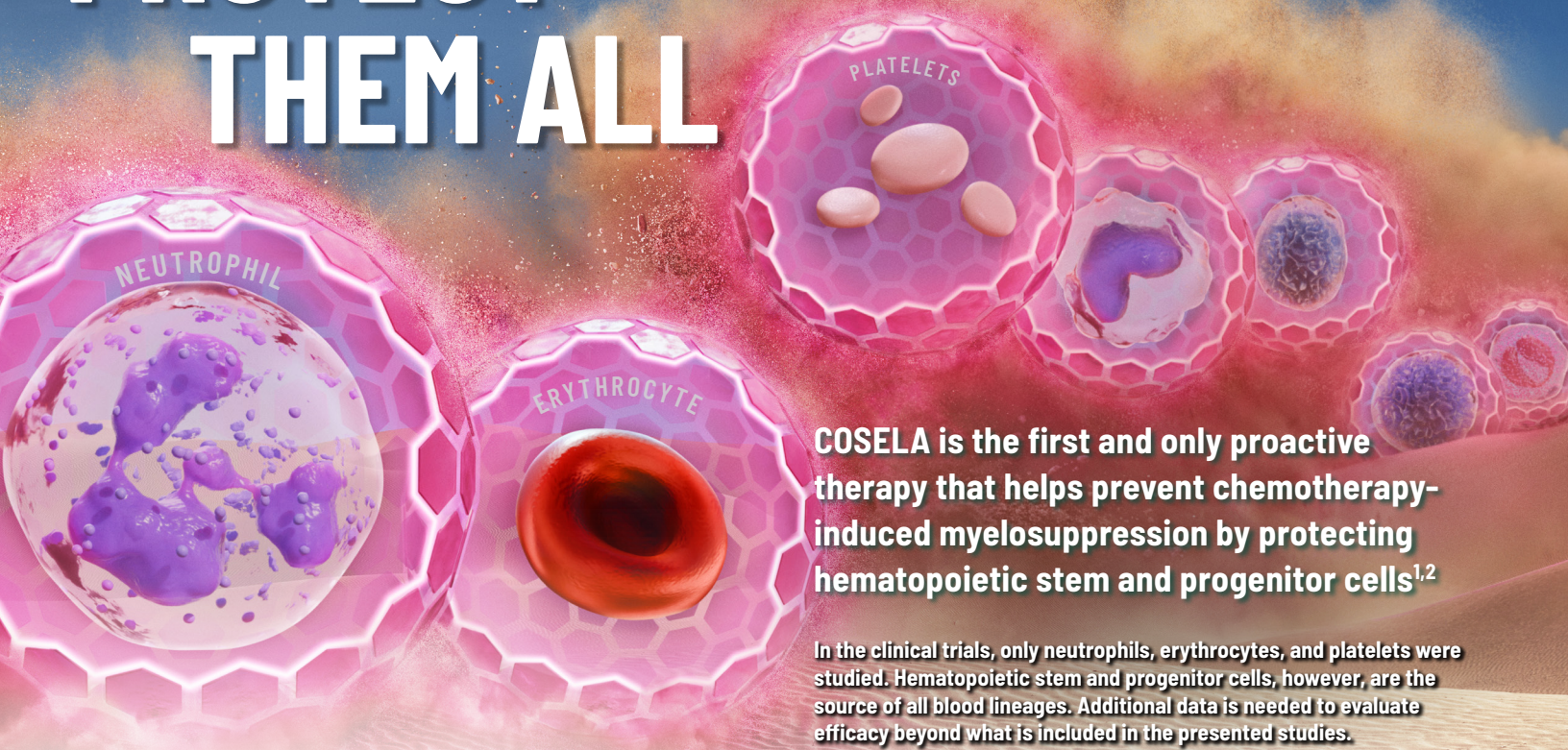
To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

For extensive-stage small cell lung cancer (ES-SCLC)

COSELA®
trilaciclib for injection 300 mg

PROTECT THEM ALL



COSELA is the first and only proactive therapy that helps prevent chemotherapy-induced myelosuppression by protecting hematopoietic stem and progenitor cells[1,2]

In the clinical trials, only neutrophils, erythrocytes, and platelets were studied. Hematopoietic stem and progenitor cells, however, are the source of all blood lineages. Additional data is needed to evaluate efficacy beyond what is included in the presented studies.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

WARNINGS AND PRECAUTIONS

Injection-Site Reactions, Including Phlebitis And Thrombophlebitis

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

Please see Important Safety Information throughout this brochure and accompanying Full Prescribing Information.

STUDIED IN 3 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED REGISTRATIONAL STUDIES[1-4,a]

Overview of 3 studies, including patients ages 18-65+ years old[1-4,a-c]

- **Pivotal (Study 1):**
  COSELA (n=54) or placebo (n=53) + etoposide-carboplatin-atezolizumab in 1L ES-SCLC
- **Study 2:**
  COSELA (n=39) or placebo (n=38) + etoposide-carboplatin in 1L ES-SCLC
- **Study 3:**
  COSELA (n=32) or placebo (n=29) + topotecan in 2L/3L ES-SCLC
- Patients were not stratified by risk of myelosuppression or other baseline risk factors

Key endpoints in Pivotal Study and Study 3

- **Primary:**
  Percentage of patients and mean number of days (in Cycle 1) with Grade 4 neutropenia[1,2]
- **Secondary[1,2,4,d]:**
  - Percentage of patients requiring: G-CSFs,[d] red blood cell transfusions (on/after week 5),[d] platelet transfusions,[e] ESAs[f]
  - Percentage of patients with Grade 3 or 4 hematologic laboratory abnormalities[f]
  - All-cause chemotherapy dose reductions[d]
  - Safety and tolerability
- Study 2 was a proof-of-concept study with the primary objectives of assessing safety and tolerability; efficacy objectives were secondary or exploratory[3]

1L=1st-line; 2L=2nd-line; 3L=3rd-line; ES-SCLC=extensive-stage small cell lung cancer; ESA=erythropoiesis-stimulating agent; G-CSF=granulocyte colony-stimulating factor.

[a]During Cycle 1, primary prophylactic G-CSF and ESA use was prohibited in all 3 studies. Both ESAs and primary prophylactic G-CSF were allowed from Cycle 2 onwards as clinically indicated. Therapeutic G-CSF, red blood cells, and platelet transfusions were allowed at any time during the studies as clinically indicated.[1]
[b]All studies were treated until disease progression or unacceptable toxicity.[1]
[c]All studies were stratified by Eastern Cooperative Oncology Group Performance Status (0/1 vs 2). In Study 1 also stratified by presence of brain metastases, and in Study 2 by sensitivity to 1L treatment.[1]
[d]Key secondary endpoints in the Pivotal Study and Study 3.
[e]Platelet transfusions were a supportive secondary endpoint in the Pivotal Study and a key secondary endpoint in Study 3.
[f]Supportive secondary endpoints in the Pivotal Study and Study 3.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Interstitial Lung Disease/Pneumonitis

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

Please see Important Safety Information throughout this brochure and accompanying Full Prescribing Information.

COSELA REDUCES THE RISK OF EVENTS RELATED TO CHEMOTHERAPY-INDUCED MYELOSUPPRESSION[1]

In clinical trials, patients with ES-SCLC who received COSELA had:

- **Reduced rates** of neutropenia, anemia, and thrombocytopenia from chemotherapy[1,a]
- **Lower incidence** of chemotherapy dose reductions/delays[2-4]
- **Fewer G-CSF and ESA** administrations and red-blood cell transfusions[2-4]

COSELA is the first and only transient IV CDK4/6 inhibitor[1,2]

In a pooled analysis, patients with ES-SCLC who received COSELA:

- **Experienced lower rates** of hospitalizations due to chemotherapy-induced myelosuppression or sepsis[5]
- Reported **slower rates of decline** in health-related quality of life[5]

Dose COSELA prior to every chemotherapy infusion

- The recommended dose of COSELA is 240 mg/m^2 per dose. Administer as a 30-minute intravenous infusion completed within 4 hours before starting chemotherapy on each day chemotherapy is administered[1]
  - The interval between doses of COSELA on sequential days should not be greater than 28 hours[1]

ESA=erythropoiesis-stimulating agent; G-CSF=granulocyte colony-stimulating factor.
[a]Including a platinum/etoposide-containing regimen or topotecan-containing regimen.

IMPORTANT SAFETY INFORMATION (continued)

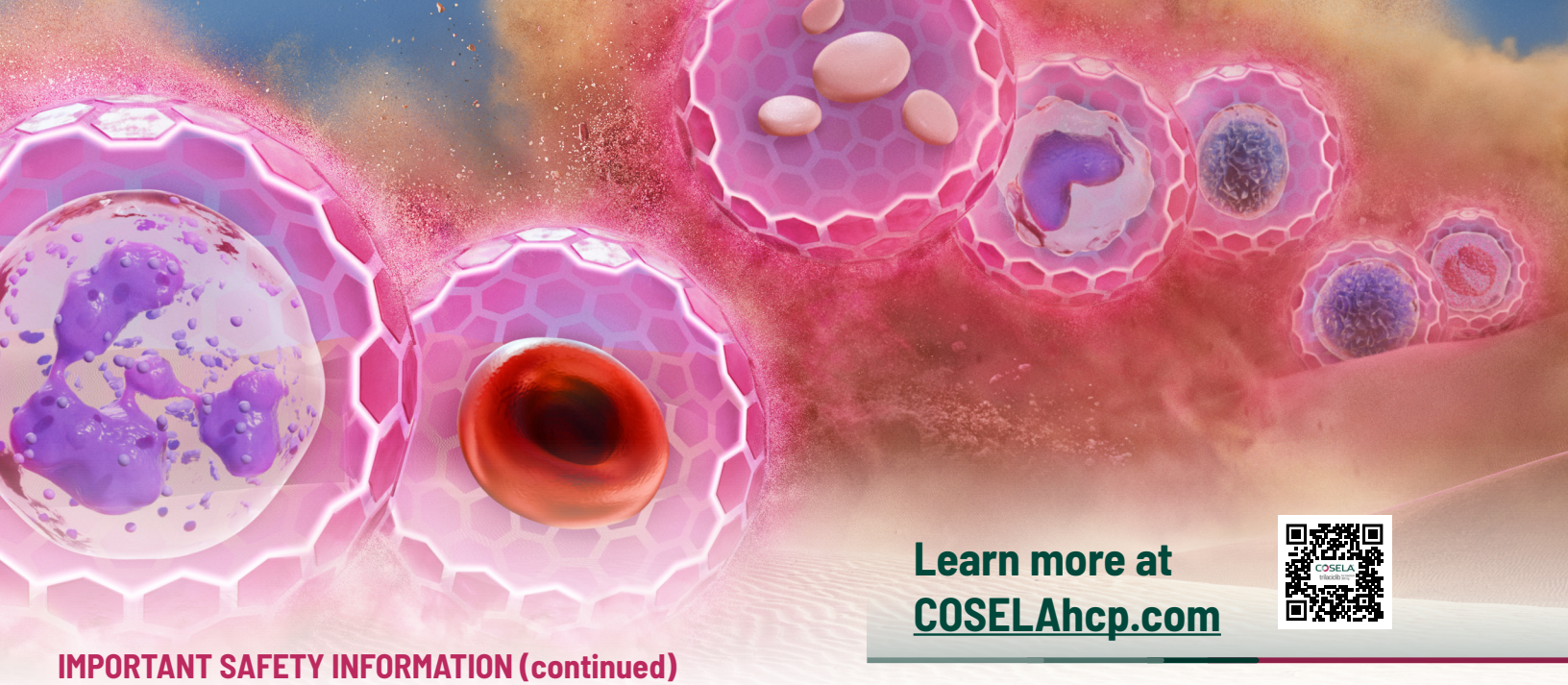
WARNINGS AND PRECAUTIONS (continued)

Embryo-Fetal Toxicity

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

Please see Important Safety Information throughout this brochure and accompanying Full Prescribing Information.

COSELA®
trilaciclib for injection 300 mg



Learn more at COSELAhcp.com

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.
- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).
- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

To report suspected adverse reactions, contact Pharmacosmos Therapeutics at 1-800-790-4189 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Important Safety Information throughout this brochure and accompanying Full Prescribing Information.

References: 1. COSELA (trilaciclib) Prescribing Information. Pharmacosmos Therapeutics Inc.; 2025. **2.** Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive-stage small cell lung cancer: a multicentre, randomised, double-blind, placebo-controlled phase II trial. *Int J Cancer*. 2021;148:2557-2570. **3.** Weiss JM, Csoszi T, Maglakelidze M, et al, for the G1T28-02 Study Group. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: a phase 1b/randomized phase II trial. *Ann Oncol*. 2019;30:1613-1621. **4.** Hart LL, Ferrarotto L, Andric ZG, et al. Myelopreservation with trilaciclib in patients receiving topotecan for small cell lung cancer: results from a randomized, double-blind, placebo-controlled phase II study. *Adv Ther*. 2021;38:350-365. **5.** Weiss J, Goldschmidt J, Andric Z, et al. Effects of trilaciclib on chemotherapy-induced myelosuppression and patient-reported outcomes in patients with extensive-stage small cell lung cancer: pooled results from three phase II randomized, double-blind, placebo-controlled studies. *Clin Lung Cancer*. 2021;22(5):449-460.

PHARMACOSMOS THERAPEUTICS

COSELA®
trilaciclib for injection 300 mg