Sun Pharmaceutical Industries Ltd.,
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CIN: L24230GJ1993PLC019050
www.sunpharma.com

4 February 2020.

National Stock Exchange of India Ltd,
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (East),
Mumbai – 400 051.

BSE Limited,
Market Operations Dept.
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai - 400 001.

Dear Sirs,

Sub: Press Release

Please find enclosed herewith our Press Release relating to introduction of ABSORICA LD™ (isotretinoin) capsules for management of severe recalcitrant nodular acne in the US, which we shall be releasing after sending this letter to you. This is for your information and record.

Thanking you,

Yours faithfully,
For Sun Pharmaceutical Industries Ltd

A. I. Bhuta

Ashok I. Bhuta
Compliance Officer

Encl: as above

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Sun Pharma Introduces ABSORICA LD™ (isotretinoin) Capsules for Management of Severe Recalcitrant Nodular Acne in the U.S.

- *Newest isotretinoin formulation features micronization technology to optimize absorption at a lower dose*

- *Can be taken with or without food, removing uncertainty surrounding timing of dosing and making absorption more predictable*

Mumbai, India & Princeton, NJ, February 4, 2020 -- Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" including its subsidiaries and/or associate companies) today announced that one of its wholly owned subsidiaries has launched ABSORICA LD™ (isotretinoin) capsules in U.S. for the management of severe recalcitrant nodular acne in patients 12 years of age and older. ABSORICA LD is the only isotretinoin formulation to feature Sun Pharma's micronization technology, which utilizes micronized particles to optimize absorption at a 20% lower dose. ABSORICA LD can be taken with or without food.

"The launch of ABSORICA LD – which offers the proven efficacy and safety of ABSORICA® at a lower dose – underscores our commitment to making a difference in the lives of people with severe recalcitrant nodular acne," said Abhay Gandhi, CEO, North America, Sun Pharma.

"Severe recalcitrant nodular acne is characterized by nodules, which are hard, solid, painful lumps in the skin, and primarily affects teens and young adults," noted Nicholas Squittieri, MD, Chief Medical Officer, North America, Sun Pharma. "Ineffective acne treatment can cause lifelong physical scars as well as psychosocial issues such as feelings of isolation. ABSORICA LD makes visibly clearer skin possible within just five months, removes the uncertainty surrounding timing of dosing, and makes absorption more predictable. The availability of a low-dose, highly bioavailable oral isotretinoin option should be welcome news for those suffering from this very severe form of acne."

Relapse and retreatment rates for severe recalcitrant nodular acne are associated with insufficient absorption of isotretinoin. In a recent Phase IV open-label study evaluating the long-term efficacy and safety of ABSORICA in 166 patients, a single 20-week course of therapy resulted in complete and prolonged remission of severe recalcitrant nodular acne. After one 20-week course of ABSORICA therapy, 95% of patients didn't require additional isotretinoin treatment and 82% of patients didn't require any additional acne treatment (OTC or prescription) up to two years post-treatment.

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ABSORICA and ABSORICA LD can cause severe life-threatening birth defects and are contraindicated in pregnancy. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking any amount of ABSORICA or ABSORICA LD even for short periods of time. Because of the risk of embryo-fetal toxicity, ABSORICA and ABSORICA LD are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the iPLEDGE REMS.

ABSORICA LD 32 mg is bioequivalent to ABSORICA 40 mg under fed conditions. ABSORICA LD also delivers twice the level of absorption of ABSORICA in a fasted state, with a comparable safety profile. ABSORICA LD provides maximal isotretinoin absorption with a 20% lower dose, and is not substitutable with any other currently available isotretinoin.

The most common adverse reactions (incidence ≥ 5%) with ABSORICA LD or ABSORICA are: dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, increased creatine kinase, cheilitis, musculoskeletal discomfort, upper respiratory tract infection, and reduced visual acuity.

For more information visit www.AbsoricaLD.com

INFORMATION FOR ABSORICA & ABSORICA LD:

INDICATIONS AND USAGE

ABSORICA and ABSORICA LD (isotretinoin) capsules are indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with their use, ABSORICA and ABSORICA LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Limitations of Use:

If a second course of ABSORICA or ABSORICA LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy

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IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY – CONTRAINDICATED IN PREGNANCY

ABSORICA and ABSORICA LD can cause severe life-threatening birth defects and are contraindicated in pregnancy. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking any amount of ABSORICA or ABSORICA LD even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining prenatally whether an exposed fetus has been affected. If pregnancy occurs, discontinue ABSORICA and ABSORICA LD immediately and refer the patient to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Because of the risk of embryo-fetal toxicity, ABSORICA and ABSORICA LD are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the iPLEDGE REMS.

CONTRAINDICATIONS

Pregnancy: ABSORICA and ABSORICA LD are contraindicated in pregnancy

Hypersensitivity: ABSORICA and ABSORICA LD are contraindicated in patients with hypersensitivity to isotretinoin (or Vitamin A, given the chemical similarity to isotretinoin) or to any of its components (anaphylaxis and other allergic reactions have occurred)

WARNINGS AND PRECAUTIONS

ABSORICA and ABSORICA LD are Not Substitutable: The bioavailability and the recommended dosage of ABSORICA and ABSORICA LD are different. For example, while ABSORICA and ABSORICA LD both have a 20 mg strength, these strengths have different bioavailability and are not substitutable.

Psychiatric Disorders: ABSORICA and ABSORICA LD may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. Prior to and during therapy, assess for these conditions.

Patients should immediately stop ABSORICA and ABSORICA LD and promptly contact their prescriber if they develop depression, mood disturbance, psychosis, or aggression. Discontinuation of ABSORICA and ABSORICA LD may be insufficient; further evaluation may be necessary such as a referral to a mental healthcare professional.

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Intracranial Hypertension (Pseudotumor Cerebri): Isotretinoin use has been associated with cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided with ABSORICA and ABSORICA LD use.

Serious Skin Reactions: There have been postmarketing reports of erythema multiforme and severe skin reactions [e.g., Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)] associated with isotretinoin use. These reactions may be serious and result in death, life-threatening events, hospitalization, or disability. Patients should be monitored closely for severe skin reactions, and ABSORICA and ABSORICA LD should be discontinued if they occur.

Acute Pancreatitis: Acute pancreatitis has been reported with isotretinoin use in patients with either elevated or normal serum triglyceride levels. In rare instances, fatal hemorrhagic pancreatitis has been reported. If symptoms of pancreatitis occur, the patient should discontinue ABSORICA and ABSORICA LD and seek medical attention.

Lipid Abnormalities: Elevations of serum triglycerides above 800 mg/dL have been reported with isotretinoin use. These lipid changes were reversible upon isotretinoin capsule cessation. Some patients have been able to reverse triglyceride elevation by reduction in weight and restriction of dietary fat and alcohol while continuing isotretinoin or through dosage reduction. The cardiovascular consequences of hypertriglyceridemia associated with isotretinoin are unknown.

Hearing Impairment: Impaired hearing has been reported in patients taking isotretinoin; in some cases, the impairment has been reported to persist after therapy has been discontinued. Mechanism(s) and causality for this reaction have not been established. Patients who experience tinnitus or hearing impairment should discontinue ABSORICA or ABSORICA LD treatment and be referred for specialized care for further evaluation.

Hepatotoxicity: Clinical hepatitis has been reported with isotretinoin use. Additionally, mild to moderate elevations of liver enzymes have been observed in approximately 15% of individuals treated during clinical trials with isotretinoin capsules, some of which normalized with dosage reduction or continued administration of the drug. If normalization does not readily occur or if hepatitis is suspected during treatment, ABSORICA and ABSORICA LD should be discontinued.

Inflammatory Bowel Disease: Isotretinoin has been associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. In some instances, symptoms have been reported to persist after isotretinoin treatment has been stopped. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue ABSORICA or ABSORICA LD immediately.

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Musculoskeletal Abnormalities: Effects of multiple courses of isotretinoin on the developing musculoskeletal system are unknown. There is some evidence that long-term, high-dose, or multiple courses of therapy with isotretinoin have more of an effect than a single course of therapy on the musculoskeletal system. It is important that ABSORICA and ABSORICA LD be given at the recommended dose for no longer than the recommended duration.

Ocular Abnormalities: Visual problems should be carefully monitored. If visual difficulties occur, the patient should discontinue ABSORICA and ABSORICA LD treatment and obtain an ophthalmological examination.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 5%) are: dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, increased creatine kinase, cheilitis, musculoskeletal discomfort, upper respiratory tract infection, reduced visual acuity.

DRUG INTERACTIONS

Vitamin A: ABSORICA and ABSORICA LD are closely related to vitamin A. Therefore, the use of both vitamin A and ABSORICA or ABSORICA LD at the same time may lead to vitamin A related adverse reactions. Patients treated with ABSORICA and ABSORICA LD should be advised against taking supplements containing Vitamin A to avoid additive toxic effects.

Tetracyclines: Concomitant treatment with ABSORICA and ABSORICA LD and tetracyclines should be avoided because isotretinoin use has been associated with a number of cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines

USE IN SPECIFIC POPULATIONS

There are no data on the presence of isotretinoin in either animal or human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in nursing infants from isotretinoin, advise patients that breastfeeding is not recommended during treatment with ABSORICA and ABSORICA LD, and for at least 8 days after the last dose of ABSORICA or ABSORICA LD.

These are not all of the possible side effects of ABSORICA LD. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or Sun Pharmaceutical Industries, Inc. at 1-800-818-4555.

Please see full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

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About Sun Dermatology

Sun Dermatology (the branded dermatology division of a wholly owned subsidiary of Sun Pharmaceutical Industries Inc.) is committed to expanding its dermatology portfolio to bring healthcare providers and patients around the world more treatment options and ongoing support for conditions like moderate-to-severe plaque psoriasis. Sun Pharmaceutical Industries Ltd., along with its subsidiaries, is ranked second in dermatology prescription volume within the U.S. per IQVIA and is the fourth largest specialty generic pharmaceutical company globally. In addition to ABSORICA LD, Sun Dermatology is comprised of several branded products with a focus on various dermatologic conditions.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

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