For Immediate Release

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American Regent Announces the FDA Approval of Hydroxyprogesterone Caproate Injection, USP; the First Preservative Free, AP Rated Generic to Makena®*[1]

Shirley, NY - American Regent today announced the launch of Hydroxyprogesterone Caproate Injection, USP, the only preservative free generic alternative to Makena®.

Hydroxyprogesterone Caproate Injection, USP is indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. "The approval of this preservative free, generic alternative represents our commitment to ensuring both patients and providers have access to additional, affordable treatment options for this women's health concern," said Ken Keller, President and CEO of American Regent, Inc.

Hydroxyprogesterone Caproate Injection, USP is not intended for use in women with multiple gestations or other risk factors for preterm birth.

Hydroxyprogesterone Caproate Injection, USP will be available in a 250 mg/mL, 1mL preservative free Single Dose Vial and can be ordered through wholesalers/distributors within the next several days. Customers may also contact our Customer Support Group at 1-800-645-1706. For additional ordering information, please visit americanregent.com.

Hydroxyprogesterone Caproate Injection, USP is supplied as follows:

NDC#	Strength	Supplied As	Shelf Pack
0517-1767-01	250 mg/mL	1 mL SDV	1

*Makena® is a trademark of AMAG Pharma USA, Inc.

See the following Important Safety Information in addition to the Full Prescribing Information.

Reference: 1. Approved Drug Products with Therapeutic Equivalence Evaluations.
https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=210723. Accessed June 2018

Hydroxyprogesterone Caproate Injection, USP

For intramuscular use.

INDICATIONS AND USAGE
Hydroxyprogesterone caproate injection is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.
It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Current or history of thrombosis or thromboembolic disorders; Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions; Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; Cholestatic jaundice of pregnancy; Liver tumors, benign or malignant, or active liver disease; Uncontrolled hypertension

WARNINGS AND PRECAUTIONS
Thromboembolic disorders: Discontinue if thrombosis or thromboembolism occurs
Allergic reactions: Consider discontinuing if allergic reactions occur
Decreased glucose tolerance: Monitor prediabetic and diabetic women receiving hydroxyprogesterone caproate injection
Fluid retention: Monitor women with conditions that may be affected by fluid retention, such as preeclampsia, epilepsy, cardiac or renal dysfunction
Depression: Monitor women with a history of clinical depression; discontinue hydroxyprogesterone caproate injection if depression recurs
Jaundice: Monitor women who develop jaundice while receiving hydroxyprogesterone caproate injection and consider whether the benefit of use warrants continuation
Hypertension: Monitor women who develop hypertension while receiving hydroxyprogesterone caproate injection and consider whether the benefit of use warrants continuation

ADVERSE REACTIONS
Most common adverse reactions reported in ≥2% of subjects and at a higher rate in the hydroxyprogesterone caproate injection group than in the control group were injection site reactions (pain [35%], swelling [17%], pruritus [6%], nodule [5%]), urticaria (12%), pruritus (8%), nausea (6%), and diarrhea (2%). For the most serious adverse reactions to the use of progestins, see *Warnings* and *Precautions*.

Postmarketing Experience
The following adverse reactions have been identified during post approval use of hydroxyprogesterone caproate injection. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Body as a whole: Local injection site reactions (including erythema, urticaria, rash, irritation, hypersensitivity, warmth); fatigue; fever; hot flashes/flushes
Digestive disorders: Vomiting
Infections: Urinary tract infection

Nervous system disorders: Headache, dizziness
Pregnancy, puerperium and perinatal conditions: Cervical incompetence, premature rupture of membranes
Reproductive system and breast disorders: Cervical dilation, shortened cervix
Respiratory disorders: Dyspnea, chest discomfort
Skin: Rash

USE IN SPECIFIC POPULATIONS
Pregnancy Risk Summary:
Data from the placebo-controlled clinical trial and the infant follow-up safety study did not show a difference in adverse developmental outcomes between children of hydroxyprogesterone caproate injection-treated women and children of control subjects. However, these data are insufficient to determine a drug-associated risk of adverse developmental outcomes as none of the hydroxyprogesterone caproate injection-treated women received the drug during the first trimester of pregnancy.

Lactation Risk Summary: Low levels of progestins are present in human milk with the use of progestin containing products, including hydroxyprogesterone caproate. Published studies have reported no adverse effects of progestins on the breastfed child or on milk production.

Pediatric Use: Hydroxyprogesterone caproate injection is not indicated for use in women under 16 years of age.

Hepatic Impairment: Hydroxyprogesterone caproate injection is extensively metabolized and hepatic impairment may reduce the elimination of hydroxyprogesterone caproate injection.

OVERDOSAGE
In the case of overdosage, the patient should be treated symptomatically.

For additional Safety Information, please see Full Prescribing Information.

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:
Email: pv@luitpold.com; Fax: 1-610-650-0170; Phone: 1-800-734-9236

ADEs may also be reported to the FDA at 1-800-FDA-1088 or to **www.fda.gov/Medwatch**

Drug Information:
1-888-354-4855 (9:00 am - 5:00 pm Eastern Time, Monday - Friday)

1-877-845-6371 (Available outside of normal business hours)

About American Regent
American Regent is a leader in the development, manufacturing and sales of generic and branded IV products. With a history of 50 years in generic specialty injectables, American Regent has sales approaching one billion dollars.

American Regent strives for continuous improvement to bring to market high quality innovative medications to meet unmet medical needs, and produces high quality accessible generic medications covering a wide array of therapeutic areas. American Regent is a member of the Daiichi Sankyo Group; and is headquartered in Shirley, NY.

For more information, please visit americanregent.com.

About Daiichi Sankyo

Daiichi Sankyo is a global pharmaceutical company with corporate origins in Japan. We provide innovative products and services in more than 20 countries around the world. With more than 100 years of scientific expertise, our company draws upon a rich legacy of innovation and a robust pipeline of promising new medicines to help patients.

Through the outstanding knowledge and commitment of our 15,000 employees worldwide, we create innovative new and generic medicines, and new methods of drug discovery and delivery. We share a passion for innovation, as well as compassion for the patients around the world who are in need of our medicines.

For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.