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Statement In Response To Texas Ruling Upending FDA Approval of Mifeprex®

Danco Laboratories Will Seek Stay While Immediately Appealing

APRIL 7, 2023 – Danco Laboratories strongly disagrees with the unprecedented preliminary injunction issued by US District Judge Matthew Kacsmaryk in *The Alliance for Hippocratic Medicine, et al., v. U.S. Food and Drug Administration, et al.* The lawsuit seeks to overturn FDA's two-plus-decade old approval of Mifeprex and its approval of a generic version of the drug mifepristone. The ruling states that the court is "staying" the 2000 approval of Mifeprex and all subsequent challenged actions related to that approval for the duration of the lawsuit. The ruling is set to take effect in seven days, during which time the Defendants will seek a stay from the US Court of Appeals for the Fifth Circuit.

Danco is the manufacturer of Mifeprex, the branded drug product approved for use in medical abortion and the reference product for generic mifepristone. Danco affirmatively joined the case as a defendant to protect the availability of Mifeprex for pregnant women and the company's only product, recognizing the importance of mifepristone as the only drug approved for medication abortion. "This is a dark day for public health, especially for reproductive rights and the reliance on science and medical expertise to guide decisions about what drugs are safe and effective and should be available to patients," said Abby Long, Danco's Director of Public Affairs. "The court's order fails to account for the meticulous, well-documented FDA decision-making process that led to the initial 2000 approval and the subsequent approvals setting the conditions under which Mifeprex has been distributed for 23 years. The court blithely strikes down access to a treatment that is safe and effective and has been essential for millions of people for decades – and that remains legal in many states today."

Jessica Ellsworth, a partner in the international law firm Hogan Lovells and the lead counsel for Danco in this case, said "The court's ruling rewrites the facts and the law to tell its preferred narrative—which is a storyline that conflicts with established legal principles and with Mifeprex's well-established safety profile. Danco is appealing this ruling and feels strongly that the rule of law should prevail in this case, which would result in a reversal of this ruling. Danco will continue to take all steps available in this litigation to protect the availability and accessibility of Mifeprex."

"Today's decision is wrong on the medicine and science, wrong as a matter of public health policy, wrong as a matter of reproductive rights, and wrong as a matter of law," Long said. "We will appeal this to the Fifth Circuit and to the Supreme Court, if necessary, while working hard and creatively with FDA, state authorities, healthcare providers, reproductive rights organizations and others to maintain access and do all we can to make Mifeprex available legally."

Over 5 million women have used Mifeprex® in the United States since its approval for the termination of early pregnancy in 2000. Mifeprex® is ~97% effective in terminating early

pregnancy; approximately 3% of women will require surgical intervention for ongoing pregnancy, heavy bleeding, incomplete expulsion, or other reasons such as patient request.

MIFEPREX: Important Safety Information

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis.**
- **Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.**

MIFEPREX is only available through a restricted program called the Mifepristone REMS Program.

Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.

Contraindications

- Administration of MIFEPREX and misoprostol for the termination of pregnancy is contraindicated in patients with any of the following conditions:
- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy)
- Chronic adrenal failure (risk of acute renal insufficiency)
- Concurrent long-term corticosteroid therapy (risk of acute renal insufficiency)
- History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported)
- Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)
- Inherited porphyrias (risk of worsening or of precipitation of attacks)
- Use of MIFEPREX and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device (“IUD”) in place (the IUD might interfere with pregnancy termination). If the IUD is removed, MIFEPREX may be used.

Warnings and Precautions

Infection and Sepsis

As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of MIFEPREX. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.

A high index of suspicion is needed to rule out sepsis if a patient reports abdominal pain, discomfort, or general malaise (including weakness, nausea, vomiting or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise.

Uterine Bleeding

Uterine bleeding occurs in almost all patients during a medical abortion. Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion.

Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Because heavy bleeding requiring surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

Mifepristone REMS Program

MIFEPREX is available only through a restricted program under a REMS called the Mifepristone REMS Program, because of the risks of serious complications. Notable requirements of the Mifepristone REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form.
- Patients must sign a Patient Agreement Form.
- MIFEPREX must only be dispensed to patients by or under the supervision of a certified prescriber, or by certified pharmacies on prescriptions issued by certified prescribers.

Ectopic Pregnancy

MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy.

Women who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

Rhesus Immunization

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

Adverse Reactions

Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. The frequency of adverse reactions varies between studies and may be dependent on many factors including the patient population and gestational age.

This is the Important Safety Information. For more information, please see the Full Prescribing Information, including **BOXED WARNING and Medication Guide**, available at **www.earlyoptionpill.com**.