualityBio; BICR = blinded independent central review; DoR = duration of response; ECOG = Eastern Cooperative Oncology Group; HER2 = human epidermal growth factor receptor 2; ICI = immune checkpoint inhibitor; IHC = immunohistochemistry; N = number of patients; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; PS = performance status; R = randomization; RECIST = Response Evaluation Criteria in Solid Tumors; Accessed May 2024; BNT323 / DB-1303 is an unapproved investigational product; its safety and efficacy have not been established. Future commercially availability is not guaranteed.

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Endometrial Cancer Trials: Discussion

Bradley Monk, MD
Florida Cancer Specialists & Research Institute
West Palm Beach, FL, USA

Nicoletta Colombo, MD, PhD
University Milano-Bicocca Oncology
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Graziela Dal Molin, MD
Beneficencia Portuguesa de Sao Paulo Brazil

Keiichi Fujiwara, MD, PhD
Global Oncology Trials Japan
Japan

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Republic of Korea

Stephanie Lheureux, MD, PhD
Princess Margaret Cancer Centre
Ontario, Canada

Ovarian Cancer Trials: Insights, New Opportunities and Navigating the Competitive Landscape

Bradley Monk, MD

Florida Cancer Specialists & Research Institute
West Palm Beach, Florida, USA

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

ENGOT European Network of Gynaecological Oncological Trial groups

KGOG Korean Gynecologic Oncology Group

eva Brazilian Gynecologic Oncology Group

LACOG Latin American Cooperative Oncology Group

GOTJ Global Oncology Trials Japan

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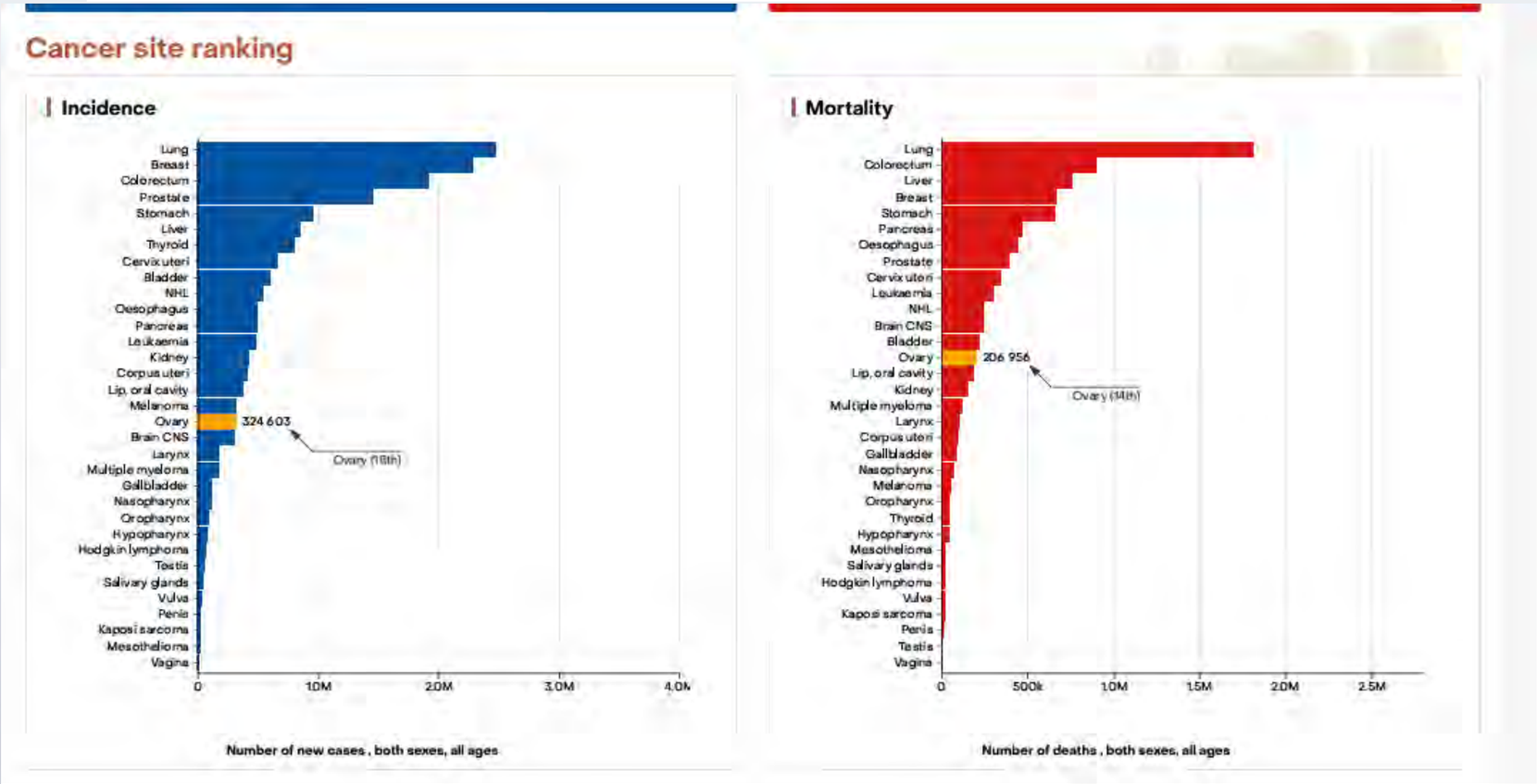
OVARIAN CANCER 2024

Ovarian Cancer is ranked 18th for incident cases and 14th of the most lethal cancer* in the world

324,604 new cases*	206,956 deaths*



*Gco.irac.who Ovarian Fact Sheet:chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://gco.iarc.who.int/media/globocan/factsheets/cancers/25-ovary-fact-sheet.pdf

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

ENGOT European Network of Gynaecological Oncological Trial groups

KGOG Korean Gynecologic Oncology Group

eva Brazilian Gynecologic Oncology Group

LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP

GOTJ Global Oncology Trials Japan

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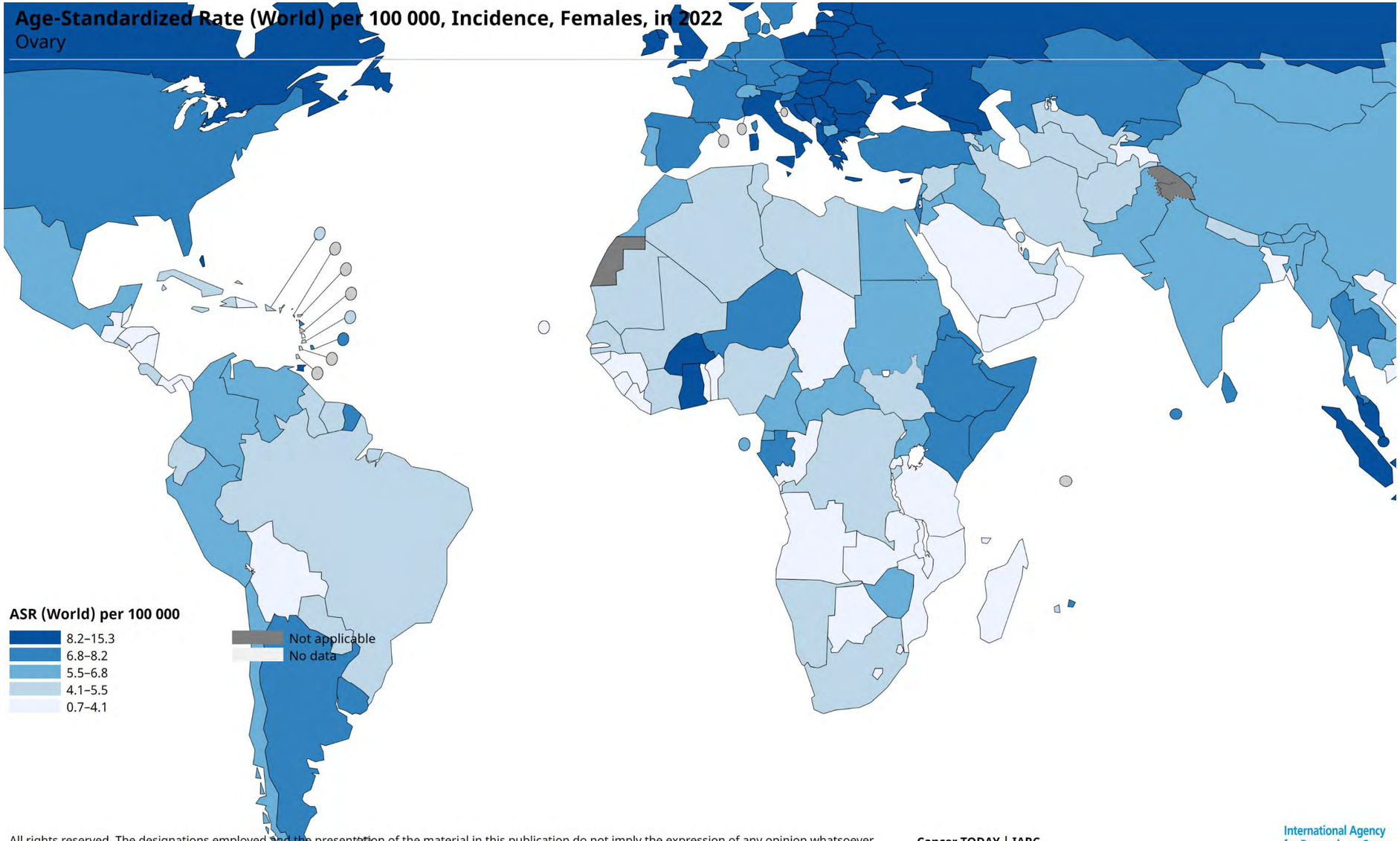

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Cancer TODAY | IARC
https://gco.iarc.who.int/today
Data version: Globocan 2022 (version 1.1) - 08.02.2024
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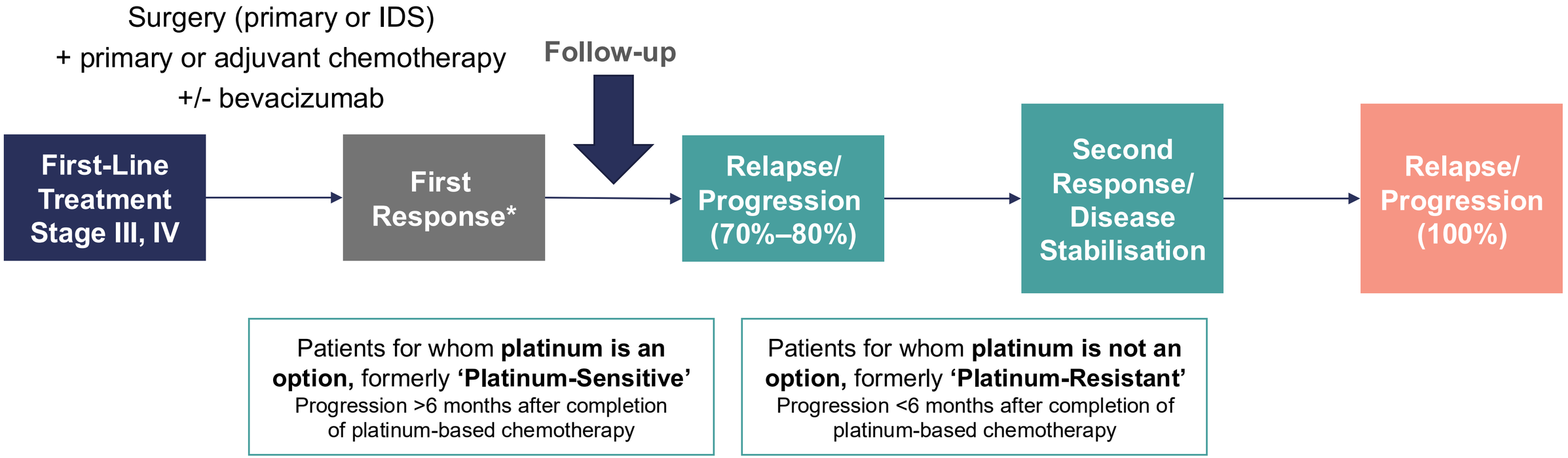
International Agency for Research on Cancer
World Health Organization

https://gco.iarc.fr/today/en/dataviz/maps-ranking?mode=ranking&key=total&cancers=25&sexes=2

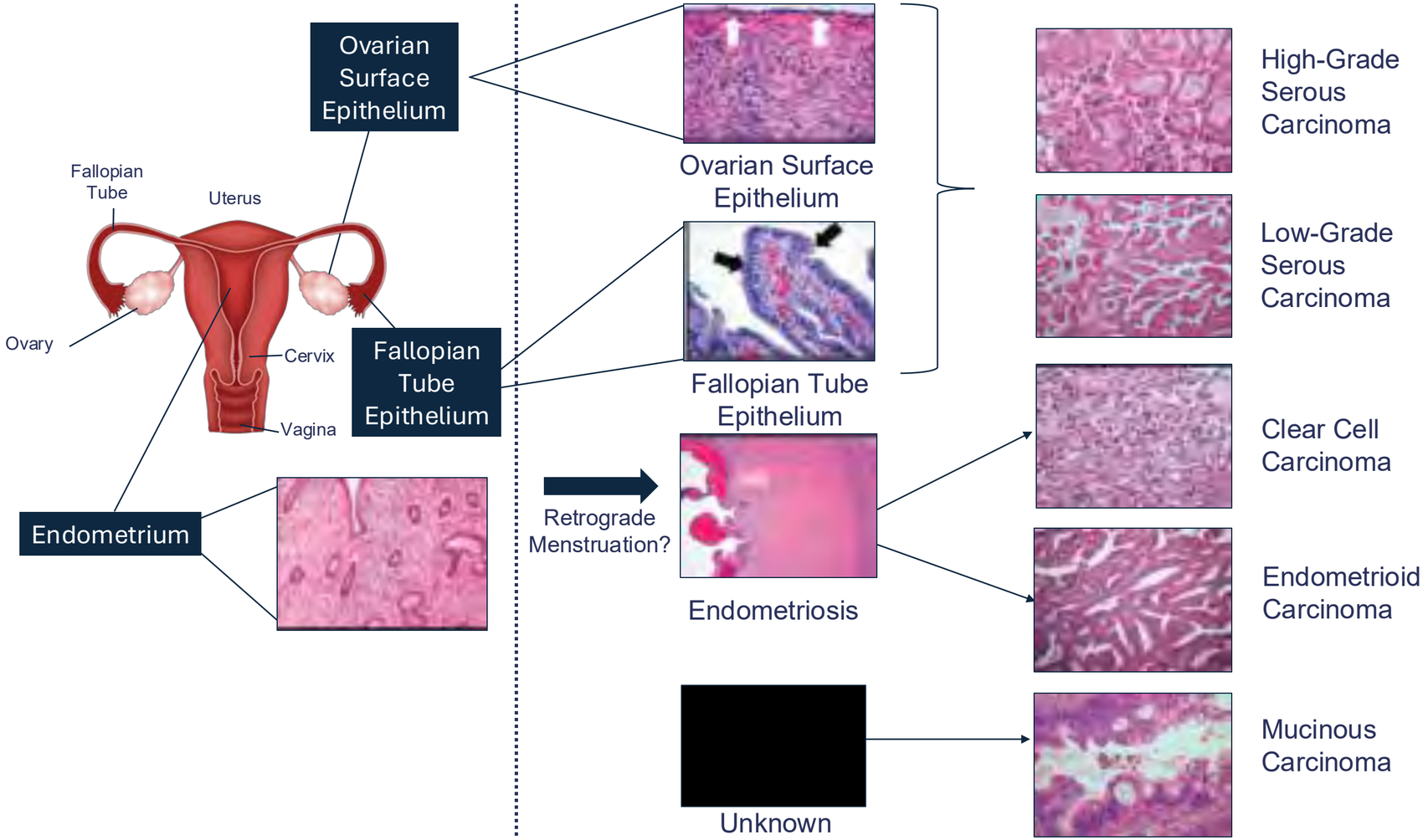
The Typical Course of Advanced Ovarian Cancer and Opportunities for Development



*Around 5% of patients are primary treatment-refractory, meaning disease progressed during therapy or within 4 weeks after the last dose.
IDS=interval debulking surgery.

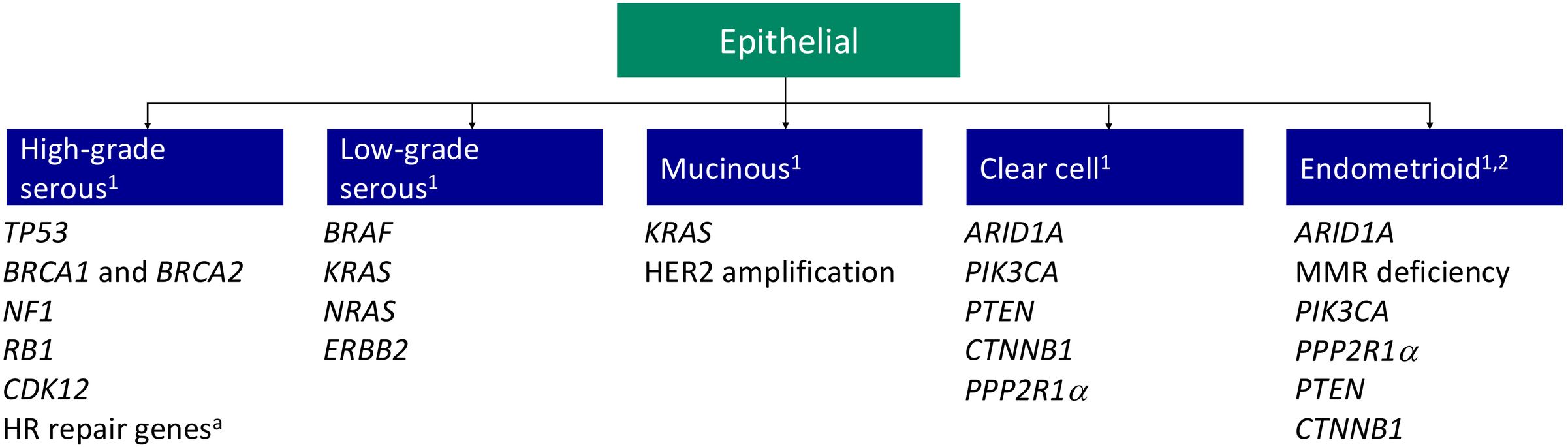
1. Ledermann JA et al. *Ann Oncol.* 2013;24(Suppl 6):vi24-vi32. 2. Giornelli GH. *Springerplus.* 2016;5(1):1197. 3. Pignata S et al. *Ann Oncol.* 2017;28(suppl_8):viii51-viii56. 4. du Bois A et al. *Cancer.* 2009;115(6):1234-1244. 5. Wilson MK et al. *Ann Oncol.* 2017;28(4):727-732.

Potential Cellular Origins of Ovarian Carcinomas



Epithelial Ovarian Cancer (Peritoneal and Tubal) Subtypes Are Associated With Different Mutations and Molecular Aberrations

Epithelial ovarian cancer can be characterized as a heterogeneous disease, not only histologically, but through identification of distinct molecular pathway alterations



- [a] *CHK2*, *BARD1*, *BRIP1*, *PALB2*, *RAD50*, *RAD51C*, *ATM*, *ATR*, *EMSY*, and Fanconi anemia genes.
- HR, homologous recombination; MMR, mismatch repair.
- **1.** Banerjee S, et al. *Clin Cancer Res.* 2013;19(5):961-8. **2.** McConechy MK, et al. *Mod Pathol*. 2014;27(1):128-34.

Significant progress has been made in the first-line management of ovarian cancer over the past decade

2003

Chemotherapy

No further improvement in survival with chemotherapy alone since the introduction of platinum–taxane chemotherapy[1,2]

2011

Paradigm shift 1:
Bevacizumab

Bevacizumab improved PFS versus chemotherapy alone[3,4]

2018

Paradigm shift 2:
PARP inhibitors for BRCA-mutated ovarian

Olaparib	**SOLO-1**[5] *NCT01844986*

2019–2022

Paradigm shift 3:
PARP inhibitors beyond BRCA mutation

Olaparib + bevacizumab	**PAOLA-1**[6] *NCT02477644*
Niraparib	**PRIMA**[7] *NCT02655016*
[a]Rucaparib	**ATHENA-mono**[8] *NCT03522246*

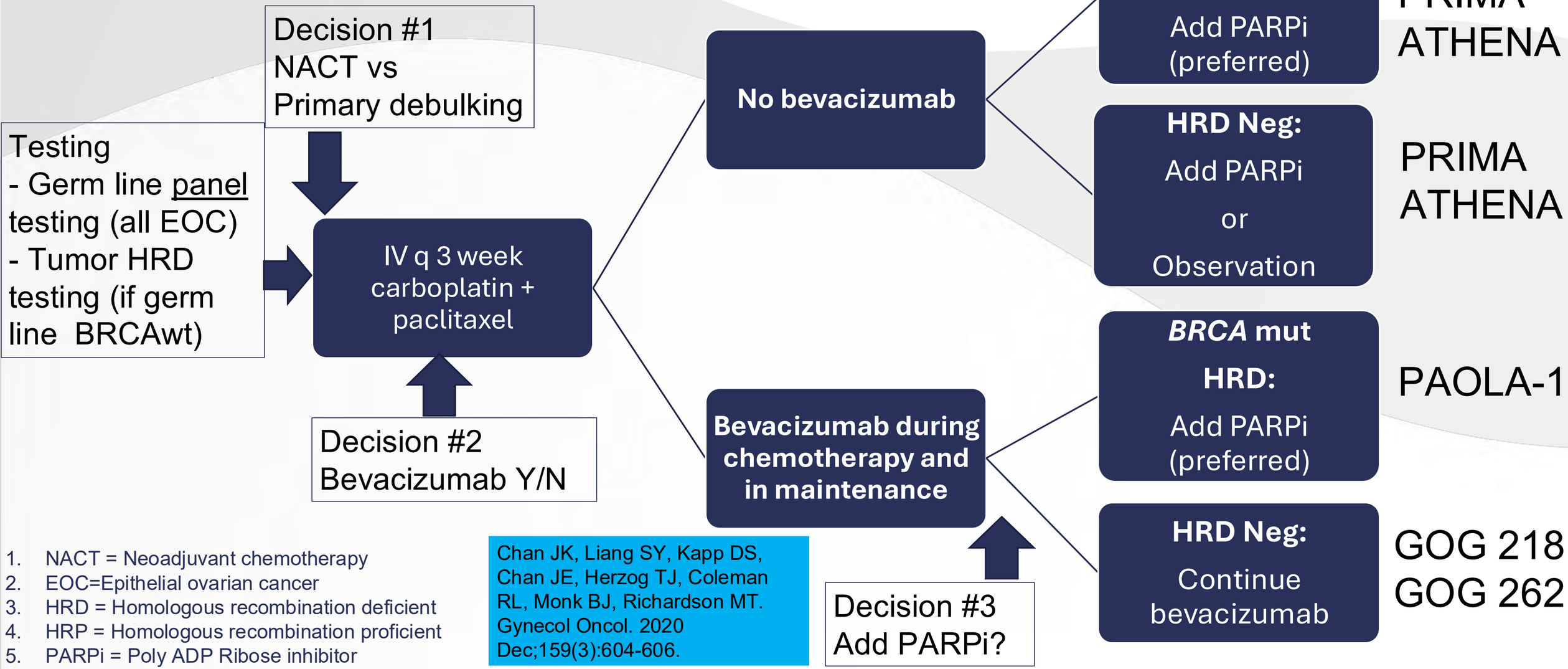
Several studies with PARP inhibitor maintenance for newly-diagnosed advanced ovarian cancer[5–8]

[a]Please note: Rucaparib is not licensed for first-line maintenance treatment in patients with newly-diagnosed ovarian cancer

BRCA, *BRCA*1 and/or *BRCA*2; PARP, poly(adenosine diphosphate ribose) polymerase; PFS, progression-free survival

1. McGuire WP, et al. *N Engl J Med* 1996;334:1–6; 2. du Bois A, et al. *J Natl Cancer Inst* 2003;95:1320–1329; 3. Burger RA, et al. *N Engl J Med* 2011;365:2473–2483; 4. Perren TJ, et al. *N Engl J Med* 2011;365:2484–2496; 5. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT01844986 (Accessed March 2022); 6. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02477644 (Accessed March 2022); 7. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02655016 (Accessed March 2022); 8. Monk JM, et al. *J Clin Oncol* 2022. doi: http://ascopubs.org/doi/full/10.1200/JCO.22.01003 [Epub ahead of print]

Integrated Maintenance Treatment Paradigm for Use in 1-L Ovarian Cancer (Chan et al. 2020)



1. NACT = Neoadjuvant chemotherapy
2. EOC=Epithelial ovarian cancer
3. HRD = Homologous recombination deficient
4. HRP = Homologous recombination proficient
5. PARPi = Poly ADP Ribose inhibitor

Chan JK, Liang SY, Kapp DS, Chan JE, Herzog TJ, Coleman RL, Monk BJ, Richardson MT. Gynecol Oncol. 2020 Dec;159(3):604-606.

Moving Beyond the Platinum-Sensitive/Resistant Paradigm

Emerging new multiplex classification system

Histology

1. HGSC/ endometrioid
2. Other, specify

Molecular signature

1. BRCA mutation
2. BRCA-like
3. Other, specify

Treatment-free interval

1. < 3 months
2. 3-12 months
3. > 12 months

Number of prior chemotherapy regimens

1. 3 or fewer
2. > 3
3. Prior Bev or PARP

Alvarez RD, Matulonis UA, Herzog TJ, Coleman RL, Monk BJ, Markman M. Gynecol Oncol. 2016 Apr 8. pii: S0090-8258(16)30063-4.

Platinum-Sensitive Recurrent Ovarian, Tubal and Peritoneal Cancer: A Spectrum

PFI = Platinum Free Interval

Patients for Which Platinum Is not an Option

FDA approved Nov 14, 2014

Bevacizumab in Combination With Chemotherapy: AURELIA Trial

Platinum-resistant OC
- ≤2 prior anticancer regimens
- No history of bowel obstruction/abdominal fistula, or clinical/ radiological evidence of rectosigmoid involvement

R

Chemotherapy → Treat to PD/toxicity → Optional BEV monotherapy[c]

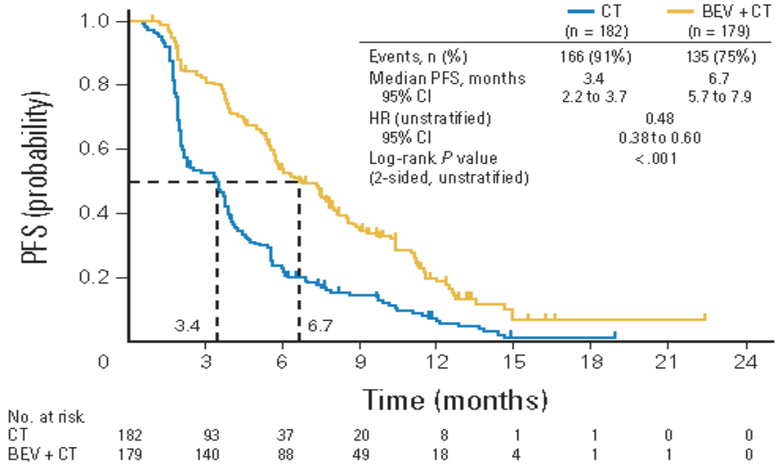
BEV 15 mg/kg q 3 w[b] + chemotherapy → Treat to PD/toxicity → Investigator's choice* (without BEV)

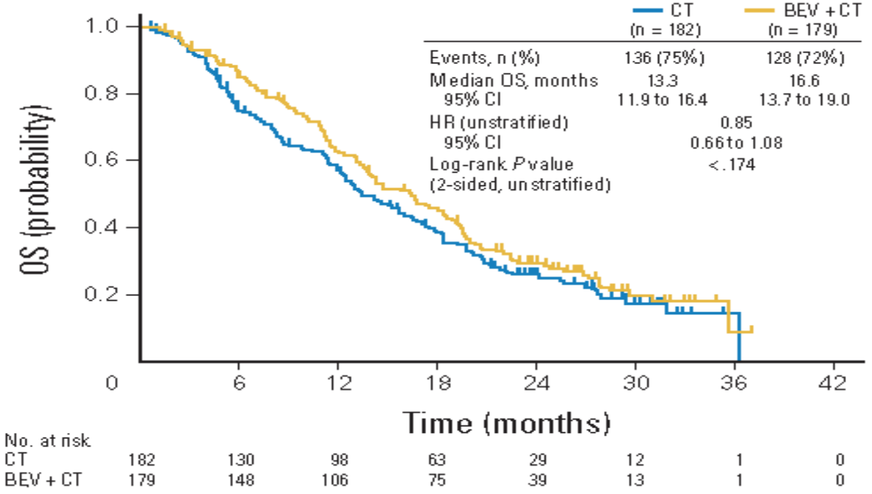
*Chemotherapy options (investigator's choice):

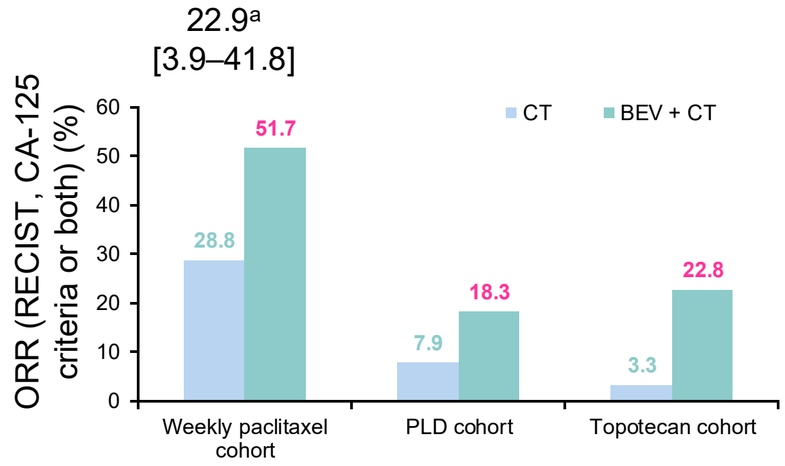
Paclitaxel 80 mg/m^2 days 1, 8, 15, & 22 q 4 w

Topotecan 4 mg/m^2 days 1, 8, & 15 q 4 w (or 1.25 mg/m^2, days 1–5 q 3 w)

PLD 40 mg/m^2 day 1 q 4 w







Pujade-Lauraine E, et al. *J Clin Oncol*. 2014;32(13):1302-1308.

Poveda AM, et al; *J Clin Oncol*. 2015;33(32):3836-3838.

HR = hazard ratio

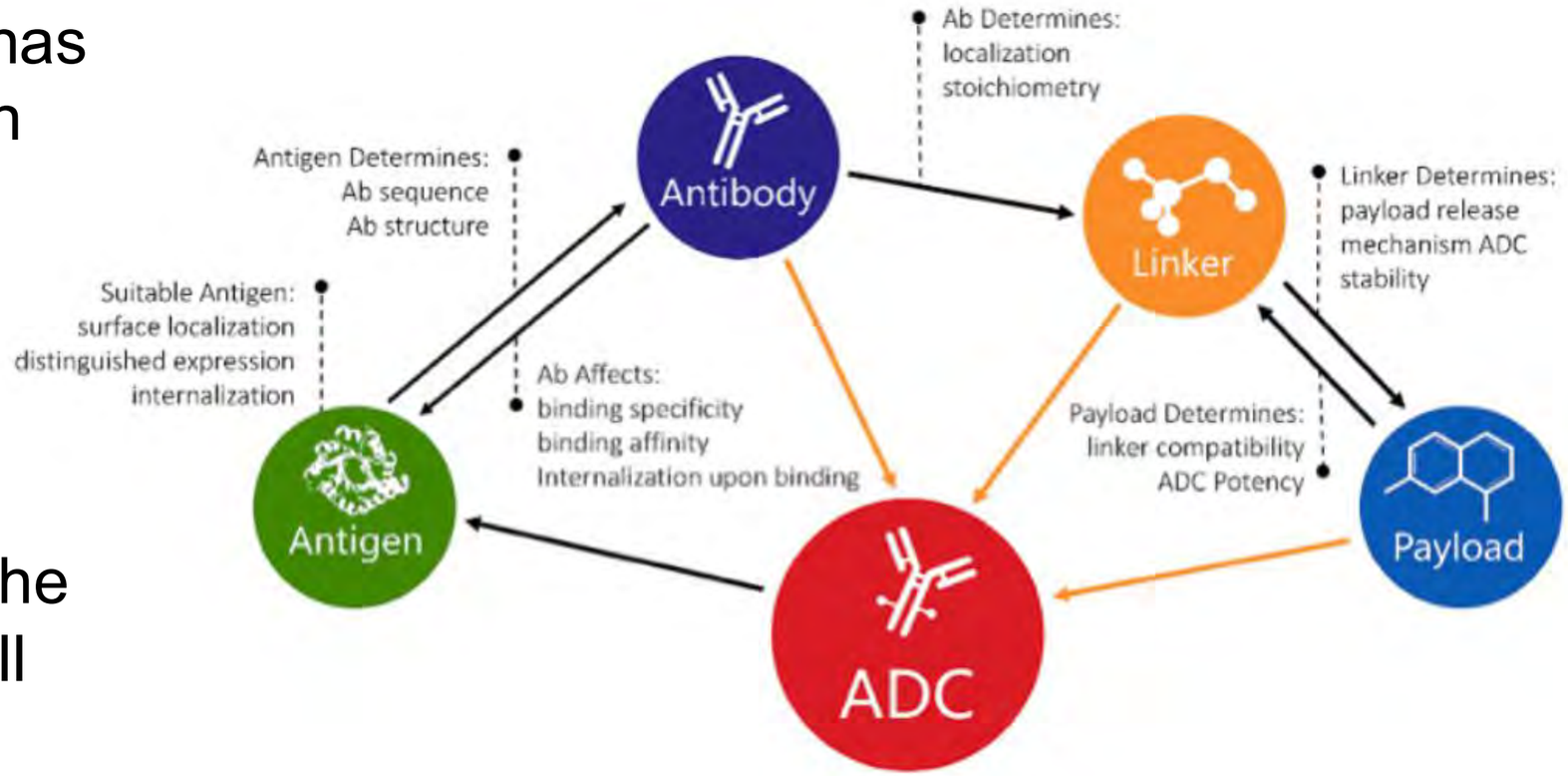
[a]Difference in ORR; 95% CI with Hauck–Anderson continuity correction

Antibody Drug Conjugates: A Paradigm Shift

1. Highly selective monoclonal antibodies (mAb) for a tumor associated antigen that has limited to no exposure on normal cells

2. A potent cytotoxic

3. A linker that is stable in circulation but releases the cytotoxic in the target cell



https://www.adcreview.com/the-review/antibody-drug-conjugate-development/

Graziela Dal Molin, MD

Beneficencia Portuguesa de Sao Paulo Brazil

Presenting:

- **ROSELLA/GOG 3073/ENGOT-0V72/LACOG 0023**: A phase 3, randomized, 2-arm, open-label, multicenter study of relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy in patients with recurrent platinum-resistant, high-grade serous, epithelial ovarian, primary peritoneal, or fallopian tube cancer
- **DS6000-109|ENGOT-ov77|GOG-3096|REJOICE-Ovarian01A** Phase 2/3, Multicenter, Randomized Study of Raludotatug Deruxtecan (R-DXd), a CDH6-directed Antibody-drug Conjugate, in Subjects with Platinum-resistant, High-grade Ovarian, Primary Peritoneal, or Fallopian Tube Cancer (Dose Optimization and Phase 3 Study of R-DXd versus Investigator's Choice of Chemotherapy in Platinum resistant Ovarian Cancer)

Stephanie Lheureux, MD, PhD

Princess Margaret Cancer Centre | Ontario, Canada

Presenting:

- **STRO-002-GM3/GOG 3086/ENGOT OV79/REFRaME-O1**
  A Phase 2/3 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versus Investigator's Choice (IC) Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (Including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor Alpha

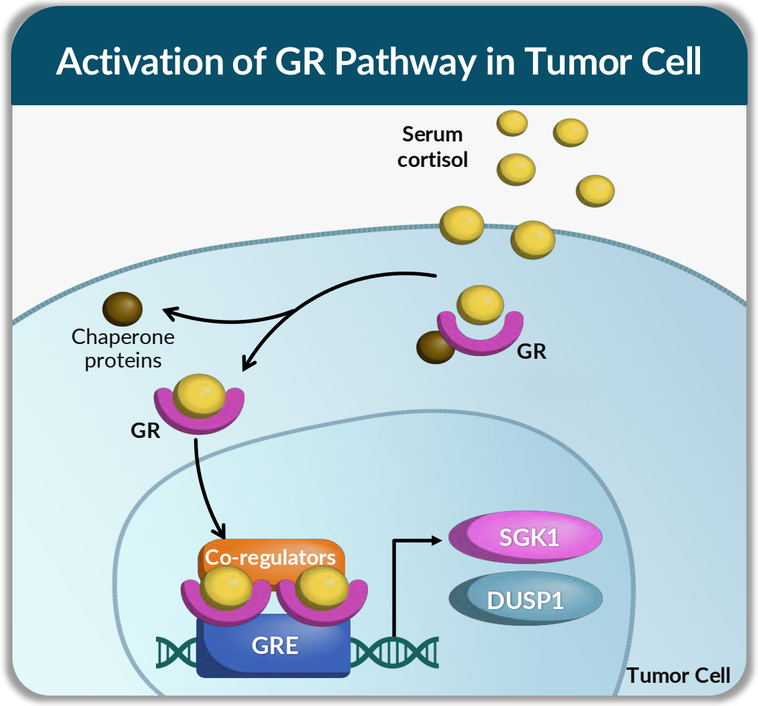
Keiichi Fujiwara, MD, PhD

Global Oncology Trials Japan | Japan

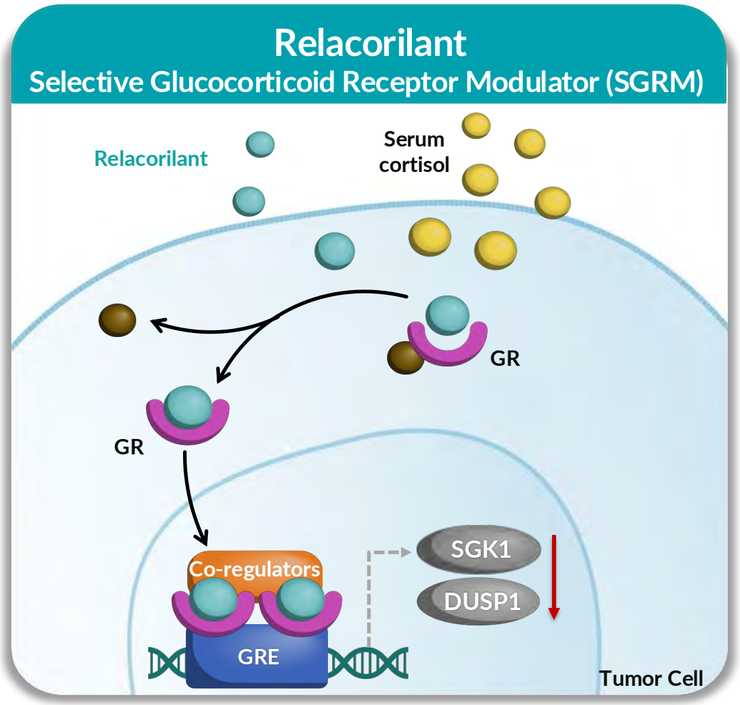
Presenting:

- **GCT1184-02/GOG 3107/ENGOT-OV86**
  A Phase 3 Randomized, Open-label Study of Rinatabart Sesutecan (Rina-S) Versus Treatment of Investigator's Choice (IC) in Patients With Platinum Resistant Ovarian Cancer

Selective Glucocorticoid Receptor Modulation



Physiological cortisol levels may reduce chemotherapy activity[1-4]



Relacorilant is an SGRM that may restore tumor sensitivity to chemotherapy[1, 5-6]

DUSP1, dual specificity protein phosphatase 1; GR, glucocorticoid receptor; GRE, glucocorticoid response element; SGK1, serum/glucocorticoid-regulated kinase.

References: 1. Greenstein AE, Hunt HJ. *Oncotarget*. 2021;12(13):1243-1255. doi:10.18632/oncotarget.27989 2. Melhem A et al. *Clin Cancer Res*. 2009;15(9):3196-3204. doi:10.1158/1078-0432.CCR-08-2131 3. Zhang C et al. *Int J Oncol*. 2006;29(5):1295-1301. Accessed August 22, 2024. https://doi.org/10.3892/ijo.29.5.1295 4. Block TS et al. *Cancer Manag Res*. 2017;9:65-72. doi:10.2147/CMAR.S124475 5. Colombo N et al. *J Clin Oncol*. 2023;41(30):4779-4789. doi:10.1200/JCO.22.02624 6. Stringer-Reasor EM et al. *Gynecol Oncol*. 2015;138(3):656-662. doi:10.1016/j.ygyno.2015.06.033.

Relacorilant is an investigational product that has not been approved for any use in any country; its safety and efficacy have not been established.

ROSELLA: A phase 3, randomized, 2-arm, open-label, multicenter study of relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy in patients with recurrent platinum-resistant, high-grade serous, epithelial ovarian, primary peritoneal, or fallopian tube cancer

Patient population

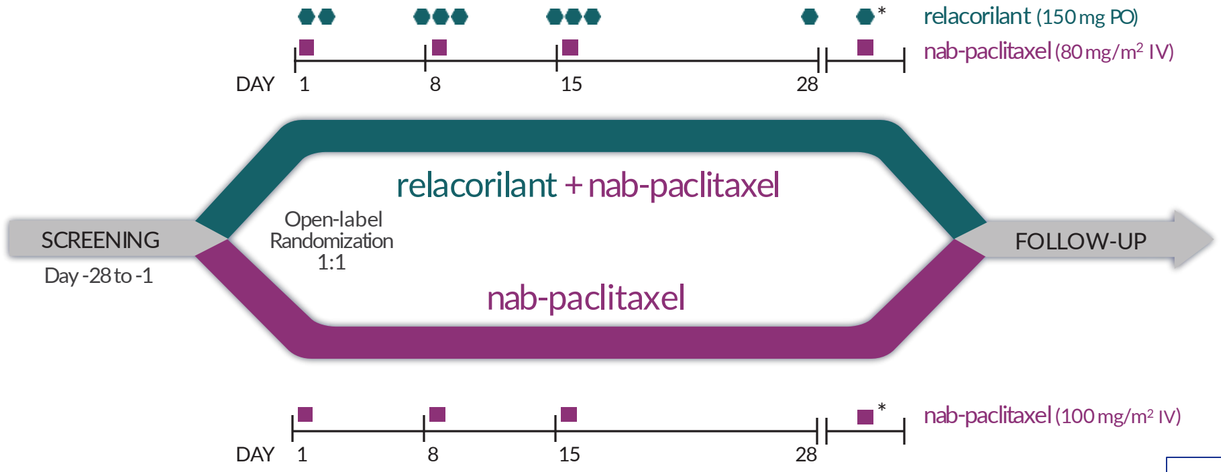
381 patients

- Confirmed high-grade serous epithelial ovarian, primary peritoneal or fallopian tube cancer
- Progression <6 months after last dose of platinum-based therapy (excludes primary platinum-refractory disease)
- 1-3 prior lines of systemic anticancer therapy
- Must have received prior bevacizumab

Stratification factors

- Region of the world (North America vs Europe vs Rest of World)
- Prior lines of therapy (1 vs >1)

ROSELLA
Relacorilant with nab-paclitaxel in Ovarian Cancer



Endpoints

Primary endpoint

- Progression-free survival by RECIST v1.1 per blinded independent central review (BICR)

Key secondary/exploratory endpoints

- Overall survival
- Safety
- Patient-reported outcomes (PROs) and quality of life (QOL)

Study Status

- Last patient enrolled: April 8, 2024
- **Topline data expected End of Year 2024**

In collaboration with:

GOG FOUNDATION Transforming the standard of care
ENGOT European Network of Gynaecological Oncological Trial groups
APGOT Asia-Pacific Gynecologic Oncology Trials Group
LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP
ANZ GOG

* Ongoing cycles.

IV, intravenous; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

Relacorilant in combination with nab-paclitaxel in advanced, platinum-resistant, high-grade epithelial ovarian, primary peritoneal, or fallopian-tube cancer. ClinicalTrials.gov identifier NCT05257408. Updated August 5, 2024. Accessed May 28, 2024. https://clinicaltrials.gov/study/NCT05257408

Relacorilant is an investigational product that has not been approved for any use in any country; its safety and efficacy have not been established.

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DS6000-109|ENGOT-ov77|GOG-3096|REJOICE-Ovarian01

A Phase 2/3, Multicenter, Randomized Study of Raludotatug Deruxtecan (R-DXd), a CDH6-directed Antibody-drug Conjugate, in Subjects with Platinum-resistant, High-grade Ovarian, Primary Peritoneal, or Fallopian Tube Cancer (Dose Optimization and Phase 3 Study of R-DXd versus Investigator's Choice of Chemotherapy in Platinum resistant Ovarian Cancer)

Global PI: Isabelle Ray-Coquard, MD
GOG PI: Deborah Richardson, MD

DS6000-109 (REJOICE-Ovarian01)

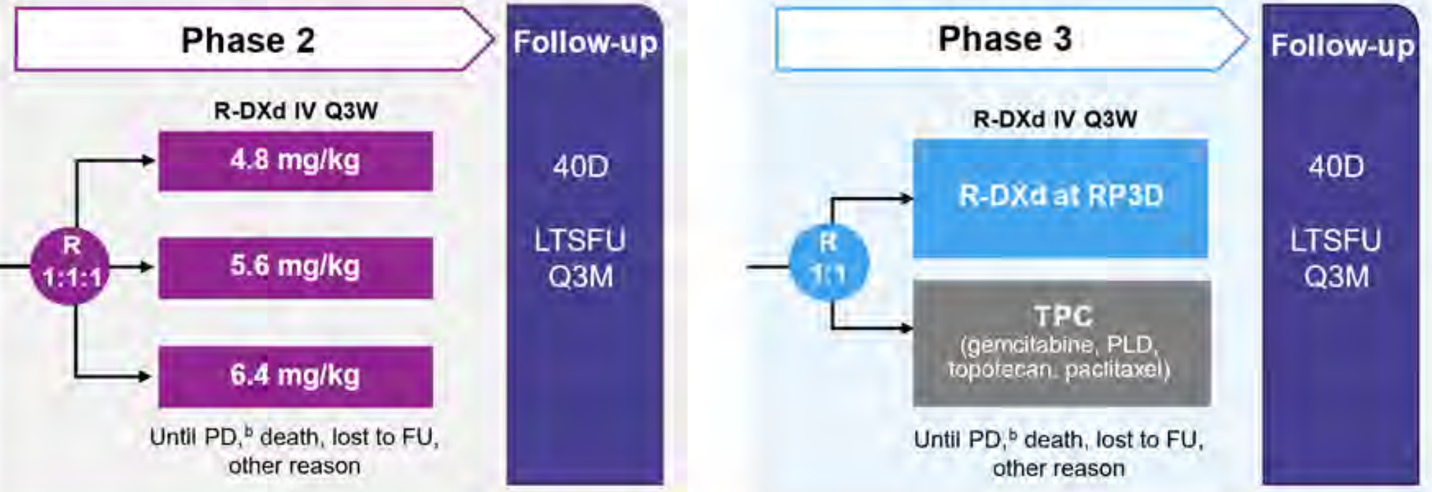
REJOICE-Ovarian01: Phase 2/3 randomized study of R-DXd in platinum-resistant OVC (NCT06161025)

Key eligibility criteria:

- High-grade serous or endometrioid ovarian, primary peritoneal, or fallopian tube cancer
- 1–3 prior LOT (inc. bevacizumab)
- Platinum-resistant disease
- Prior MIRV if high FRα[a]
- ECOG PS 0–1
- No prior CDH6-targeting agents or ADCs with linked TOPO I inhibitor
- Patients with primary platinum-refractory disease are not eligible

Stratification:

- Number of prior LOT (1 vs 2/3)
- CDH6 expression (high vs low)
- TPC (paclitaxel vs others; *Ph 3 only*)



Phase 2	
Primary endpoints:	**Key secondary endpoints:**
• ORR per BICR[b]	• ORR per inv[b] • DOR

Phase 3	
Primary endpoints:	**Key secondary endpoints:**
• ORR per BICR[b] • PFS per BICR[b]	• OS • QOL

[a]Unless ineligible, not approved or available locally. [b]Per RECIST 1.1. ADC, antibody–drug conjugate; BICR, blinded independent central review; CDH6, cadherin 6; D, days; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FRα, folate receptor alpha; FU, follow-up; inv, investigator; IV, intravenous; LOT, lines of therapy; LTSFU, long-term survival follow up; MIRV, mirvetuximab soravtansine; ORR, objective response rate; OS, overall survival; OVC, ovarian cancer; RP3D, recommended phase 3 dose; PD, progressive disease; PLD, pegylated liposomal doxorubicin; Q3M, every 3 months; QOL, quality of life; Q3W, every 3 weeks; R, randomization; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; TEAEs, treatment-emergent adverse events; TOPO I, topoisomerase I; TPC, treatment of physician's choice.

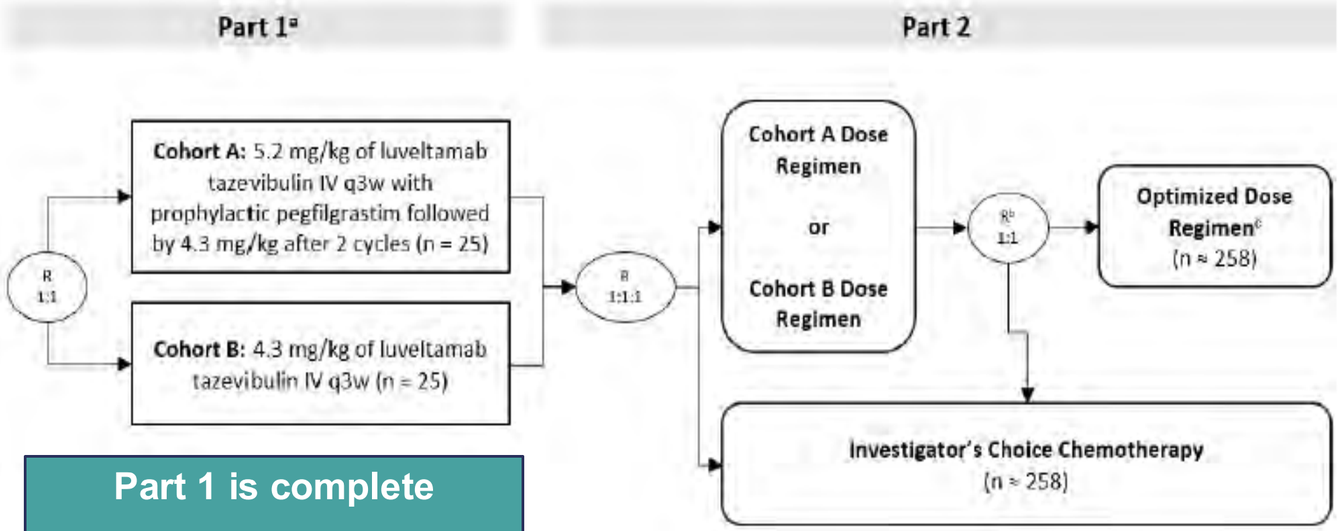
ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06161025.

SGO ANNUAL MEETING ON WOMEN'S CANCER San Diego, CA • 2024

GOG 3086/ENGOT-OV79/STRO-002-GM3/REFRaME-O1

A Phase 2/3 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versus Investigator's Choice (IC) Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (Including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor Alpha

(PI: Wendel Naumann, MD)



Part 1 is complete

Dose selection expected to be announced in December

Key Eligibility Criteria

- Platinum-resistant 1-3 prior lines
- Exclude primary platinum refractory
- FOLR1 expression ≥ 25%

FOLR1=folate receptor alpha; IV=intravenous; q3w=every 3 weeks; R= Randomization.

a The interim analysis will occur when at least 25 subjects from both cohorts in Part 1 have completed 4 cycles of treatment.

b Enrollment will be limited to a 1:1 randomization to the optimized dosing regimen or IC chemotherapy. The non-selected luveltamab tazevibulin treatment arm will be closed to further enrollment.

c The optimized dosing regimen in Part 2 will be determined following review of the efficacy and safety data at the interim analysis.

NCT05870748

Key Amendment Changes:

- **Study Design**
  - Addition of investigator's choice chemo control arm (gemcitabine, paclitaxel, PLD, topotecan) to Part 2
  - 1:1:1 randomization until an optimal dose is selected; then 1:1 randomization in Part 2
  - PFS as primary endpoint with OS as supportive endpoint
- **Eligibility**
  - Exclusion of third spacing
  - Allow bevacizumab naïve in randomized portion but will limit to cap of 35% of enrolled
  - PFS as primary endpoint with OS as supportive endpoint
  - Serum albumin ≥ 2.5 g/dL; CrCL modified to ≥ 30 mL/min
- **SoA**
  - q4w SoA table was added to accommodate for chemotherapy schedules
  - Tumor assessment frequency modified – every 6 weeks for the first 36 weeks
  - LTFU will be collected until death, withdrawal of participation, or end of study
- **Study Size**
  - Total of 600 subjects

PLEASE ENROLL on this global trial!
PART 2 is estimated to enroll 550 subjects!

Luvelta Demonstrated the Ability to Treat 8 out of 10 Women with Ovarian Cancer Due to FolRα expression ≥25%

FolRα Eligibility

IHC test (Ventana FolR1), but with different cut-off than mirvetuxemab

Selection for GOG-3086/REFRaME-O1 is ≥ 25% staining of any intensity (TPS) and includes PS 1+,2+,3+

Luvelta addresses low and medium FolRα expression (≥25% TPS with any intensity) that currently receive chemotherapy, while approved ADC is limited to high expressing FolRα (≥75% TPS with PS 2+, 3+)

For patients with prior FOLR1 test, please inform your monitor. Screening activities can be done in parallel while sending tissue samples to LabCorp for FOLRα testing using the Luvelta cut off

Separate consent can be obtained to pre-screen / pre-test patients for Frα prior starting full screening

Comparison of Potential Luvelta Population with Approved ADC Population

TPS	Staining Intensity 1+	Staining Intensity 2+	Staining Intensity 3+
0 - <25%	Chemo	Chemo	Chemo
25 - <50%	Potential Luvelta Population TPS ≥ 25%		
50 - <75%			
75 - 100%		Approved ADC Population/Luvelta (PS2+ ≥ 75%)	

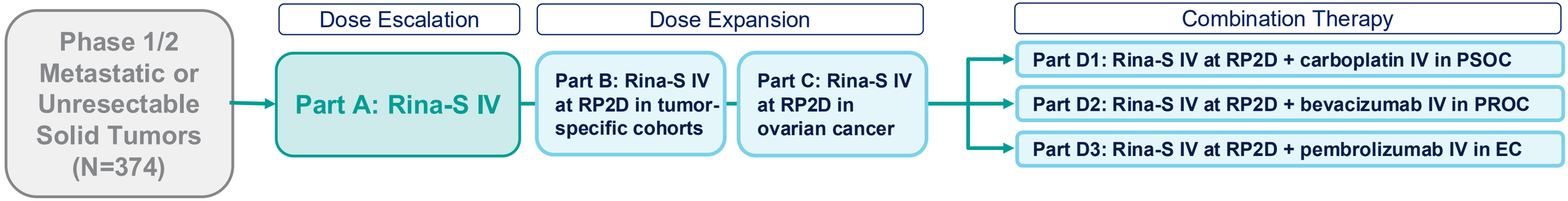
~80%

~35%

Sources: 1. ImmunoGen Third Quarter 2023 Financial Results, Nov 2023. 2. Jun 2023 ASCO oral presentation “Luveltamab tazevibulin (STRO-002), an anti-folate receptor alpha (FolRα) antibody drug conjugate (ADC), safety and efficacy in a broad distribution of FolRα expression in patients with recurrent epithelial ovarian cancer (OC): Update of STRO-002-GM1 phase 1 dose expansion cohort.”.

CONFIDENTIAL

GCT1184-01 | Rinatabart Sesutecan in Solid Tumors



Evaluation of Study Objectives*

Primary Endpoints

Parts A, B, D only
- TEAEs,

Parts A, and D only
- DLTs

Parts C only
- ORR per RECIST v1.1

Secondary Endpoints

Parts A–D
- PFS, DOR

Parts A, B, D only
- BOR, ORR, DCR, PK

Part C
- OS

Parts C and D only
- CA-125 response by GCIG criteria

Part C only
- AEs

Key Inclusion Criteria*

Parts A–D
- Histologically or cytologically confirmed metastatic or unresectable solid malignancy including:
  - Ovarian cancer
  - Endometrial cancer
  - NSCLC
  - Breast cancer (HR-positive, HER2-negative, and triple-negative)
  - Mesothelioma
- Previously received therapies known to confer clinical benefit
- ECOG PS 0–1
- Measurable disease per RECIST v1.1 for all tumor types, except mRECIST v1.1 for pleural mesothelioma

Part C only
- Platinum-resistant/refractory ovarian cancer
- Prior treatment with bevacizumab or mirvetuximab soravtansine
- Treatment with PARP inhibitor if having known or suspected deleterious germline or somatic BRCA mutation

Part D1 only
- Platinum-sensitive ovarian cancer
- Received 1–3 prior lines of therapy

Part D2 only
- Platinum-resistant/refractory ovarian cancer

Part D3 only
- Endometrial cancer (any subtype excluding sarcoma)
- Received prior platinum-based chemotherapy

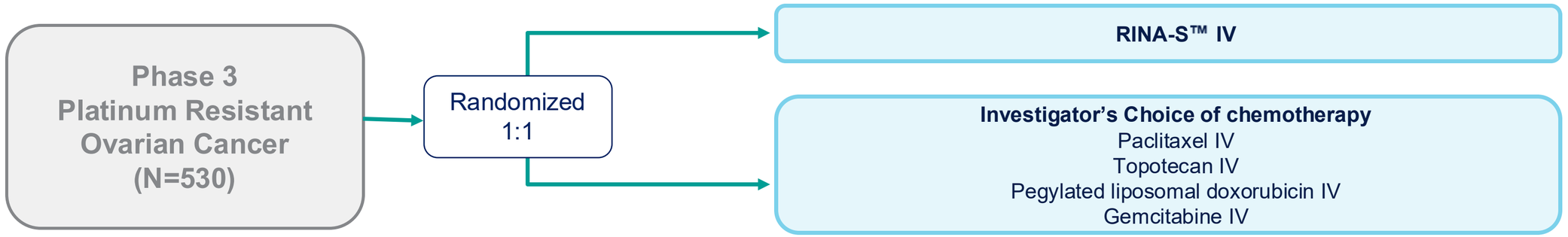
*Not comprehensive.

AE, adverse events; BOR, best overall response; DLT, dose-limiting toxicity; DOR, duration of response; EC, endometrial cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; GCIG, Gynecologic Cancer Intergroup; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PARP, poly ADP-ribose polymerase; PFS, progression-free survival; PK, pharmacokinetics; PROC, platinum-resistant/refractory ovarian cancer; PSOC, platinum-sensitive ovarian cancer; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended phase 2 dose; TEAE, treatment-emergent adverse event.

https://www.clinicaltrials.gov/study/NCT05579366 – NCT05579366.

Provided in response to an unsolicited Medical Information request

GCT1184-02 / ENGOT-OV86 / GOG 3107 | Rinatabart Sesutecan in PROC



Evaluation of Study Objectives*

Primary Outcome Measure

- Progression-Free Survival

Secondary Outcome Measures

- Overall Survival
- Objective Response Rate
- Duration of Response
- CA-125 response by GCIG criteria
- Adverse Events
- GHS/QoI (EORTC-QLQ-C30)

Key Inclusion Criteria*

- Histologically or cytologically confirmed high grade serous or endometrioid epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer
- Prior treatment with the following:
  - Platinum-based therapy
  - Bevacizumab (unless contraindicated)
  - PARP inhibitor (if known BRCA mutation)
  - Mirvetuximab (if positive FRα expression and available in the region)
- Platinum-resistant disease
- No prior ADC therapy containing a topoisomerase 1 inhibitor
- No known active central nervous system metastases or carcinomatous meningitis

*Not comprehensive.
ADC, anti-drug conjugate; CA, cancer antigen; EORTC-QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Core 30 questionnaire; FRα, folate receptor alpha; GCIG, Gynecologic Cancer Intergroup; GHS/QoI; Global Health Status/Quality of Life; IV, intravenous; PROC, Platinum Resistant Ovarian Cancer
https://clinicaltrials.gov/study/NCT06619236

Provided in response to an unsolicited Medical Information request

Jae-Hoon Kim, MD, PhD

Gangnam Severance Hospital | Seoul, South Korea | Republic of Korea

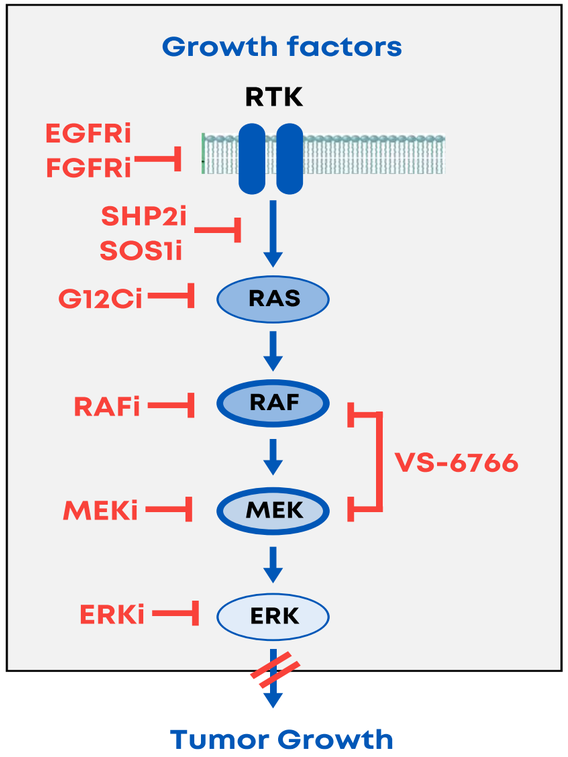
Presenting:

- **GOG-3097/ENGOT-ov81/NCRI/RAMP 301**

  A Phase 3, Randomized, Open-Label Study of Combination Therapy with Avutometinib plus Defactinib Versus Investigator's Choice of Treatment in Patients with Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)

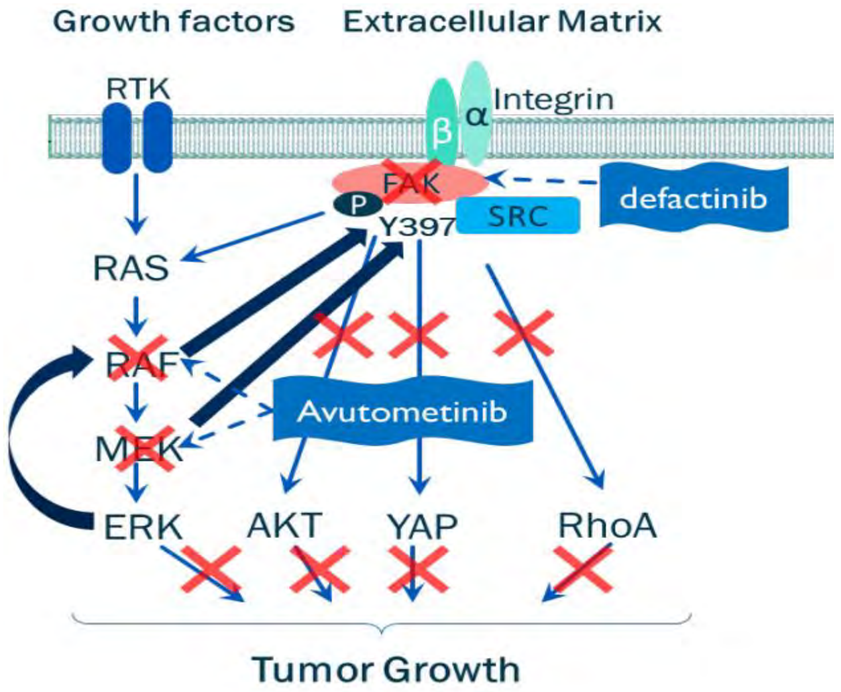
LGSOC & RAS-regulated pathway

Avutometinib (VS-6766) Pathway



- LGSOC may harbor alterations affecting the intracellular **RAS-regulated RAF/MEK/ERK (MAPK) pathway**
- **Avutometinib (VS-6766)** is a MAPK inhibitor- A unique orally bioavailable small molecule RAF/MEK clamp that blocks MEK kinase activity
- **Avutometinib** blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK
- **Defactinib (FAK inhibitor)**

Combination Therapy- Synergistic



- Acquired resistance to MAPK inhibitor therapy develops in most cancer patients
- This acquired resistance may be mediated through **focal adhesion kinase (FAK)** & mitigated by **FAK inhibition**.
- Defactinib's FAK inhibition, when combined with Avutometinib's RAF/MEK clamp ind uced better anti-tumor efficacy than either agent alone

GOG-3097/ENGOT-ov81/NCRI/RAMP 301:

A Phase 3, Randomized, Open-Label Study of Combination Therapy with Avutometinib plus Defactinib Versus Investigator's Choice of Treatment in Patients with Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)

Key Inclusion Criteria

- Confirmed LGSOC diagnosis
- Recurrent disease after prior platinum therapy
- Documented *KRAS* mutation status
- Measurable disease per RECIST v1.1
- Prior MEKi allowed
- Prior Bev allowed

NCT06072781

1:1 Randomization
N = 270

Stratification Factors
KRAS mutation status: wt vs mt
Number of prior therapies: 1-3 vs ≥4
Geography: North America/Europe vs ROW

Avutometinib + Defactinib
N = 135

Avutometinib 3.2 mg PO BIW
Defactinib 200 mg PO BID
3 weeks on, 1 week off

May crossover upon BICR confirmed PD

Investigator's Choice
N = 135

Pegylated Liposomal Doxorubicin
Paclitaxel
Letrozole
Anastrozole

Primary Endpoint
PFS via RECIST v1.1 per BICR

Secondary Endpoints
OS
PFS via RECIST v1.1 per INV Assessment
ORR
DoR
DCR
Safety
Pharmacokinetics
PROs

Summary of Analyses
Interim analysis at 50% of planned PFS events for possible sample-size adjustment to maintain power
Hierarchical Evaluation of Primary PFS Endp.:
– KRAS mutant LGSOC only
– All recurrent LGSOC

- Sparse PK samples to be collected only from patients randomized to the avutometinib/defactinib arm

RECIST, response evaluation criteria in solid tumors; BICR, blinded independent central review; BID: twice a day; BIW: twicea week; DCR: disease control rate; DoR: duration of response; INV: investigator; mt: mutant; wt, wild type; PFS: progression free survival; ORR: objective response rate; OS: overall survival;PD: progressive disease; PROs: patient reported outcomes; ROW: rest of world

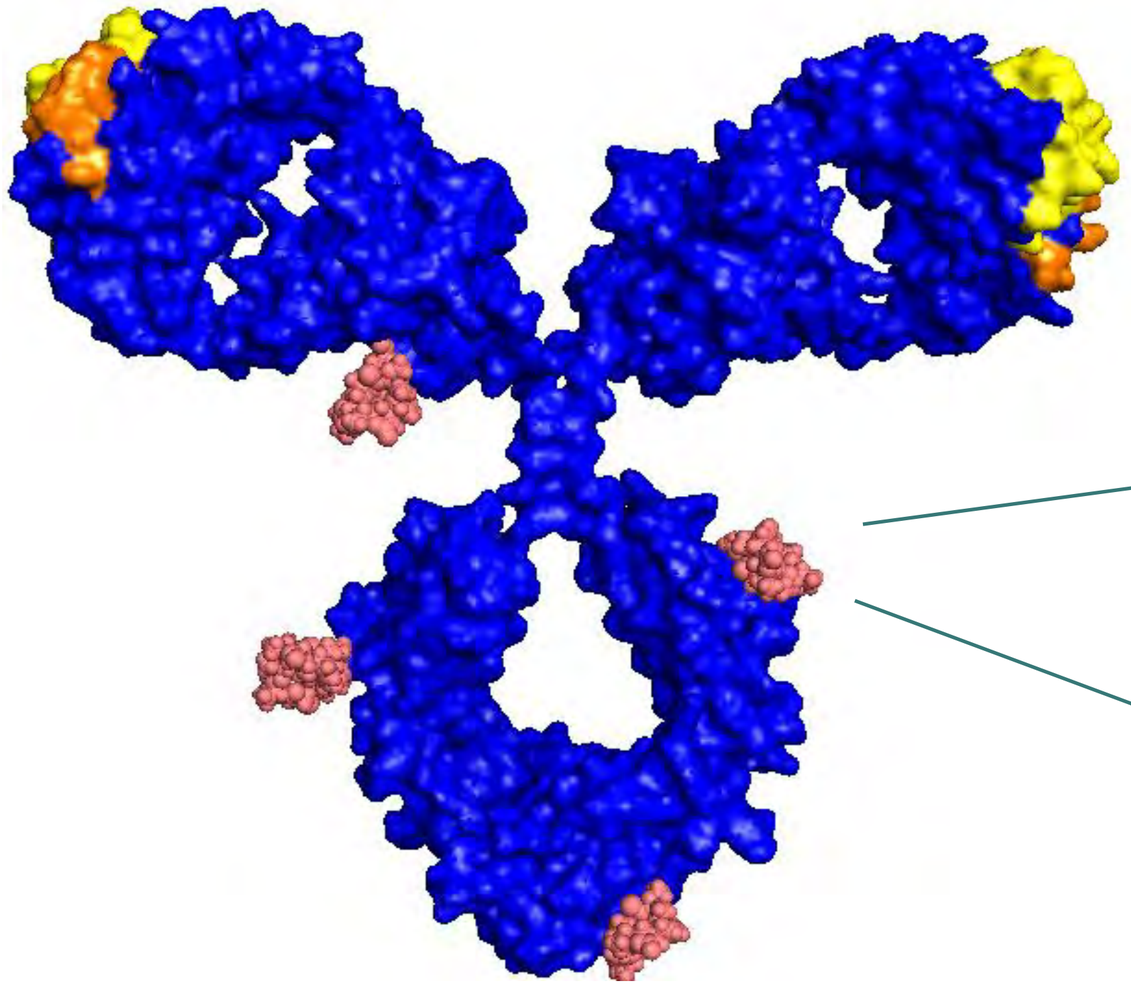
Nicoletta Colombo, MD, PhD

University Milano-Bicocca Oncology | Milan, Italy

Presenting:

- GOG-3078 | ENGOT-ov76 | IMGN853-0421 |GLORIOSA
  Randomized Phase 3 Trial for Mirvetuximab + Bevacizumab Maintenance in FRα-high Platinum Sensitive Ovarian Cancer

Mirvetuximab soravtansine (MIRV, previously called IMGN853)

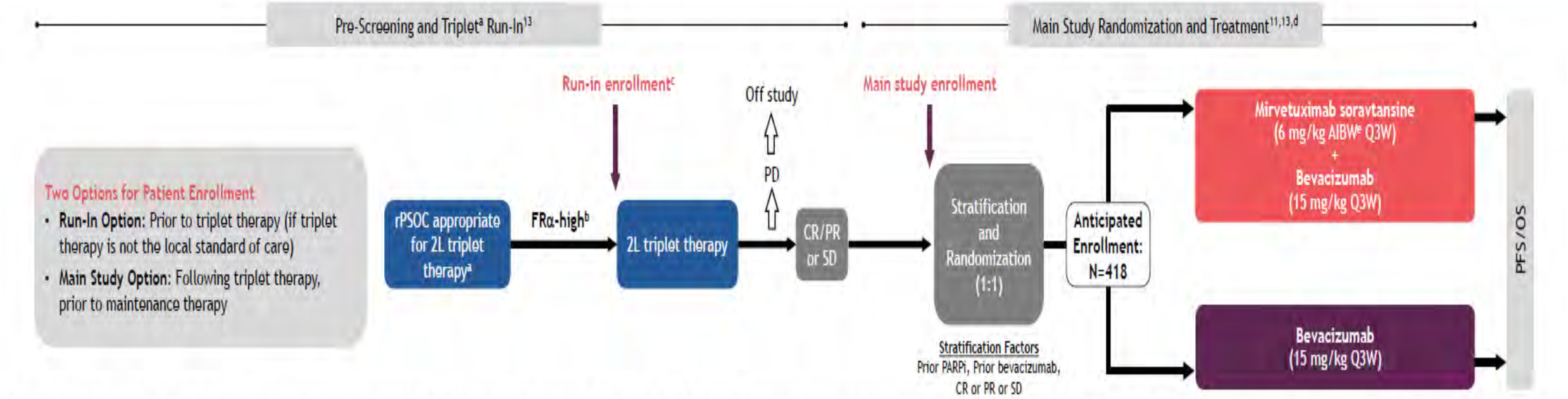


Monoclonal Antibody
- Fully humanized
- High affinity for FRα

sulfo-SPDB Linker
- ADC stable in the circulation

DM4 Payload
- Maytansine derivative with anti-microtubule activity
- 100-1000-fold more potent than vinca alkaloids
- Average of 3-4 DM4 molecules per antibody.

GOG-3078 | ENGOT-ov76 | IMGN853-0421 |GLORIOSA



[a]Triplet treatment consists of platinum+chemotherapy+bevacizumab for planned 6 cycles (minimum 4 and maximum 8 cycles), including at least 3 cycles of bevacizumab. [b]Pre-screening consent must be obtained for tissue testing for FRα expression by Ventana FOLR1 Assay. [c]FRα-high patients who desire to be treated and followed while on their run-in triplet therapy must sign a run-in consent as part of the main consent form if they meet eligibility criteria as assessed by the investigator. [d]Maintenance treatment must begin ≤12 weeks from last dose of triplet therapy and within 30 days of randomization. Treatment continues until PD, unacceptable toxicity, withdrawal of consent, death, or sponsor study termination. [e]AIBW, also known as AdjBW, is calculated as IBW (kg) + 0.4 (actual weight – IBW). IBW for females is calculated as 0.9*height (cm) – 92.

Key Eligibility Criteria:

Platinum-sensitive HGS ovarian cancer

- **1 prior platinum treatment**
- **Prior PARPi required if BRCA+**
- **CR, PR, or SD after treatment with platinum-based doublet + bevacizumab required**

PLEASE ENROLL

NCT05445778

ENGOT European Network of Gynaecological Oncological Trial groups

GOG FOUNDATION

Ovarian Cancer Trials: Discussion

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Princess Margaret Cancer Centre
Ontario, Canada

Global Clinical Trials, Managing Opportunities, and Engaging Important Relationships

THANK YOU

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SUTRO BIOPHARMA

THANK YOU

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