Sun Pharma US
600 College Rd East
Princeton, NJ 08540
Tel: (609) 720-5000
Fax.: (609) 720-1155
www.sunpharma.com

FOR IMMEDIATE RELEASE

Sun Pharma announces its association with World Champion Snowboarder Kelly Clark for Absorica®

Kelly Clark documents her five-month successful treatment for severe recalcitrant nodular acne

Princeton, NJ – December 02, 2015 – Sun Pharma, today, announced its association with gold medalist snowboarder and 2015 ESPY Best Female Action Sports Athlete Kelly Clark. Through this association, Kelly Clark will share her life experience of living with severe recalcitrant nodular acne and her recent treatment with Absorica® (isotretinoin) capsules. The engagement with Kelly Clark is part of Sun Pharma's efforts to introduce a patient education program "Leave Acne Behind" and develop a variety of patient help resources and tools.

Absorica (isotretinoin) capsules are indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older[1]. This is the most severe form of acne for patients who are unresponsive to conventional therapy[1], including antibiotics. Kelly Clark has struggled with this condition since her early teens. She recently underwent successful treatment with Absorica.

Commenting on her treatment with Absorica, Kelly Clark said, "Living with severe recalcitrant nodular acne was challenging, I never knew when I would have a flare-up," explained Kelly. "Often it would be the day of an important competition or television interview and trying to conceal it was frustrating," she added. "I was relieved to learn about Absorica, not only because it offered me hope, but as a competitive athlete, it would not compromise my training diet. I can't be eating the high fat meals that would have been necessary with other isotretinoin treatments."

As part of the patient education tools Sun Pharma is creating, Kelly Clark has chronicled her journey by recording a bi-weekly vlog (video log) documenting her five month treatment regimen. Patients can access the vlogs on www.absorica.com along with an information video featuring Kelly and her treating dermatologist. These vlogs also feature the importance of mandatory patient participation in the iPLEDGE™ Program during isotretinoin treatment. The iPLEDGE Program is a safeguard to ensure that females of reproductive potential are not pregnant and don't get pregnant while taking isotretinoin.

The absorica.com website also hosts a patient educational brochure which explains how Absorica, unlike other generic isotretinoin therapies available, can be taken without regard to food so high-fat meals are not necessary.[1,2] The website also provides a highlight to PARTNERx SHIP™, which is Absorica's special delivery program. The PARTNERx SHIP program ensures timely delivery of medication, even to those who may be traveling away from home.

Commenting on Sun Pharma's association with Kelly Clark, Dr. Ashish Anvekar, Vice President, Brand Division - USA said, "We're very pleased that Kelly had such a positive treatment experience with Absorica. We hope that her successful journey inspires others with severe recalcitrant nodular acne to speak to their dermatologist about treatment options."

Isotretinoin is the standard treatment for the diagnosis of severe recalcitrant nodular acne. Absorica (isotretinoin) 10, 20, 25*, 30, 35*, 40 mg, launched in 2012, has become the most prescribed branded oral isotretinoin in the U.S., as per a recent sample survey conducted with 300 Dermatologists and other oral isotretinoin writers[3]. The product is licensed to Ranbaxy Laboratories Inc. (a SUN PHARMA company) by Cipher Pharmaceuticals, Inc.

Sun Pharma US
600 College Rd East
Princeton, NJ 08540
Tel: (609) 720-5000
Fax.: (609) 720-1155
www.sunpharma.com

Due to its high lipophilicity, oral absorption of isotretinoin is enhanced when given with a high-fat meal; however, Absorica which is formulated using a patented Lidose® Technology, can be given without regards to meals. The fasted AUC_{0-t} of Absorica is approximately 83% greater than that of Accutane® (isotretinoin) capsules, while both products are bioequivalent under fed conditions. Absorica is therefore not interchangeable and not substitutable with generic products of Accutane. Absorica, NDA, was approved based on a large pivotal clinical trial enrolling 925 patients.

*Launched in 2014

Please refer to the Absorica Safety Notice for a summary of important risk information, below. For more information see the package insert for full Prescribing Information for Boxed Warnings, Contraindications and other important Warnings and Precautions at http://www.absorica.com/absorica_pi.pdf.

SAFETY NOTICE

WARNING: CAUSES BIRTH DEFECTS

Pregnancy Category X

- **ABSORICA must not be used by female patients who are or may become pregnant.**
- **There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking ABSORICA in any amount, even for short periods of time.**
- **Potentially any fetus exposed during pregnancy can be affected.**
- **There are no accurate means of determining whether an exposed fetus has been affected.**
- **Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion and premature births have been reported.**
- **Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain abnormalities previously noted.**
- **If pregnancy does occur during the treatment of a female patient who is taking ABSORICA, ABSORICA must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.**

Special Prescribing Requirements

- **Because of the risk of teratogenicity and to minimize fetal exposure, ABSORICA is available only through a restricted Program under a Risk Evaluation and Mitigation Strategy (REMS) called iPLEDGE™. Under the ABSORICA REMS, prescribers, patients, pharmacies, and distributors must enroll and be registered in the Program.**

Sun Pharma US
600 College Rd East
Princeton, NJ 08540
Tel: (609) 720-5000
Fax.: (609) 720-1155
www.sunpharma.com

SUMMARY OF RISK INFORMATION FOR ABSORICA

CONTRAINDICATIONS

- **Pregnancy:** Major congenital malformations, spontaneous abortions, and premature births have been documented following pregnancy exposure to isotretinoin in any amount and even for short periods of time.
- **Hypersensitivity (Anaphylactic and Other Allergic Reactions):** ABSORICA is contraindicated in patients hypersensitive to ABSORICA or its components, or Vitamin A.

WARNINGS AND PRECAUTIONS

- **Teratogenicity:** Major congenital malformations, spontaneous abortions, and premature births have been documented following pregnancy exposure to isotretinoin.
- **Patients must be informed not to donate blood during isotretinoin therapy and for 1 month following discontinuation because the blood may be given to a pregnant female whose fetus must not be exposed to isotretinoin.**
- **Unacceptable Contraception:** Micro-dosed progesterone preparations are not an acceptable method of contraception during ABSORICA therapy.
- **Psychiatric Disorders:** Isotretinoin may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. No mechanism of action has been established for these reactions. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of ABSORICA therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary.
- **Pseudotumor Cerebri:** Isotretinoin use has been associated with cases of pseudotumor cerebri (benign intracranial hypertension), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided. Early signs and symptoms of pseudotumor cerebri include papilledema, headache, nausea and vomiting, and visual disturbances.
- **Serious Skin Reactions:** There have been post-marketing 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.
- **Acute pancreatitis, rarely fatal hemorrhagic pancreatitis, in patients with either elevated or normal serum triglyceride levels.**
- **Lipid Abnormalities:** Elevations of serum triglycerides in excess of 800 mg/dL have been reported in patients treated with isotretinoin. Some patients taking isotretinoin have developed a decrease in high-density lipoproteins (HDL), and an increase in cholesterol levels has been reported in some patients.
- **Hearing Impairment:** Impaired hearing has been reported in patients taking isotretinoin; in some cases, the hearing impairment has been reported to persist after therapy has been 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.
- **Bone Mineral Density Changes:** Isotretinoin may have a negative effect on bone mineral density (BMD) in some patients. Therefore, physicians should use caution when prescribing ABSORICA to patients with a history of childhood osteoporosis conditions, osteomalacia, or other disorders of bone metabolism.
- **Skeletal Abnormalities:** Back pain, arthralgias (in two trials of pediatric patients, back pain and arthralgias occurred in 29% and 22% of patients, respectively, including severe back pain and arthralgias in 13.5% and 7.6%, respectively), premature epiphyseal closure.
- **Ocular Abnormalities:** Visual problems should be carefully monitored. Decreased night vision has been reported during isotretinoin therapy and in some instances the event has persisted after therapy was discontinued. Corneal opacities and dry eye have also been reported.

Sun Pharma US
600 College Rd East
Princeton, NJ 08540
Tel: (609) 720-5000
Fax.: (609) 720-1155
www.sunpharma.com

- **Blood lipid determinations** should be performed before ABSORICA is given and then at intervals until the lipid response to ABSORICA is established, which usually occurs within 4 weeks. Especially careful consideration must be given to risk/benefit for patients who may be at high risk of triglyceridemia during ABSORICA therapy (patients with diabetes, obesity, increased alcohol intake, lipid metabolism disorder or familial history of lipid metabolism disorder).
- **Hepatotoxicity:** Since elevations of liver enzymes have been observed during clinical trials, and hepatitis has been reported in patients on isotretinoin, pretreatment and follow-up liver function tests should be performed at weekly or biweekly intervals until the response to ABSORICA has been established.
- **Glucose control problems and elevated CPK levels, including rare cases of rhabdomyolysis.**

ADVERSE REACTIONS

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

PLEASE SEE FULL PRESCRIBING INFORMATION FOR BOXED WARNING, CONTRAINDICATIONS, AND OTHER IMPORTANT WARNINGS AND PRECAUTIONS.

PATIENTS, PARENTS/LEGAL GUARDIANS OF MINORS SHOULD READ THE MEDICATION GUIDE.

Reference: 1. ABSORICA [prescribing information]. Jacksonville, FL: Ranbaxy Laboratories Inc; September 2015. 2. ABSORICA Medication Guide. Jacksonville, FL: Ranbaxy Laboratories Inc.; September 2015. 3. ABSORICA Claims Validation Study: Final Report. ITG Market Research, Inc. Data on file. Jacksonville, FL: Ranbaxy Laboratories Inc; August 5, 2014. [Confidence interval of ± 4.98% (based on a 95% confidence level). Based on a double-blind online survey of a randomly selected sample of 300 prescribers who wrote 35 or more oral isotretinoin prescriptions from January through March 2014.]

For more information please call 1-888-726-2299.

About Sun Pharma: Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 50 manufacturing facilities spread across 5 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2015 are approximately US$ 4.5 billion, of which US contributes US$ 2.2 billion. In India, the company enjoys leadership across 13 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of over 7% of annual revenues. For further information please visit www.sunpharma.com. Follow us on Twitter @SunPharma_Live

For Further Information Please Contact

Jill Metzger | RF|Binder | 212-994-7542 | jill.metzger@rfbinder.com

Frederick Castro | +91 9920665176 | Frederick.castro@sunpharma.com