VIRTUAL 2020 ESMO congress

Patient-Reported Outcomes in Patients Receiving Niraparib in the PRIMA/ENGOT-OV26/GOG-3012 Trial

Bhavana Pothuri

Gynecologic Oncology Group (GOG) and the Department of Obstetrics/Gynecology, Perlmutter Cancer Center, NYU Langone Health, New York, NY, USA

GOG FOUNDATION

ENGOT European Network of Gynaecological Oncological Trial groups

VIRTUAL 2020 ESMO congress

Complete Authors and Affiliations

Authors: **Bhavana Pothuri**,[1] Sileny Han,[2] Dana Chase,[3] Florian Heitz,[4] Robert Burger,[5] Lydia Gaba,[6] Linda Van Le,[7] Eva Guerra,[8] David Bender,[9] Jacob Korach,[10] Noelle Cloven,[11] Philippe Follana,[12] Jean-François Baurain,[13] Carmela Pisano,[14] Ulla Peen,[15] Johanna Maenpaa,[16] Emeline Bacque,[17] Yong Li,[17] Antonio González-Martin,[18] Bradley J. Monk[3]

Affiliations: [1]Gynecologic Oncology Group (GOG) and the Department of Obstetrics/Gynecology, Perlmutter Cancer Center, NYU Langone Health, New York, NY, USA; [2]Department of Obstetrics and Gynecology, University Hospitals Leuven, Leuven, Belgium; [3]Arizona Oncology (US Oncology Network), University of Arizona College of Medicine, Phoenix, AZ, USA; [4]Department for Gynecology and Gynecologic Oncology, Kliniken Essen-Mitte, Essen, Germany; [5]University of Pennsylvania, Philadelphia, PA, USA; [6]Medical Oncology Department, Hospital Clinic de Barcelona, Barcelona, Spain; [7]Department of Ob/Gyn, Division of Gynecologic Oncology, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [8]Medical Oncology Department, Breast and Gynecological Cancer Unit, Hospital Ramon y Cajal, Madrid, Spain; [9]Department of Obstetrics and Gynecology, University of Iowa, Iowa City, IA, USA; [10]Department of Oncology, The Chaim Sheba Medical Center, Sackler Medical School Tel Aviv University, Ramat Gan, Israel; [11]Texas Oncology, Fort Worth, TX, USA; [12]GINECO and Centre Antoine Lacassagne, Nice, France; [13]Université Catholique de Louvain and Cliniques Universitaires Saint-Luc, Brussels, Belgium; [14]Department of Urology and Gynecology, Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Naples, Italy; [15]Herlev University Hospital, Herlev, Denmark; [16]Tampere University Central Hospital, Tampere, Finland; [17]GlaxoSmithKline, Waltham, MA, USA; [18]Grupo Español de Investigación en Cáncer de Ovario (GEICO) and Medical Oncology Department, Clínica Universidad de Navarra, Madrid, Spain

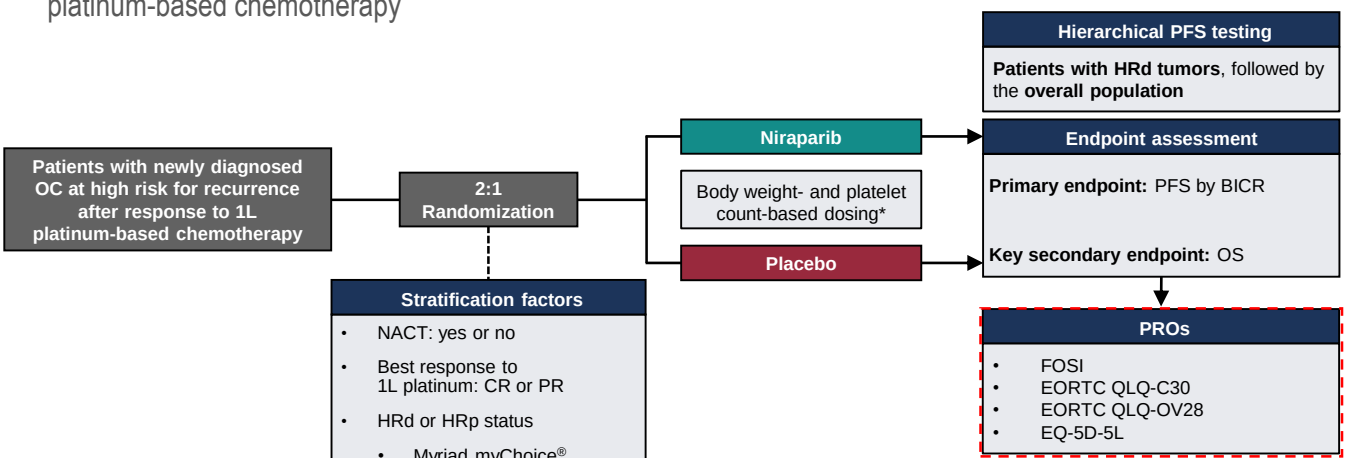
Dr. Bhavana Pothuri Disclosures

Dr. Bhavana Pothuri has received consulting fees and/or research funding from the following:

- AstraZeneca
- Celgene
- Clovis
- Eisai
- Genentech
- GlaxoSmithKline
- ImmunoGen
- Takeda

PRIMA Trial Design

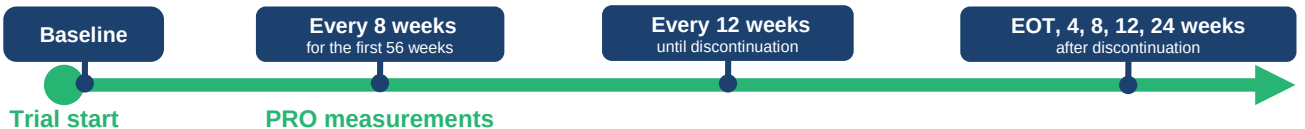
- PRIMA is a randomized, double-blind, placebo-controlled phase 3 trial of niraparib vs placebo in patients with newly diagnosed advanced ovarian, primary peritoneal, or fallopian tube cancer with a CR or PR to 1L platinum-based chemotherapy



Patients received treatment until disease progression or a maximum of 36 months.
*After November 27, 2017, patients with baseline body weight <77 kg and/or platelet count <150,000/μL started at 200 mg QD; all other patients started at 300 mg QD. 1L, first-line; BICR, blinded independent central review; CR, complete response; EORTC QLQ-C30/OV28, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire/Ovarian Cancer Module; EQ-5D-5L, EuroQol 5-Dimension 5-Level; FOSI, Functional Ovarian Symptom Index; HRd, homologous recombination deficient; NACT, neoadjuvant chemotherapy; OC, ovarian cancer; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival 2; PR, partial response; PRO, patient-reported outcome; QD, once daily; TFST, time to first subsequent therapy.

VIRTUAL 2020 ESMO congress

PRO Instruments

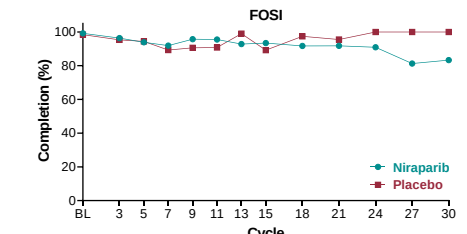


Instrument	Domains assessed	Score	Higher score indicates	Clinically meaningful change from baseline
FOSI Functional Ovarian Symptom Index	**Symptoms**: Fatigue, nausea, bloating, worry, pain, vomiting, cramping, QoL	Total 0–32	Better symptoms/HUI	± 2
EORTC QLQ-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire	**Functional scale**: Physical, role, emotional, cognitive, social function	0–100	Better functioning	± 10
	Symptoms: Fatigue, nausea & vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, financial difficulties	0–100	Worse symptoms	
	Global health status/QoL	0–100	Better QoL	
EORTC QLQ-OV28 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Ovarian Cancer Module	**Functional scale**: Body image, sexuality, attitude toward disease/treatment	0–100	Better functioning	± 10
	Symptoms: Abdominal/GI symptoms, peripheral neuropathy, hormonal/menopausal symptoms, other chemotherapy side effects, hair loss	0–100	Worse symptoms	
EQ-5D-5L EuroQol 5-Dimension 5-Level	**Health state for five domains**: Mobility, self-care, usual activities, pain/discomfort, anxiety/depression	HUI 0–1	Better QoL	-
	Visual analog scale (VAS)	VAS 0–100	Better QoL	

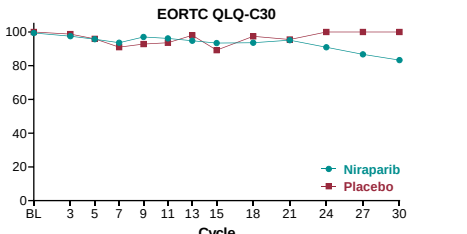
EOT, end of treatment; GI, gastrointestinal; HUI, health utility index; PRO, patient-reported outcome; QoL, quality of life; VAS, visual analog scale.

High Compliance Rates by PRO Instrument

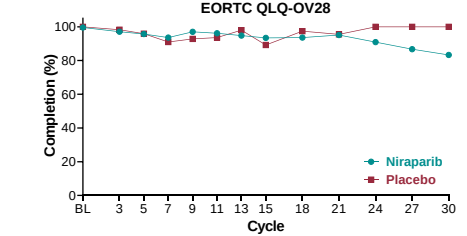
- Patient compliance rates remained consistently high (>80%) across all PRO instruments throughout the trial



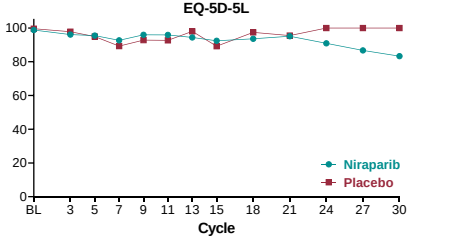
	BL	3	5	7	9	11	13	15	18	21	24	27	30
Niraparib	483	425	352	316	286	254	231	185	100	56	30	13	5
Placebo	242	221	185	158	125	99	97	74	38	21	8	5	4



	BL	3	5	7	9	11	13	15	18	21	24	27	30
Niraparib	484	430	359	322	290	256	236	185	102	58	30	13	5
Placebo	246	229	188	161	128	102	96	74	38	21	8	5	4



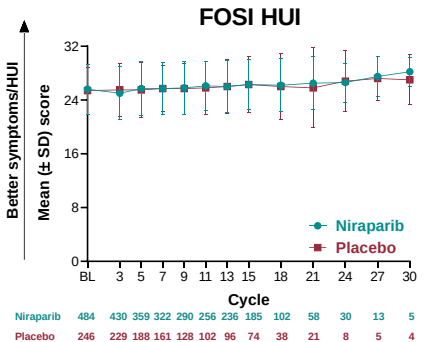
	BL	3	5	7	9	11	13	15	18	21	24	27	30
Niraparib	485	428	359	322	290	256	236	185	102	58	30	13	5
Placebo	246	228	188	161	128	102	96	74	38	21	8	5	4



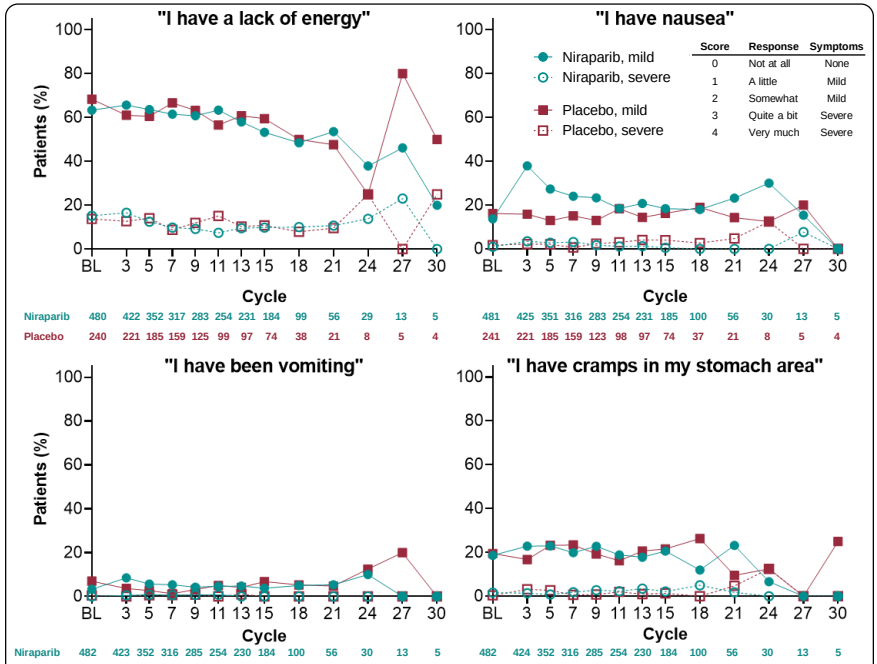
	BL	3	5	7	9	11	13	15	18	21	24	27	30
Niraparib	481	424	358	319	287	255	235	183	102	58	30	13	5
Placebo	245	227	186	158	128	101	96	74	38	21	8	5	4

BL, baseline; EORTC QLQ-C30/OV28, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire/Ovarian Cancer Module; EQ-5D-5L, EuroQol 5-Dimension 5-Level; FOSI, Functional Ovarian Symptom Index; PRO, patient-reported outcome.

FOSI-Assessed Symptoms



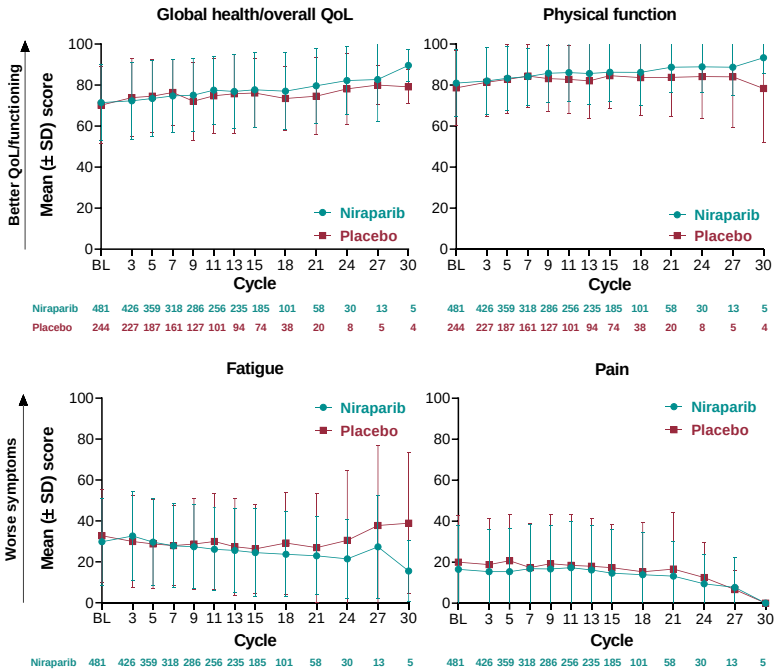
- Mean FOSI HUI scores were similar in both the niraparib-treated and placebo patients
- The overall percentage of patients with FOSI-assessed symptoms in niraparib-treated and placebo-treated patients were similar



BL, baseline; FOSI, Functional Ovarian Symptom Index; HUI, health utility index.

EORTC QLQ-C30

- EORTC QLQ-C30 scores were comparable for both niraparib and placebo groups
- No difference in QoL and physical function was observed for patients receiving niraparib vs placebo
- No difference in fatigue or pain was reported for patients receiving niraparib compared with placebo

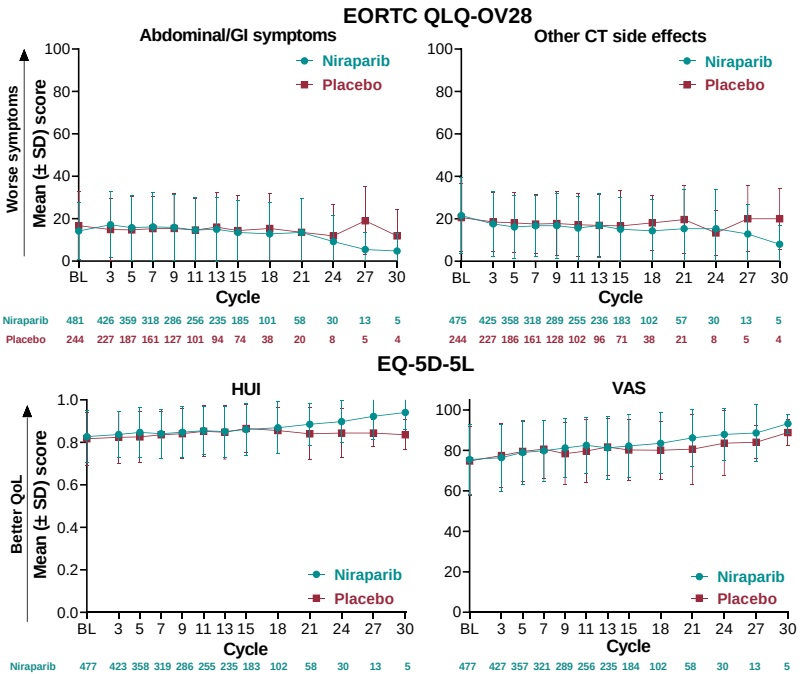


BL, baseline; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; SD, standard deviation.

EORTC QLQ-OV28 and EQ-5D-5L

- Ovarian specific EORTC QLQ-OV28 PRO assessments showed no difference in mean abdominal symptoms and other CT side effect scores
- EQ-5D-5L assessment revealed no meaningful difference in HUI-assessed change from baseline between niraparib and placebo
- EQ-5D-5L scores obtained with a visual analogue scale (VAS) also showed no differences between niraparib and placebo

BL, baseline; CT, chemotherapy; EORTC QLQ-OV28, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Ovarian Cancer Module; EQ-5D-5L, EuroQol 5-Dimension 5-Level; GI, gastrointestinal; HUI, health utility index; QoL, quality of life; SD, standard deviation; VAS, visual analog scale.



VIRTUAL 2020 ESMO congress

Conclusions

- Patient compliance rates were high across all PRO instruments (>80%)
- FOSI scores between niraparib and placebo were comparable
  - Percentages of patients reporting lethargy, nausea, vomiting, and abdominal cramps were similar in niraparib and placebo arms
- QoL were comparable between niraparib and placebo, as indicated by the EORTC QLQ-C30 instrument
- Abdominal/GI symptoms and other CT effects were comparable in both arms, as assessed by the EORTC QLQ-OV28 instrument
- Overall QoL was similar in patients receiving niraparib compared with those receiving placebo, as assessed by the EQ-5D-5L instrument
- Consistent with PRO results in the NOVA study, patients receiving niraparib in the PRIMA trial did not experience a decrement in QoL compared with placebo during their treatment, despite AEs including grade ≥3 hematologic toxicity

AE, adverse event; CT, chemotherapy; EORTC QLQ-C30/OV28, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire/Ovarian Cancer Module; EQ-5D-5L, EuroQol 5-Dimension 5-Level; FOSI, Functional Ovarian Symptom Index; GI, gastrointestinal; PRO, patient-reported outcome; QoL, quality of life.

Acknowledgements

We sincerely thank patients and their families for participating in this trial

ENGOT

GEICO

Spain
A. Oaknin
E. Guerra
C. Churruca
R. Bratos
J. Perez
I. Romero
I. Tusquets
L. Gaba Garcia
M. Gil Martin
E. Calvo-Garcia
L. Sanchez
J. Pradera
A. Sanchez-Heras
A. Yubero
M. Romeo-Marin

ICORG

Ireland
P. Calvert

NSGO-CTU

Finland
J. Maenpaa
S. Hietanen
M. Anttila

Sweden
K. Hellman
B. Tholander

Denmark
U. Peen
A. Knudsen

Norway
A. Dorum

ISGO

Israel
J. Korach
T. Levy
A. Amit
T. Safra
M. Meirovitz

BGOG

Belgium
J-F. Baurain
S. Han
F. Forget
H. Denys
P. Vulsteke
C. Lamot
B. Honhon
E. Joosens
C. Martinez-Mena
H. Van Den Bulck

GINECO

France
M. Fabbro
P. Follana
F. Selle
F. Joly-Lobbedez
T. De La Motte Rouge
D. Berton-Rigaud
S. Abadie Lacourtoisie

AGO

Germany
I. Braicu
V. Hanf
F. Heitz
F. Marme
A. Scheeweiss
A. Burges
B. Schmalfeldt
G. Emons

MITO

Italy
G. Artioli

United Kingdom
J. Krell
J. Mcgrane
D. Badea
R. Bhana
C. Chau
R. Bowen
C. Gourley
J. Forrest
R. Glasspool

Poland
R. Madry
M. Sikorska
J. Podlodowska

Czechia
D. Cibula
L. Rob
D. Berezovskiy

Switzerland
P. Imesch
V. Heinzelmann
M. Rabaglio

Hungary
R. Poka
T. Pinter

Germany
M. Karthaus

Ireland
P. Donnellan

GOG

United States
L. Holman
M. Gold
S. Yap
M. Callahan
T. Myers
D. O'Malley
L. Rojas
E. Chalas
C. Zarwan
L. Perry
K. ElSahwi
A. Brown
S. Memarzadeh
D. Bender
J. Barter
L-M. Chen
P. Disilvestro
E. Ratner
J. Lesnock
K. Yost
S. Lewin
P. Rose
M. Bergman
B. Slomovitz
J. Press
D. Moore
K. Wade
J. Burke
T. Werner
J. Chan
Y. Zhuo
W. Gajewski
L. Van Le
S. Ghamande
S. Chambers

United States
P. Braly
S. Keck
G. Colon-Otero
A. Lee
S. Sharma

Ukraine
A. Kryzhanivska
H. Adamchuk
I. Bondarenko
O. Kolesnik
I. Lytvyn
S. Shevnia
I. Sokur

USOR
N. Cloven
J. Buscema
D. Chase
C. Anderson
C. Lee
A. Santillan-Gomez
C. Bailey

Canada
D. Provencher
A. Oza
J. Weberpals
S. Lau
S. Welch
A. Kumar
D. Mirchandani
A. Covens

Russian Federation
V. Vladimirov
E. Gotovkin
V. Moiseenko
S. Safina
D. Yukalchuk
V. Shirinkin
A. Buiniakova
O. Gladkov
O. Mikheeva
N. Musaeva
M. Nechaeva
T. Semiglazov