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FOR IMMEDIATE RELEASE

Sun Pharma Odomzo® (Sonidegib) New Label Approval Shows Sustained Duration of Response of 26 Months in Treatment of Locally Advanced Basal Cell Carcinoma

Incorporates 30-month data showing sustained, durable efficacy and safety of 200-mg dose

Mumbai, September 20, 2017: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries or associate companies) today announced that one of its wholly owned subsidiaries has received approval from the US Food and Drug Administration (FDA) for a new label for Odomzo® (sonidegib), an oral hedgehog inhibitor indicated for the treatment of patients with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.
Odomzo® was approved by the FDA in July 2015, based on 12-month follow-up results from the pivotal Phase II Basal Cell Carcinoma Outcomes with LDE225 Treatment (BOLT) clinical trial, a multicenter, double-blind study involving 194 patients with laBCC and 36 patients with metastatic basal cell carcinoma (mBCC). The new label now incorporates long-term data from the 30-month analysis of BOLT trial, in which Odomzo® continued to show sustained durable tumor response of 26 months with no new safety concerns.

"We are pleased to incorporate the additional data to the Odomzo® label, as they show that Odomzo® is the only clinically proven hedgehog inhibitor which, by independent central review, maintains lasting tumor response for 26 months," said Kirti Ganorkar, Global Head – Business Development at Sun Pharma. "The rigor of the BOLT study design and results analyses should reassure patients and physicians that Odomzo® can treat this devastating and sometimes disfiguring disease over the long term."

BOLT Clinical Trial Overview
The BOLT trial enrolled 230 patients who were randomized 1:2 to receive either a 200-mg/day dose (laBCC, n = 66; mBCC, n = 13) or an 800-mg/day dose (laBCC, n = 128; mBCC, n = 23) of Odomzo®. Tumor response to Odomzo® was assessed via central review, based on the BCC-modified Response Evaluation Criteria In Solid Tumors (mRECIST), the most stringent response criteria for studying treatment efficacy in laBCC. The primary efficacy outcome was objective response rate (ORR), which was defined as the proportion of patients with a best overall response of complete response (CR) or partial response (PR). Duration of Response (DoR) was a key secondary outcome measure.

With 30 months of follow-up in the pivotal BOLT trial, Odomzo® treatment continued to demonstrate sustained antitumor activity and prolonged clinical benefit in patients with laBCC. Among patients treated with the 200-mg dose (approved dose), the ORR was 56%. The median duration of response was 26.1 months.

As in the primary (12 month) analysis, the 200-mg Odomzo® dose exhibited a low rate of grade 3/4 adverse events (AEs; 43.0%) and AEs leading to discontinuation (30.4%).

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The 30-month BOLT data, which were presented as a poster at the 2016 annual meeting of the American Society of Clinical Oncology (ASCO)[1], were recently published online in the Journal of the European Academy of Dermatology and Venereology on August 28, 2017.[2]

About Odomzo®

Odomzo® works by inhibiting a molecular pathway, known as the hedgehog signaling pathway, which is implicated in the origination and development of basal cell carcinoma when the pathway malfunctions. By blocking the hedgehog pathway, Odomzo® may halt or slow the growth of cancerous lesions. Odomzo® was acquired by Sun Pharma from Novartis in December 2016.

INDICATION

Odomzo® (sonidegib) is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

DOSAGE AND ADMINISTRATION

Recommended dose: 200 mg orally once daily taken on an empty stomach, at least 1 hour before or 2 hours after a meal.

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY

- Odomzo® can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. ODOMZO is embryotoxic, fetotoxic, and teratogenic in animals
- Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females of reproductive potential to use effective contraception during treatment with Odomzo® and for at least 20 months after the last dose
- Advise males of the potential risk of exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential during treatment with Odomzo® and for at least 8 months after the last dose

Embryo-fetal Toxicity: Odomzo® can cause embryo-fetal death or severe birth defects when administered to a pregnant woman.

Females of Reproductive Potential: Verify pregnancy status prior to initiating Odomzo®. Advise females to use effective contraception and not to breastfeed, due to the potential for serious adverse reactions in breastfed infants, during treatment and for at least 20 months after the last dose. Based on animal studies, female fertility may be compromised. Report pregnancies to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

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Males: Advise males to use condoms, even after a vasectomy, and to not donate semen during treatment and for at least 8 months after the last dose to avoid potential drug exposure in pregnant females or females of reproductive potential.

Blood Donation: Advise patients not to donate blood or blood products while taking Odomzo®, and for at least 20 months after the last dose because their blood or blood products might be given to a female of reproductive potential.

Musculoskeletal Adverse Reactions: Musculoskeletal adverse reactions, which may be accompanied by serum creatinine kinase (CK) elevations, occur with Odomzo® and other drugs which inhibit the hedgehog pathway. In a pooled safety analysis of 12 clinical studies involving 571 patients with various advanced cancers treated with Odomzo®, at doses ranging from 100 mg to 3000 mg, rhabdomyolysis (defined as serum CK increase of more than ten times the baseline value with a concurrent 1.5-fold or greater increase in serum creatinine above baseline value) occurred in 1 patient (0.2%) treated with Odomzo® 800 mg.

In Study 1, musculoskeletal adverse reactions occurred in 68% of patients treated with Odomzo® 200 mg daily, with 9% reported as Grade 3 or 4 serum CK elevations. The most frequent musculoskeletal manifestations reported were muscle spasms (54%), musculoskeletal pain (32%), and myalgia (19%). Increased serum CK laboratory values occurred in 61% of patients, with 8% having Grade 3 or 4. Musculoskeletal pain and myalgia usually preceded serum CK elevation. Odomzo® was temporarily interrupted in 8% of patients or permanently discontinued in 8% of patients for musculoskeletal adverse reactions. The incidence of musculoskeletal adverse reactions requiring medical intervention (magnesium supplementation, muscle relaxants, analgesics or narcotics) was 29%, including four patients (5%) who received intravenous hydration or were hospitalized.

Obtain baseline serum CK and creatinine levels prior to initiating Odomzo®, periodically during treatment, and as clinically indicated (e.g., if muscle symptoms are reported). Obtain serum creatinine and CK levels at least weekly in patients with musculoskeletal adverse reactions with concurrent serum CK elevation greater than 2.5 times ULN until resolution of clinical signs and symptoms. Temporary dose interruption or discontinuation may be required. Advise patients starting Odomzo® of the risk of muscle-related adverse reactions and to promptly report any new unexplained muscle pain, tenderness, or weakness occurring during treatment or that persists after discontinuing Odomzo®.

Drug Interactions: Avoid concomitant administration of Odomzo® with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, administer for less than 14 days and monitor closely for adverse reactions, particularly musculoskeletal. Avoid concomitant administration of Odomzo® with strong and moderate CYP3A inducers.

Geriatric Use: There was a higher incidence of serious adverse events, Grade 3 and 4, and events requiring dose interruption or discontinuation in patients ≥65 years compared with younger patients; this was not attributable to an increase in any specific adverse event.

Most Common Adverse Reactions: The most common adverse reactions occurring in ≥10% of patients were muscle spasms (54%), alopecia (53%), dysgeusia (46%), fatigue (41%), nausea (39%), musculoskeletal pain (32%), diarrhea (32%), decreased weight (30%), decreased appetite (23%),

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myalgia (19%), abdominal pain (18%), headache (15%), pain (14%), vomiting (11%), and pruritus (10%).

Please see U.S. Full Prescribing Information for Odomzo®, including **Boxed WARNING** regarding Embryo-Fetal Toxicity.

About Basal Cell Carcinoma

Non-melanoma skin cancer is the most common form of skin cancer globally, and basal cell carcinoma (BCC) is the most common type of non-melanoma skin cancer.[3] BCC is characterized by abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the outermost layer of the skin. The disease is most frequently seen on the most exposed areas to sun such as the head or neck.[4] BCC accounts for approximately 80% of non-melanoma skin cancers[5], and its worldwide incidence is rising by 10% each year due to factors such as an aging population and increased ultraviolet exposure.[6] BCC that spreads from where it started is called locally advanced and can be highly disfiguring. Advanced BCC is thought to represent roughly 1-10% of cases of BCC.

References

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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, 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 42 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 11 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 3 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 approximately 8% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live

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