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STATEMENT OF DANCO LABORATORIES REGARDING MIFEPREX®

March 17, 2023 – Danco Laboratories forcefully defended the approval of Mifeprex® in a four-hour hearing held in federal court in Amarillo, Texas in *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*. The plaintiffs in this case raise a series of meritless challenges to FDA's approval of Mifeprex®, including the agency's analysis of the drug's safety profile, which dates back to 2000, and to the REMS that has governed the distribution and use of Mifeprex since 2008. The hearing laid bare both the unprecedented nature of the plaintiffs' legal theory and the speculative nature of their factual allegations.

No court has ever found that doctors can ask a court to suspend or withdraw the approval of a drug based on attenuated theories of potentially having to treat side effects or complications of a drug another doctor prescribed. Here, the plaintiff doctors admittedly do not prescribe mifepristone, and are speculating that *other doctors* may prescribe it for *those other doctor's patients* who seek a medication abortion, and that those patients might hypothetically one day in the future be treated for follow-up care by the plaintiff doctors. The consequences of this far-fetched theory are stark: It would undermine the FDA drug approval process and the pharmaceutical industry if doctors (or other hypothetically and tangentially related parties) could seek to overturn the approval of a drug in these circumstances.

Additionally, the plaintiffs argued for a reading of the Food, Drug, and Cosmetic Act that would remove the ability of FDA to exercise its scientific and medical expertise to determine the appropriate labeling for a drug based on the agency's assessment of clinical trials and other data submitted in support of approval. This too would upend the pharmaceutical industry and has no basis in (and in fact contradicts) the statute, FDA's regulations or case law. The plaintiffs ultimately were forced to admit that they could point to no precedent consistent with their view of the federal statutes at issue. They acknowledged that no court has ever ordered FDA to withdraw approval of a drug that, like Mifeprex®, has been approved and safely used for more than 20 years.

Because of the many legal and factual shortcomings in the plaintiffs' theory, which came into the spotlight at the hearing, Danco asked the court to deny plaintiffs' request that the court enjoin the decades' old approval of Mifeprex® and the approval of generic mifepristone. Danco joined this lawsuit in order to ensure that the FDA approval of Mifeprex® remains in force and people continue to have access to this safe and effective product.

Over 5 million women in the United States have used Mifeprex® since its approval in 2000 for the termination of early pregnancy. 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. The safety profile for mifepristone is well-established and has remained consistent for the more than two decades the drug has been marketed in the United States. Mifepristone is approved in 82 countries and on the World Health Organization's Model List of Essential Medicines for more than 15 years.

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**.