Corcept Therapeutics is excited to announce that on March 25, 2026, the US Food and Drug Administration (FDA) approved LIFYORLI™ (relacorilant) for use in combination with nab-paclitaxel for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1-3 prior systemic treatment regimens, at least one of which included bevacizumab.[1]

LIFYORLI, a first-in-class selective glucocorticoid receptor antagonist, enhances chemosensitivity.[1,2]*

LIFYORLI plus nab-paclitaxel **significantly extended overall survival** with no biomarker requirement.[1,2]

In the **Phase 3, randomized, controlled, open-label, ROSELLA trial of 381 women with platinum-resistant ovarian cancer,** LIFYORLI + nab-paclitaxel demonstrated[1,2]:

- **Median OS: 16.0 months** (13.0-18.3) with LIFYORLI + nab-paclitaxel vs **11.9 months** (10.0-13.8) with nab-paclitaxel alone; HR, 0.65 (95% CI, 0.51-0.83); *P*=0.0004[1†]
- **Median PFS: 6.5 months** (5.6-7.4) with LIFYORLI + nab-paclitaxel vs **5.5 months** (3.9-5.9) with nab-paclitaxel alone; HR, 0.70 (95% CI, 0.54-0.91); *P*=0.0076[1†]

*Enhanced sensitivity in nonclinical models.[1]

†Two-sided *P* value based on a stratified log-rank test.[1]

HR, hazard ratio; OS, overall survival; PFS, progression-free survival.

Serious adverse reactions occurred in 35% of patients who received LIFYORLI in combination with nab-paclitaxel. Serious adverse reactions (≥2%) in patients were neutropenia (4%), pneumonia (3.2%), pleural effusion (3.2%), febrile neutropenia (2.1%), and fatigue (2.1%). Fatal adverse reactions (2.1%) in patients were septic shock (0.5%), cardiac arrest (0.5%), ischemic stroke (0.5%), and intestinal perforation (0.5%).[1]

The most common adverse reactions (>20%) of patients treated with LIFYORLI plus nab-paclitaxel, including laboratory abnormalities, were decreased hemoglobin, decreased neutrophils, fatigue, nausea, diarrhea, decreased platelets, rash, and decreased appetite.[1]

LIFYORLI is now available through:

- Specialty distributors for community oncology medically integrated dispensaries and hospital-owned pharmacies
- Onco360, an in-network, independent specialty pharmacy, for practices without dispensing capabilities

The National Drug Code (NDC) for LIFYORLI is as follows[1]:

150 mg

76346-550-09
9-dose supply: 3 cartons (NDC 76346-550-03)‡ each containing one blister card with three 150 mg doses

76346-450-01
1-dose supply: 1 blister card containing one 150 mg dose

‡NDC 76346-550-03 is a 3-dose supply carton and can be dispensed individually if needed. Each 150 mg dose consists of one 100 mg capsule and two 25 mg capsules.

125 mg

76346-525-09
9-dose supply: 3 cartons (NDC 76346-525-03)§ each containing one blister card with three 125 mg doses

76346-425-01
1-dose supply: 1 blister card containing one 125 mg dose

§NDC 76346-525-03 is a 3-dose supply carton and can be dispensed individually if needed. Each 125 mg dose consists of one 100 mg capsule and one 25 mg capsule.

LIFYORLI is administered in combination with nab-paclitaxel.[1]

- Nab-paclitaxel (80 mg/m^2): Administered intravenously on Days 1, 8, and 15 of a 28-day cycle
- LIFYORLI (150 mg or 125 mg): Administered orally daily for 3 days (the day before, the day of, and the day after administering nab-paclitaxel)

INDICATIONS & USAGE

LIFYORLI is indicated in combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1-3 prior systemic treatment regimens, at least one of which included bevacizumab.

IMPORTANT SAFETY INFORMATION

Contraindications:

LIFYORLI is contraindicated in patients receiving systemic glucocorticoids for lifesaving purposes (e.g., immunosuppression after organ transplantation) because LIFYORLI antagonizes the effect of glucocorticoids.

Warnings and Precautions:

Neutropenia and Severe Infections

LIFYORLI in combination with nab-paclitaxel can cause neutropenia, including febrile neutropenia and severe infections. There was one fatal event of septic shock with febrile neutropenia. Thirty-eight percent of patients initiated granulocyte colony-stimulating factor (G-CSF) during the first or second cycle of therapy. Monitor complete blood counts prior to each weekly treatment with LIFYORLI in combination with nab-paclitaxel and as clinically indicated. Based on the severity of neutropenia, delay dose, reduce dose, or permanently discontinue LIFYORLI in combination with nab-paclitaxel. Consider short-acting G-CSF administration as applicable. Consider the possibility of concurrent adrenal insufficiency, particularly in the setting of serious infection.

Adrenal Insufficiency

LIFYORLI is a reversible glucocorticoid receptor antagonist and can cause adrenal insufficiency. Adrenal insufficiency can occur at any time during treatment with LIFYORLI. The risk of adrenal insufficiency is increased in situations of stress, such as acute illness, infection, or surgery. Consider whether supplemental glucocorticoids are required in the perioperative period in patients who have received LIFYORLI within 30 days of surgery. Monitor patients receiving LIFYORLI for signs and symptoms of adrenal insufficiency. Withhold LIFYORLI and administer glucocorticoid therapy if adrenal insufficiency is suspected. High doses of supplemental glucocorticoids may be needed to overcome the glucocorticoid receptor

antagonism produced by LIFYORLI. After resolution of adrenal insufficiency, resume previous dose, reduce dose, or permanently discontinue LIFYORLI based on severity.

Exacerbation of Conditions Treated with Glucocorticoids

Use of LIFYORLI in patients taking systemic glucocorticoids for other conditions (e.g., autoimmune disorders) may exacerbate these conditions. LIFYORLI is a glucocorticoid receptor antagonist that may make systemic glucocorticoids less effective. Similarly, coadministration of systemic glucocorticoids may make LIFYORLI less effective. Monitor patients for reduced effectiveness of LIFYORLI and glucocorticoids in patients receiving both.

Embryo-Fetal Toxicity

LIFYORLI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Verify pregnancy status of females of reproductive potential prior to initiating LIFYORLI treatment. Advise females of reproductive potential, including male patients with female partners of reproductive potential, to use effective contraception during treatment with LIFYORLI and for 1 week after the last dose.

Adverse Reactions:

Serious adverse reactions occurred in 35% of patients who received LIFYORLI in combination with nab-paclitaxel. Serious adverse reactions (≥2%) in patients were neutropenia (4%), pneumonia (3.2%), pleural effusion (3.2%), febrile neutropenia (2.1%), and fatigue (2.1%). Fatal adverse reactions (2.1%) in patients were septic shock (0.5%), cardiac arrest (0.5%), ischemic stroke (0.5%), and intestinal perforation (0.5%).

Permanent discontinuation of LIFYORLI in combination with nab-paclitaxel due to adverse reactions occurred in 9% of patients. The adverse reaction (>2%) that resulted in permanent discontinuation of LIFYORLI in patients

was intestinal obstruction (2.6%). Dosage interruptions of LIFYORLI due to an adverse reaction occurred in 72% of patients. Adverse reactions (≥5%) that required dosage interruptions of LIFYORLI in combination with nab-paclitaxel in patients included neutropenia (44%), anemia (12%), and fatigue (7%).

Adverse reactions requiring dose reductions of LIFYORLI included fatigue (1.6%), decreased appetite (1.2%), abdominal pain (0.5%), neutropenia (0.5%), edema (0.5%), and sciatica (0.5%). LIFYORLI should be interrupted or discontinued when nab-paclitaxel is interrupted or discontinued.

The most common adverse reactions (>20%) of patients treated with LIFYORLI plus nab-paclitaxel, including laboratory abnormalities, were decreased hemoglobin, decreased neutrophils, fatigue, nausea, diarrhea, decreased platelets, rash, and decreased appetite.

Drug Interactions:

- **Strong CYP3A Inducers:** Avoid coadministration of LIFYORLI plus nab-paclitaxel with strong CYP3A inducers. Both relacorilant and paclitaxel are CYP3A substrates. Coadministration of strong CYP3A inducers can decrease concentrations of relacorilant and paclitaxel, which may reduce their effectiveness.

- **CYP2C8 and Moderate CYP3A Inducers:** Monitor for reduced effectiveness of LIFYORLI plus nab-paclitaxel with CYP2C8 inducers and moderate CYP3A inducers. Paclitaxel is a substrate of CYP2C8 and CYP3A, and relacorilant is a CYP3A substrate. Coadministration of CYP2C8 and moderate CYP3A inducers can decrease concentrations of paclitaxel and relacorilant, which may reduce their effectiveness.

- **CYP2C8 Inhibitors:** Monitor for increased adverse reactions and modify the dosage for adverse reactions as recommended. Paclitaxel is a substrate of CYP2C8. Coadministration of CYP2C8 inhibitors may increase concentrations of paclitaxel, which may increase the risk of adverse reactions.

- **CYP3A Substrates:** Avoid concomitant use unless otherwise recommended in the Prescribing Information for CYP3A substrates. Relacorilant is a strong CYP3A inhibitor. Relacorilant increases exposure of CYP3A substrates which may increase the risk for adverse reactions related to these substrates.

- **Certain CYP2C8 Substrates:** Avoid concomitant use unless otherwise recommended in the Prescribing Information for CYP2C8 substrates where minimal concentration changes may lead to reduced effectiveness. Relacorilant is a weak CYP2C8 inducer. Relacorilant decreases exposure of CYP2C8 substrates which may decrease the effectiveness related to these substrates.

Use in Specific Populations:

- **Lactation:** Advise women not to breastfeed during treatment with LIFYORLI and for 1 week after the last dose.

- **Geriatric Use:** A higher incidence of grade 3-4 adverse events and dosage modification occurred in patients aged ≥65 years compared to younger adult patients.

- **Hepatic Impairment:** Avoid LIFYORLI in combination with nab-paclitaxel in patients with moderate or severe hepatic impairment (total bilirubin >1.5 to 10x ULN and any AST).

Please see the full Prescribing Information for additional Important Safety Information.

References: 1. LIFYORLI™. Prescribing information. Corcept Therapeutics, Inc.; 2026. **2.** Olawaiye AB, et al. Relacorilant and nab-paclitaxel in patients with platinum-resistant ovarian cancer (ROSELLA): an open-label, randomised, controlled, phase 3 trial. Lancet. 2025;405(10496):2205-2216. doi:10.1016/S0140-6736(25)01040-2 **3.** [Data on file. Corcept Therapeutics.]