

Relacorilant + Nab-Paclitaxel Improves Survival Without Increasing Side Effect Burden in Patients with Ovarian Cancer

March 31, 2022



Safe Harbor

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Торіс	Presenter
Company Overview	Joseph Belanoff, MD Chief Executive Officer
Corcept Oncology Overview	Bill Guyer, PharmD Chief Development Officer
Platinum-Resistant Ovarian Cancer	Thomas Herzog, MD Professor of Obstetrics & Gynecology, Deputy Director, University of Cincinnati Cancer Center
Closing Remarks	Bill Guyer, PharmD Chief Development Officer



Joseph Belanoff, MD Chief Executive Officer

Discovering, developing and commercializing medications that treat severe diseases by modulating the effects of the stress hormone CORTISOL

- Essential for life
 - Produced by the adrenal glands
 - Diurnal rhythm
 - Binds to receptors found in nearly every tissue type
- Excess cortisol activity causes and exacerbates serious diseases
- Korlym[®] and our proprietary next-generation of selective cortisol modulators compete with cortisol at the glucocorticoid receptor (GR)
 - Selective cortisol modulators don't bind to the progesterone receptor (PR) and have other important differentiating attributes

Steroids



Three Series of Selective Cortisol Antagonists

	GR Binding (Cortisol)	PR Binding (Progesterone)
Korlym	1.0 nM	1.0 nM
Fused-ring Azadecalins	0.5 nM	>1000 nM
Azadecalins	4.0 nM	>1000 nM
Pyrimidinediones	9.0 nM	>1000 nM

Korlym Compared to Relacorilant



Glucocorticoid Receptor (GR) Co-Regulators



Corcept's Model for Growth



Cash Generating Operating Model



1) EBITDA defined as operating income plus stock-based compensation and depreciation & amortization

Rich Therapeutic Platform

Program	Compound	Stage of Development / Status
Cushing's Syndrome		
GRACE	Relacorilant	Phase 3 / NDA Submission Q2'23
GRADIENT	Relacorilant	Phase 3 / Enrolling
Oncology		
Ovarian	Relacorilant + Abraxane	Phase 2 / Initiate Phase 3 Q2'22
Prostate	Relacorilant / Exicorilant + Xtandi	Phase 1/2a / Select molecule and dose Q2'22
Adrenal	Relacorilant + Keytruda	Phase 1/2 / Enrolling
Metabolic		
GRATITUDE (recent AIWG)	Miricorilant	Phase 2 / Complete enrollment mid'22; Data Q4'22
GRATITUDE II (long-standing AIWG)	Miricorilant	Phase 2 / Completed enrollment; Data Q4'22
NASH	Miricorilant	Phase 1b / Enrolling
CNS		
ALS	Dazucorilant	Phase 2 / Initiate Q2'22

Academic Collaborations Inform and Augment Our Development Efforts

ONCOLOGIC

Mifepristone Clinical Research:

- Triple-Negative Breast Cancer
- Castration-resistant Prostate Cancer in Combination
 with Enzalutamide

Mifepristone and/or New Chemical Entity Basic Science Research:

- Triple-Negative Breast Cancer
- Ovarian Cancer
- Prostate Cancer (2 studies)
- Non-Small Cell Lung Cancer
- Cachexia
- · Ewing sarcoma

CARDIOVASCULAR

Mifepristone and/or New Chemical Entity Basic Science Research:

Atherosclerosis and GR

NEUROLOGIC

New Chemical Entity Clinical Research:

• Mild cognitive impairment due to dementia

Mifepristone and/or New Chemical Entity Basic Science Research:

- Amyotrophic Lateral Sclerosis (ALS) and GR
- · Alzheimer's disease
- Epilepsy
- Neuroinflammation
- · Spinal cord injury

METABOLIC

Mifepristone Clinical Research:

- Type 2 Diabetes, randomized trial
- Petrosal sinus sampling

Mifepristone and/or New Chemical Entity Basic Science Research:

- Hepatic steatosis in mice
- Cushing's Syndrome in mouse model
- Adrenal Tumors in mice
- Metabolic Syndrome
- · Muscle wasting
- Inflammation
- Metabolic effects of early life stress

PSYCHIATRIC

Mifepristone Clinical Research:

- Alcohol Dependence, randomized trial
- Anxiety, open label trial
- GR and Alcohol Withdrawal
- Use of PET to Evaluate Cerebral Glucose Metabolism and Dopamine Receptor 2 Availability in PD patients
- Tobacco use disorder
- Major Depression

New Chemical Entity Clinical Research:

- Alcohol use disorder
- Post traumatic stress disorder
- Alzheimer's disease

Mifepristone and/or New Chemical Entity Basic Science Research:

- Cocaine Administration
- Stress
- GR Signaling in the Brain
- Alcohol Use Disorder
- Eating disorders

OPHTHALMOLOGIC

Mifepristone Clinical Research:

 Central Serous Chorioretinopathy multicenter randomized clinical study



Bill Guyer, PharmD Chief Development Officer

Cortisol Modulation Has Broad Potential in Oncology

GR expression is prevalent with high intensity in many tumor types¹



Cortisol Modulation Has Broad Potential in Oncology

High GR expression is associated with significantly higher risk of disease progression vs. low GR expression¹



Anti-Tumor Activity Observed in Relacorilant Phase 1 Trial in Ovarian Cancer and Other Solid Tumors



Corcept Oncology Program: Summary

Compound	Study Population	Combination	Mechanism of Action
Relacorilant			
Phase 2	Advanced platinum-resistant ovarian cancer	Abraxane (nab-paclitaxel)	Apoptosis
Phase 1	Metastatic castration-resistant prostate cancer (mCRPC)	Xtandi (enzalutamide)	Growth Pathway
Phase 1/2	Adrenal cancer with cortisol excess	Keytruda (pembrolizumab)	Immunosuppression
Exicorilant			
Phase 1/2a	mCRPC	Xtandi (enzalutamide)	Growth Pathway

Cortisol Modulation May Enhance and/or Restore Chemotherapy Sensitivity

 Apoptosis is the tumor-killing effect that chemotherapy is meant to stimulate

 Cortisol increases expression of anti-apoptotic genes, such as Serum and Glucocorticoid-Regulated Kinase 1 (SGK1)

 Relacorilant, a selective cortisol modulator, competes with cortisol at the GR and may enhance and/or restore chemotherapy sensitivity

Today's Guest Speaker: Thomas Herzog, MD



Key Current Positions:

- Deputy Director of the University of Cincinnati Cancer Center
- Professor of Obstetrics and Gynecology at the University of Cincinnati College of Medicine
- Board of Directors, Gynecologic Oncology Group (GOG) Partners

Background:

- Fellowship in gynecologic oncology: Washington University School of Medicine, St. Louis
- Director of the division of gynecologic oncology: Columbia University
- Fellowship Director: Columbia and Cornell Medical Schools
- Extensive clinical trial design and regulatory strategy experience
- Expert consultant/advisor to Aravive, AstraZeneca, Caris, Clovis Oncology, Eisai, Epsilogen, GSK, Johnson & Johnson, Merck, and Roche/Genentech
- National Institutes of Health- and American Cancer Societyfunded researcher with over 320 published manuscripts

Ovarian Cancer: Increasing Prevalence

Ovarian Cancer Prevalence 2001–2018



Source: National Cancer Institute Surveillance, Epidemiology and End Results Program (SEER). SEER Cancer Statistics Review (CSR) 1975-2016 - Ovary. 2016; <u>https://seer.cancer.gov/csr/1975_2016/sections.html</u>. Accessed Apr 14, 2020.; <u>https://seer.cancer.gov/statfacts/html/ovary.html</u>. Accessed Feb 08, 2021

Ovarian Cancer Patient Journey

21K newly diagnosed cases of ovarian cancer annually in the U.S.¹



~20K U.S. Drug-Treatable Patients Per Year in Platinum-Resistant Ovarian Cancer (PROC)²

Despite drug therapy,
 ~14K patients die annually
 from their disease¹

Phase II Trial Population

¹ Surveillance, Epidemiology and End Results (SEER). <u>https://seer.cancer.gov/statfacts/html/ovary.html</u>

² Clarivate | Decision Resources Group Ovarian Cancer Market Forecast Dashboard - December 2021 (www.clarivate.com)

Platinum-Resistant Ovarian Cancer: A Great Unmet Medical Need

Platinum resistance occurs in virtually all patients with recurrent ovarian cancer¹

- Therapy options are limited to sequential chemotherapy not previously administered and molecular targeted agents
 - Most drug-treated patients receive one of the FDA-approved approved single-agent chemotherapies: paclitaxel, pegylated liposomal doxorubicin, or topotecan
- Outcomes are generally poor and physicians prioritize tolerability and quality of life
- Nab-paclitaxel is used for patients at risk of infusion reactions and is considered to have comparable or superior efficacy to paclitaxel^{2, 3}

Limited Efficacy with Single-agent Chemotherapy

> **3-4 months** Progression-free survival¹

<12 months Overall survival¹

Platinum-Resistant Ovarian Cancer: A Great Unmet Medical Need

Kov Ctropothe

	key Strengths	Key Limitations
Single-Agent Chemotherapy	 Multiple FDA-approved agents with different safety profiles provide options for patients 	 Limited efficacy: 3-4 months PFS with FDA-approved agents Considered a palliative treatment strategy
Bevacizumab + Chemotherapy	 Improves ORR and PFS compared to single-agent chemotherapy Useful in treating ascites 	 Risk of serious and sometimes fatal gastrointestinal perforations^{2, 3}, severe hypertension / proteinuria and thromboembolic events No significant improvement in OS
PARPi Primary Therapy ¹	 Demonstrated meaningful efficacy in 3L+ disease All oral treatment option 	 Only approved in platinum-resistant disease for patients with BRCA1/2 mutations Risk of grade ≥3 anemia, neutropenia, and through existence is

1) The FDA labels for PARP inhibitors include indications for primary therapy for BRCA mutation positive patients following 2-3 lines of prior therapy. These agents are typically used as maintenance therapy following treatment in 1L disease or recurrent platinum-sensitive ovarian cancer. 2) Cannistra et al. 2007. 3) Avastin Label. Source: Luvero et al. 2014; Product PIs; NCCN Guidelines; Decision Resources Group Market Forecast Dashboard - Ovarian Cancer (2020-2030) IV: Intravenous. ORR: Objective response rate. OS: Overall survival. PFS: Progression-free survival.

Kovil imitations

thrombocytopenia

Relacorilant Phase 2 Study: 178 Patients with Platinum-Resistant Ovarian Cancer



	INTERMITTENT N=60	CONTINUOUS N=58	COMPARATOR N=60	Overall N=178
Age, median (range), years	60 (38, 81)	60 (45, 75)	61.5 (41, 81)	61 (38, 81)
Platinum-refractory*, no. (%)	23 (38.3%)	20 (34.5%)	22 (36.7%)	65 (36.5%)
Primary platinum-refractory**, no. (%)	7 (11.7%)	3 (5.2%)	1 (1.7%)	11 (6.2%)
Number of prior therapies, median (range)	2.5 (1, 4)	3 (1, 5)	3 (1, 4)	3 (1, 5)
Patients with ≥4 prior lines of therapy, no. (%)	7 (11.7%)	15 (25.9%)	9 (15.0%)	31 (17.4%)
Prior taxane therapy, no. (%)	59 (98.3%)	58 (100%)	60 (100%)	177 (99.4%)
Prior bevacizumab therapy, no. (%)	31 (51.7%)	37 (63.8%)	37 (61.7%)	105 (59.0%)
Prior PARP therapy, no. (%)	18 (30.0%)	27 (46.6%)	20 (33.3%)	65 (36.5%)
Molecular profiling (available in a subset of the study	population only)			
BRCA1(+), n/N (%)	5/43 (11.6%)	4/43 (9.3%)	7/49 (14.3%)	16/135 (11.9%)
BRCA2(+), n/N (%)	1/37 (2.7%)	3/39 (7.7%)	3/39 (7.7%)	7/115 (6.1%)

* Platinum-refractory: Patients previously treated with platinum agents who experience disease progression within 1 month from last platinum treatment.

** Primary platinum-refractory: Patients previously <u>un</u>treated with platinum agents who experience disease progression within 1 month of first line platinum-based chemotherapy. CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy.

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Intermittent Relacorilant + Nab-Paclitaxel Improved Progression-Free Survival (PFS) – All Patients



CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; PFS, progression-free survival; HR, hazard ratio

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Intermittent Relacorilant + Nab-Paclitaxel Improved PFS – Subgroup Analysis



Intermittent Relacorilant + Nab-Paclitaxel Improved PFS – Excluding Primary Platinum-Refractory and ≥4 Prior Lines



CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; PFS, progression-free survival; HR, hazard ratio

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Intermittent Relacorilant + Nab-Paclitaxel Improved Duration of Response (DoR) – All Patients



	0	RR
	n (%)	95% CI
INTERMITTENT	20 (35.7%)	(23.4, 49.6)
CONTINUOUS	19 (35.2%)	(22.7, 49.4)
COMPARATOR	19 (35.8%)	(23.1, 50.2)

CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; ORR, objective response rate; DoR, duration of response

Intermittent Relacorilant + Nab-Paclitaxel Improved Duration of Response (DoR) – All Patients



CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; ORR, objective response rate; DoR, duration of response

Intermittent Relacorilant + Nab-Paclitaxel Improved DoR – Excluding Primary Platinum-Refractory and ≥4 Prior Lines



CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; ORR, objective response rate; DoR, duration of response

Intermittent Relacorilant + Nab-Paclitaxel Improved Overall Survival (OS) – All Patients



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Intermittent Relacorilant + Nab-Paclitaxel Improved Overall Survival (OS) – All Patients



Intermittent Relacorilant + Nab-Paclitaxel Improved Overall Survival – Subgroup Analysis



Intermittent Relacorilant + Nab-Paclitaxel Improved OS – Excluding Primary Platinum-Refractory and ≥4 Prior Lines



CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; OS, overall survival

Intermittent Relacorilant + Nab-Paclitaxel Improved OS – Excluding Primary Platinum-Refractory and ≥4 Prior Lines



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Intermittent Relacorilant + Nab-Paclitaxel Improved PFS, DoR and OS – All Patients

	INTERMITTENT N=60	COMPARATOR N=60
PFS ¹ (median follow-up time: 11.1 months)		
Events, no. (%)	47 (78.3%)	57 (95.0%)
Median PFS, mo (95% CI)	5.6 (3.7, 7.2)	3.8 (3.5, 5.4)
HR vs Comparator, (95% CI)	0.66 (0.44, 0.98)	N/A
P-value	0.038	N/A
Duration of Response (DoR) ¹ in patients with objective r	response	
Number of patients with objective response	20	19
Events, no. (%)	13 (65.0%)	17 (89.5%)
Median DoR, mo (95% CI)	5.6 (3.8, 5.9)	3.7 (2.9, 5.1)
HR vs Comparator, (95% CI)	0.36 (0.16, 0.77)	N/A
P-value	0.006	N/A
Overall Survival ² (median follow-up time: 22.5 months)		
Events, no. (%)	37 (61.7%)	49 (81.7%)
Median OS, mo (95% CI)	13.9 (11.1, 18.4)	12.2 (7.7, 15.3)
HR vs Comparator, (95% CI)	0.67 (0.43, 1.03)	N/A
P-value	0.066	N/A

1) Primary PFS analysis as of data cutoff date March 22, 2021. 2) Pre-planned OS analysis as of data cutoff date March 7, 2022. INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; OS, overall survival Confidential – Not for Distribution

Intermittent Relacorilant + Nab-Paclitaxel Improved PFS, DoR and OS – Excluding Primary Platinum-Refractory and ≥4 Prior Lines

	INTERMITTENT N=46	COMPARATOR N=50
PFS ¹		
Events, no. (%)	36 (78.3%)	48 (96.0%)
Median PFS, mo (95% CI)	5.6 (3.7, 7.3)	3.8 (3.5, 5.4)
HR vs Comparator, (95% CI)	0.58 (0.37, 0.91)	N/A
P-value	0.016	N/A
Duration of Response (DoR) ¹ in patients with objective re	esponse	
Number of patients with objective response	18	17
Events, no. (%)	13 (72.2%)	16 (94.1%)
Median DoR, mo (95% CI)	5.6 (3.8, 5.9)	3.6 (1.9, 3.8)
HR vs Comparator, (95% CI)	0.26 (0.11, 0.62)	N/A
<i>P</i> -value	0.001	N/A
Overall Survival ²		
Events, no. (%)	29 (63.0%)	43 (86.0%)
Median OS, mo (95% CI)	13.9 (11.1, 18.4)	12.2 (7.7, 15.3)
HR vs Comparator, (95% CI)	0.52 (0.31, 0.86)	N/A
<i>P</i> -value	0.01	N/A

1) Primary PFS analysis as of data cutoff date March 22, 2021. 2) Pre-planned OS analysis as of data cutoff date March 7,2022. INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy

The Safety and Tolerability of Intermittent Relacorilant + Nab-Paclitaxel is Comparable to Nab-Paclitaxel Monotherapy

n, (%)	INTERMITTENT N=60	CONTINUOUS N=57	COMPARATOR N=60
Neutropenia ^a	12 (20.0%)	22 (38.6%)	22 (36.7%)
Grade ≥3	4 (6.7%)	15 (26.3%)	9 (15.0%)
Febrile neutropenia (Grade 3) ^b	0 (0.0%)	0 (0.0%)	1 (1.7%)
Anemia ^c	29 (48.3%)	37 (64.9%)	34 (56.7%)
Grade ≥3	8 (13.3%)	11 (19.3%)	7 (11.7%)
Peripheral neuropathy ^d	21 (35.0%)	27 (47.4%)	18 (30.0%)
Grade ≥3	0 (0.0%)	9 (15.8%)	3 (5.0%)
Fatigue or asthenia	33 (55.0%)	41 (71.9%)	39 (65.0%)
Grade ≥3	6 (10.0%)	5 (8.8%)	1 (1.7%)

^a Neutropenia, neutrophil count decreased; ^b Secondary to E.coli urinary sepsis in this patient; ^c Anemia, hemoglobin decreased; ^d Neuropathy peripheral, neurotoxicity, peripheral motor neuropathy, peripheral sensory neuropathy

CONTINUOUS, once-daily relacorilant + nab-paclitaxel; INTERMITTENT, intermittent relacorilant + nab-paclitaxel; COMPARATOR, nab-paclitaxel monotherapy; G-CSF, granulocyte-colony stimulating factor

- ► All relacorilant-treated patients received prophylactic G-CSF per protocol to reduce the risk of neutropenia
- ► 46.7% of patients in the comparator arm received G-CSF per the investigator's standard practice

The Safety and Tolerability of Intermittent Relacorilant + Nab-Paclitaxel is Comparable to Nab-Paclitaxel Monotherapy

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Phase 2 Conclusions

- Cortisol modulation is a promising novel oncologic therapeutic platform
- This study is the first randomized, controlled, phase 2 trial of relacorilant + nab-paclitaxel in patients with platinum-resistant/refractory ovarian, primary peritoneal, or fallopian tube cancer
- In this heavily pretreated population (up to 4 lines of prior chemotherapy), substantial benefit was observed
 - In all patients, intermittent relacorilant + nab-paclitaxel improved PFS, DoR and OS compared to nab-paclitaxel alone
 - Even greater differential improvement was seen after excluding primary platinum-refractory patients and patients with 4 or more prior lines of therapy – the phase 3 population
- No additional side effect burden was observed with the addition of intermittent relacorilant compared to nab-paclitaxel alone
- A phase 3 trial evaluating intermittent relacorilant + nab-paclitaxel vs. chemotherapy will start in the second quarter of 2022

Phase 3 Working Design: Open-label, Randomized, 2-Arm Study



Ovarian Cancer Phase 3 Trial Endpoint Considerations



FDA ovarian cancer clinical trial endpoints workshop*

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A R T I C L E I N F O

Article history:

Received 6 July 2017 Received in revised form 5 August 2017 Accepted 8 August 2017 Available online xxxx

Keywords:

Clinical trial endpoints Ovarian cancer Patient reported outcomes Regulatory approval Immunotherapy Rare tumors

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Cortisol Modulation Has Significant Potential in Oncology

Clinical studies demonstrate relacorilant's differentiation in PROC

- Meaningful efficacy improvements
 - Progression Free Survival
 - Duration of Response
 - Overall Survival
- No additional side effect burden
 - Comparable to nab-paclitaxel monotherapy
- Convenient administration
 - Oral formulation
 - Intermittent dosing

Future opportunities

- Earlier lines of ovarian cancer
- Other tumors:
 - Combination with nab-paclitaxel
 - Combination with other chemotherapies
 - Combination with other antitumor agents

Questions?

