ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: April 1, 2019

ClinicalTrials.gov ID: NCT02012192

Study Identification

Unique Protocol ID:	GANNET53
Brief Title:	GANNET53: Ganetespib in Metastatic, p53-mutant, Platinum-resistant Ovarian Cancer
Official Title:	A Two-part, Multicentre, International Phase I and II Trial Assessing the Safety and Efficacy of the Hsp90 Inhibitor Ganetespib in Combination With Paclitaxel Weekly in Women With High-grade Serous, High-grade Endometrioid, or Undifferentiated, Platinum-resistant Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer
Secondary IDs:	2013-003868-31 [EudraCT Number]

Study Status

Record Verification:	April 2019
Overall Status:	Terminated [production of IMP has stopped]
Study Start:	July 4, 2014 [Actual]
Primary Completion:	November 30, 2017 [Actual]
Study Completion:	December 4, 2017 [Actual]

Sponsor/Collaborators

Sponsor:	Medical University Innsbruck
Responsible Party:	Principal Investigator Investigator: Nicole Concin [nconcin] Official Title: Univ.-Prof. Dr. Affiliation: Medical University Innsbruck
Collaborators:	European Commission

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved
Approval Number: 04/22/2014
Board Name: Ethical Committee
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Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary: Epithelial ovarian cancer (EOC) is the most lethal gynaecological malignancy causing 41900 deaths annually in Europe. The predominance of aggressive Type II tumours, which are characterised by a high frequency of p53 mutations, and primary or acquired resistance to platinum-based chemotherapy profoundly contribute to the high mortality rate. With current standard therapy the median overall survival of metastatic platinum-resistant (Pt-R) ovarian cancer patients is only 14 month. There is a pressing need for more effective, innovative treatment strategies to particularly improve survival in this subgroup of EOC patients. This is a drug strategy targeting a central driver of tumour aggressiveness and metastatic ability, namely mutant p53, via an innovative new Hsp90 (heat shock protein 90) inhibition mechanism. The most advanced, second-generation Hsp90 inhibitor will be used, Ganetespib. The first part (Phase I) of the GANNET53 trial will test the safety of Ganetespib in a new combination with standard chemotherapy (Paclitaxel weekly) in Pt-R EOC patients. The second part (randomised Phase II) will examine the efficacy of Ganetespib in combination with standard chemotherapy versus standard chemotherapy alone in EOC patients with Pt-R tumours.

Detailed Description:

Conditions

Conditions: Epithelial Ovarian Cancer
Fallopian Tube Cancer

Primary Peritoneal Cancer

Keywords: High-grade serous
high-grade endometrioid
undifferentiated

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1/Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: None (Open Label)

Allocation: Randomized

Enrollment: 133 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Ganetespib + Paclitaxel Drug: ganetespib, dose will depend on phase I results, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle); Drug: paclitaxel, 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression.	Drug: Ganetespib Drug: Paclitaxel
Active Comparator: Paclitaxel Drug: paclitaxel: 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression	Drug: Paclitaxel

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: Female

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Ability to understand and willingness to sign and date a written informed consent document
- Female patients ≥18 years of age
- High-grade serous, high-grade endometrioid, or undifferentiated epithelial ovarian, fallopian tube or primary peritoneal cancer
- Patients in part II: High-grade serous, high-grade endometrioid, or undifferentiated epithelial ovarian, fallopian tube or primary peritoneal cancer confirmed by central histopathology through archival formalin-fixed paraffin embedded (FFPE) or fresh-frozen tumour samples.

- Platinum-resistant disease:
- primary platinum-resistant disease: progression > 1 month and ≤ 6 months after completion of primary platinum-based therapy
- secondary platinum-resistant disease (including secondary platinum-refractory disease): progression ≤ 6 months after (or during) reiterative platinum-based therapy
- Patients must have disease that is measurable according to RECIST 1.1 or assessable according to the GCIG (Eastern Cooperative Oncology Group) CA-125 criteria
- ECOG performance status of 0-1
- Life expectancy of at least 3 months as assessed by the investigator

Adequate function of the bone marrow:

- Platelets ≥100 x 109/L
- Absolute neutrophil count (ANC) ≥ 1.5 x 109/L
- Haemoglobin ≥ 8.5 g/dl. Patients may receive blood transfusion(s) to maintain haemoglobin values > 8.5 g/dl.

Adequate organ functions:

- Creatinine < 2 mg/dl (<177 µmol/L)
- Total bilirubin ≤ 1.5 x upper limit of normal
- SGOT (serum glutamate oxaloacetate transaminase)/SGPT (serum glutamate pyruvate transaminase) (AST/ALT) ≤ 3 x upper limit of normal
- Urinanalysis or urine dipstick for proteinuria less than 2+. Patients with ≥ 2+ on dipstick should undergo 24-hour urine collection and must demonstrate < 1 g of protein/24 hours. Alternatively, proteinuria testing can be performed according to local standards
- Negative urine/serum pregnancy test in women of childbearing potential (WOCBP, see section 5). WOCBP who are sexually active, agree to use highly effective means of contraception during the study and for at least 6 months post-study treatment. Allowed are accepted and effective non-hormonal methods of contraception and sexual abstinence or vasectomised partners (>3 months previously). Vasectomy has to be confirmed by two negative semen analyses.
- Availability of archival ovarian cancer tissue for central histopathological review and p53 mutational analysis

Exclusion Criteria:

- Ovarian tumours with low malignant potential (i.e. borderline tumours)
- Primary platinum-refractory disease (progression during primary platinum-based chemotherapy)

PRIOR, CURRENT OR PLANNED TREATMENT:

- Previous treatment with > 2 chemotherapy regimens in the platinum-resistant setting (excluding targeted and endocrine therapies).
- More than 4 previous lines of chemotherapy.
- Major surgery within 2 weeks prior to first dose of ganetespib

PRIOR OR CONCOMITANT CONDITIONS OR PROCEDURES:

- Patients with a history of prior malignancies, except, disease-free time-frame of ≥ 3 years prior to randomisation.
- Patients with prior in-situ carcinomas, except:

complete removal of the tumour is given

- Known history of severe (grade 3 or 4) allergic or hypersensitivity reactions to excipients (e.g., polyethylene glycol [PEG] 300 and Polysorbate 80)
- History of intolerance or hypersensitivity to paclitaxel and/or adverse events related to paclitaxel that resulted in paclitaxel being permanently discontinued
- Peripheral neuropathy of grade > 2 per NCI CTCAE (Common Toxicity Criteria for Adverse Effects), version 4.03, within 4 weeks prior to randomisation
- Clinical symptomatic bowel obstruction at time of screening
- Left ventricular ejection fraction defined by MUGA (multigated acquisition)/ECHO below the institutional lower limit of normal
- Patients with symptomatic brain metastases
- Significant cardiac disease: New York Heart Association (NYHA) Class 3 or 4; myocardial infarction within the past 6 months; unstable angina; coronary angioplasty or coronary artery bypass graft (CABG) within the past 6 month; or uncontrolled atrial or ventricular cardiac arrhythmias.
- History of prolonged QT syndrome, or family member with prolonged QT syndrome
- QTc (corrected QT interval) interval > 470 msec when 3 consecutive EKG values are averaged
- Ventricular tachycardia or a supraventricular tachycardia that requires treatment with a Class Ia antiarrhythmic drug (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic drug (e.g., sotalol, amiodarone, dofetilide). Use of other antiarrhythmic drugs is permitted
- Second- or third-degree atrioventricular (AV) block, except:

treated with a permanent pacemaker

- Complete left bundle branch block (LBBB)
- Any other condition that, in the opinion of the investigator, may compromise the safety, compliance of the patient, or would preclude the patient from successful completion of the study.
- Participation in another clinical study with experimental therapy within 28 days before start of treatment.
- Women who are pregnant or are lactating

Contacts/Locations

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IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Documents

Study Protocol and Statistical Analysis Plan
Document Date: February 18, 2016
Uploaded: 03/08/2019 04:49

Study Results

Participant Flow

Reporting Groups

	Description
Ganetespib + Paclitaxel	Drug: ganetespib, 150 mg/m², given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle); Drug: paclitaxel, 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression. Ganetespib Paclitaxel
Paclitaxel	Drug: paclitaxel: 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression Paclitaxel

Overall Study

	Ganetespib + Paclitaxel	Paclitaxel
Started	90	43
Completed	63	43
Not Completed	27	0

Baseline Characteristics

Reporting Groups

	Description
Ganetespib + Paclitaxel	Drug: ganetespib, 150 mg/m², given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle); Drug: paclitaxel, 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression.

	Description
Paclitaxel	Drug: paclitaxel: 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression

Baseline Measures

		Ganetespib + Paclitaxel	Paclitaxel	Total
Overall Number of Participants		90	43	133
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	90 participants	43 participants	133 participants
	<=18 years	0 0%	0 0%	0 0%
	Between 18 and 65 years	57 63.33%	25 58.14%	82 61.65%
	>=65 years	33 36.67%	18 41.86%	51 38.35%
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	90 participants	43 participants	133 participants
	Female	90 100%	43 100%	133 100%
	Male	0 0%	0 0%	0 0%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	90 participants	43 participants	133 participants
Ethnic group	White	66 73.33%	31 72.09%	97 72.93%
	Black	0 0%	0 0%	0 0%
	Asian	1 1.11%	0 0%	1 0.75%
	Privacy	23 25.56%	12 27.91%	35 26.32%

		Ganetespib + Paclitaxel	Paclitaxel	Total
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	90 participants	43 participants	133 participants
Austria		1	1	2
Belgium		20	10	30
France		37	17	54
Germany		32	15	47

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression Free Survival (PFS)
Measure Description	evaluate the efficacy of ganetespib in combination with weekly paclitaxel compared to weekly paclitaxel alone as measured by Progression-free survival (PFS)
Time Frame	Time until progression (median w/o new drug 4 months)

Analysis Population Description
ITT population

Reporting Groups

	Description
Ganetespib + Paclitaxel	Drug: ganetespib, 150 mg/m², given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle); Drug: paclitaxel, 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression.
Paclitaxel	Drug: paclitaxel: 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression

Measured Values

	Ganetespib + Paclitaxel	Paclitaxel
Overall Number of Participants Analyzed	82	42

	Ganetespib + Paclitaxel	Paclitaxel
Progression Free Survival (PFS) Median (95% Confidence Interval) Unit of measure: months	3.5 (3.092 to 3.882)	5.3 (4.006 to 6.652)

Reported Adverse Events

Time Frame	After informed consent has been obtained but prior to initiation of the study drug, only SAEs considered to be related to a protocol-mandated intervention were reported. After initiation of study drug, all AEs and SAEs regardless of relationship to the study drug, will be reported until safety follow-up at 28 days after the last dose of IMP or EOT or until the event has resolved to baseline grade or better.
Adverse Event Reporting Description	An AE is any untoward adverse change from the subject's baseline condition, i.e. any unfavourable and unintended sign including an abnormal laboratory finding, symptom or disease which is considered to be clinically relevant by the physician that occurs during the course of the study, whether or not considered related to the study drug.

Reporting Groups

	Description
Ganetespib + Paclitaxel	Drug: ganetespib, 150 mg/m², given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle); Drug: paclitaxel, 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression.
Paclitaxel	Drug: paclitaxel: 80 mg/m2, given iv once weekly for 3 out of 4 weeks (days 1, 8, 15 of each 4-weeks/28-days cycle), until progression

All-Cause Mortality

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	66/86 (76.74%)		29/43 (67.44%)	

Serious Adverse Events

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	34/90 (37.78%)		10/43 (23.26%)	
Blood and lymphatic system disorders				
Anemia †	1/90 (1.11%)		0/43 (0%)	
Hypovolemia †	1/90 (1.11%)		0/43 (0%)	
febrile neutropenia †	1/90 (1.11%)		0/43 (0%)	
Gastrointestinal disorders				
Abdominal distention †	1/90 (1.11%)		0/43 (0%)	
Abdominal pain †	3/90 (3.33%)		1/43 (2.33%)	
Anal hemorrhage †	0/90 (0%)		1/43 (2.33%)	
Diarrhea †	3/90 (3.33%)		0/43 (0%)	
Esophagitis †	1/90 (1.11%)		0/43 (0%)	
Ileus †	2/90 (2.22%)		1/43 (2.33%)	
Rectal Ulcer †	1/90 (1.11%)		0/43 (0%)	
Small intestinal obstruction †	8/90 (8.89%)		1/43 (2.33%)	
Small intestinal perforation †	2/90 (2.22%)		0/43 (0%)	
Subileus †	1/90 (1.11%)		0/43 (0%)	
Subobstruction colon †	1/90 (1.11%)		0/43 (0%)	
Vomiting †	1/90 (1.11%)		2/43 (4.65%)	
General disorders				
Fever †	1/90 (1.11%)		1/43 (2.33%)	
General physical health deterioration †	2/90 (2.22%)		1/43 (2.33%)	
Infusion site extravasation †	0/90 (0%)		1/43 (2.33%)	
Sudden death NOS †	1/90 (1.11%)		0/43 (0%)	
Hepatobiliary disorders				
Hemobilia †	1/90 (1.11%)		0/43 (0%)	
Hepatic failure †	1/90 (1.11%)		0/43 (0%)	

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Icterus †	1/90 (1.11%)		0/43 (0%)	
Infections and infestations				
Catheter related infection †	1/90 (1.11%)		0/43 (0%)	
Erysipelas †	0/90 (0%)		3/43 (6.98%)	
Infection NOS †	0/90 (0%)		1/43 (2.33%)	
Sepsis †	6/90 (6.67%)		0/43 (0%)	
Urethral infection †	1/90 (1.11%)		0/43 (0%)	
Urinary tract infection †	5/90 (5.56%)		1/43 (2.33%)	
Injury, poisoning and procedural complications				
Rupture of renal pelvis †	1/90 (1.11%)		0/43 (0%)	
Vascular access complication †	0/90 (0%)		1/43 (2.33%)	
Metabolism and nutrition disorders				
Anorexia †	1/90 (1.11%)		0/43 (0%)	
Hyperptassemia †	1/90 (1.11%)		0/43 (0%)	
Hypokalemia †	1/90 (1.11%)		0/43 (0%)	
Nervous system disorders				
Visual acuity reduced †	1/90 (1.11%)		0/43 (0%)	
Renal and urinary disorders				
Acute kidney injury †	1/90 (1.11%)		0/43 (0%)	
Cystitis †	1/90 (1.11%)		0/43 (0%)	
Kidney insufficiency †	1/90 (1.11%)		0/43 (0%)	
Renal disorders NEC †	1/90 (1.11%)		0/43 (0%)	
Urinary tract obstruction †	0/90 (0%)		2/43 (4.65%)	
Respiratory, thoracic and mediastinal disorders				
Dyspnea †	1/90 (1.11%)		0/43 (0%)	
Pleural effusion †	1/90 (1.11%)		0/43 (0%)	
Respiratory failure †	1/90 (1.11%)		0/43 (0%)	

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Vascular disorders				
Deep vein thrombosis †	0/90 (0%)		1/43 (2.33%)	
Thromboemblic events †	1/90 (1.11%)		0/43 (0%)	

† Indicates events were collected by systematic assessment.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	88/90 (97.78%)		41/43 (95.35%)	
Blood and lymphatic system disorders				
Anemia †	56/90 (62.22%)		27/43 (62.79%)	
Thrombocytopenia †	7/90 (7.78%)		0/43 (0%)	0
Gastrointestinal disorders				
Abdominal distention †	8/90 (8.89%)		2/43 (4.65%)	
Abdominal pain †	31/90 (34.44%)		12/43 (27.91%)	
Constipation †	21/90 (23.33%)		9/43 (20.93%)	
Diarrhea †	73/90 (81.11%)		15/43 (34.88%)	
Dry mouth †	6/90 (6.67%)		2/43 (4.65%)	
Dyspepsia †	0/90 (0%)		3/43 (6.98%)	
Gastroesophageal reflux disease †	6/90 (6.67%)		2/43 (4.65%)	
Mucositis oral †	5/90 (5.56%)		0/43 (0%)	
Nausea †	41/90 (45.56%)		21/43 (48.84%)	
Vomiting †	29/90 (32.22%)		9/43 (20.93%)	
General disorders				
Astenia †	22/90 (24.44%)		11/43 (25.58%)	
Edema limbs †	7/90 (7.78%)		4/43 (9.3%)	
Edema peripheral †	6/90 (6.67%)		7/43 (16.28%)	

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Fatigue †	26/90 (28.89%)		8/43 (18.6%)	
Fever †	10/90 (11.11%)		0/43 (0%)	
Malaise †	0/90 (0%)		3/43 (6.98%)	
Mucosal inflammation †	5/90 (5.56%)		0/43 (0%)	
Immune system disorders				
Allergic reaction †	5/90 (5.56%)		3/43 (6.98%)	
Infections and infestations				
Bronchial infection †	5/90 (5.56%)		0/43 (0%)	
Urinary tract infection †	8/90 (8.89%)		6/43 (13.95%)	
Investigations				
Alanine aminotransferase increased †	0/90 (0%)		2/43 (4.65%)	
Aspartate aminotransferase increased †	0/90 (0%)		3/43 (6.98%)	
Electrocardiogram QT corrected intervall prolonged †	13/90 (14.44%)		0/43 (0%)	
Lymphocyte count decreased †	9/90 (10%)		4/43 (9.3%)	
Neutrophil count decreased †	26/90 (28.89%)		10/43 (23.26%)	
Weight loss †	9/90 (10%)		0/43 (0%)	
White blood cells decreased †	13/90 (14.44%)		6/43 (13.95%)	
Metabolism and nutrition disorders				
Anorexia †	18/90 (20%)		6/43 (13.95%)	
Hypokalaemia †	7/90 (7.78%)		3/43 (6.98%)	
Musculoskeletal and connective tissue disorders				
Anthralgia †	0/90 (0%)		2/43 (4.65%)	
Back pain †	9/90 (10%)		4/43 (9.3%)	
Muscle spasms †	11/90 (12.22%)		2/43 (4.65%)	
Myalgia †	0/90 (0%)		3/43 (6.98%)	
Pain in extremity †	9/90 (10%)		3/43 (6.98%)	

	Ganetespib + Paclitaxel		Paclitaxel	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Nervous system disorders				
Dizziness †	0/90 (0%)		2/43 (4.65%)	
Dysgeusia †	5/90 (5.56%)		5/43 (11.63%)	
Headache †	10/90 (11.11%)		2/43 (4.65%)	
Neuropath peripheral †	35/90 (38.89%)		21/43 (48.84%)	
Paresthesia †	0/90 (0%)		3/43 (6.98%)	
Psychiatric disorders				
Insomnia †	16/90 (17.78%)		4/43 (9.3%)	
Renal and urinary disorders				
Cystitis non-infective †	0/90 (0%)		3/43 (6.98%)	
Respiratory, thoracic and mediastinal disorders				
Common cold †	0/90 (0%)		3/43 (6.98%)	
Cough †	5/90 (5.56%)		3/43 (6.98%)	
Dyspnea †	13/90 (14.44%)		9/43 (20.93%)	
Epistaxis †	5/90 (5.56%)		2/43 (4.65%)	
Skin and subcutaneous tissue disorders				
Alopecia †	35/90 (38.89%)		14/43 (32.56%)	
Dry skin †	8/90 (8.89%)		0/43 (0%)	
Erythema †	0/90 (0%)		5/43 (11.63%)	
Nail infection NOS †	0/90 (0%)		2/43 (4.65%)	
Pruritus †	7/90 (7.78%)		2/43 (4.65%)	
Rash †	5/90 (5.56%)		4/43 (9.3%)	
Vascular disorders				
Flushing †	0/90 (0%)		3/43 (6.98%)	
Hot flashes †	0/90 (0%)		2/43 (4.65%)	
Hypotension †	5/90 (5.56%)		0/43 (0%)	
Lymphedema †	5/90 (5.56%)		2/43 (4.65%)	

† Indicates events were collected by systematic assessment.

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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