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**FOR IMMEDIATE RELEASE**

## **Sun Pharma Presents ODOMZO® and LEVULAN® KERASTICK® + BLU-U® Data, Offering Clinical Insights for Treating People with or at Risk of Skin Cancer**

- *Sun Pharma is focused on supporting healthcare providers using its medicines to prevent and treat skin cancer, and exploring potential benefits for others at risk of skin cancer*
- *Analyses of long-term data confirm that the continued and clinically meaningful results of ODOMZO (sonidegib) in people with locally advanced basal cell carcinoma (laBCC) are not impacted by concomitant medicines*
- *Data analysis offers insights for using LEVULAN KERASTICK (aminolevulinic acid HCl) + BLU-U to treat minimally to moderately thick actinic keratoses, a precancerous skin growth, on the forearms*

**Mumbai, India and Princeton, NJ, June 13, 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 presented data analyses for two of its specialty medicines – ODOMZO® (sonidegib) and LEVULAN® KERASTICK® (aminolevulinic acid HCl) + BLU-U® – from its dermatology portfolio, providing insights to healthcare providers treating patients who have or are at risk for different types of skin cancer. These data analyses were presented at the American Academy of Dermatology (AAD) Virtual Meeting Experience 2020, June 12-June 14, accessible [here](#).

One in every three cancers diagnosed is a skin cancer, with the most common forms being basal cell carcinoma and squamous cell carcinoma, collectively known as nonmelanoma skin cancers.<sup>1,2</sup> It is estimated that nonmelanoma cancers affect more than three million Americans each year, a rate that has more than doubled in the last 50 years.<sup>1,2</sup> Both of these types of cancers are curable if detected early and treated properly.<sup>2</sup>

“With incidence rates increasing and more treatment options needed, we are committed to providing clinical support for our medicines and helping address the needs of patients who are impacted by the different stages of skin cancer,” said Nicholas Squittieri, M.D., Senior Medical Director, Sun Pharma. “The evidence presented at the AAD Virtual Meeting Experience offers important insights

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and guidance to dermatology healthcare providers who are using ODOMZO and LEVULAN in their daily clinical practice.”

[ODOMZO](#), a hedgehog inhibitor, is used to treat adults with locally advanced basal cell carcinoma (laBCC) that has returned following surgery or radiation or that cannot be treated with surgery or radiation. Long-term analyses of the BOLT study confirmed that treatment with ODOMZO provided clinically meaningful outcomes to patients with laBCC who were taking common concomitant medicines, such as medicines for cardiovascular, inflammatory and auto-immune diseases.<sup>3,4</sup> The safety profile for ODOMZO in these patients who were an average age of 67 years old was manageable and consistent with overall findings from the BOLT study.<sup>3,4</sup>

“Our research showed that the positive efficacy and safety benefits of ODOMZO were not impacted by commonly used medicines like statins or nonsteroidal anti-inflammatory drugs that some patients may need to take simultaneously to treat other health conditions,” said one of the lead study investigators Prof. Reinhard Dummer, M.D., Vice-Chairman of the Department of Dermatology, University Hospital of Zurich, Switzerland. “Since basal cell carcinoma is more commonly found in older adults, these insights are reassuring for dermatologists who are considering ODOMZO for their older patients.”

[LEVULAN KERASTICK](#) for topical solution, 20%, plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is used to treat minimally to moderately thick actinic keratoses of the face, scalp or upper extremities, which the Skin Cancer Foundation classifies as precancerous skin growths that if left untreated may turn into squamous cell carcinoma. While only about 10% of actinic keratoses become cancerous, the majority of squamous cell carcinoma cases start as actinic keratoses.<sup>5</sup>

“Effectively treating actinic keratoses is the only way to prevent their cancerous progression,” said lead investigator Brian Berman, M.D., Ph.D., Emeritus Professor, University of Miami Department of Dermatology and Cutaneous Surgery and Co-Director of the Center of Clinical and Cosmetic Research, Aventura, FL. “We are continually researching ways to treat actinic keratoses and our analysis of LEVULAN KERASTICK plus BLU-U offers our dermatology colleagues clinical insights and confidence to use this treatment for people with minimally to moderately thick actinic keratoses not only on the face and scalp but also on the forearms.”

The post hoc analysis offered more detailed insights into the benefits of photodynamic therapy (PDT) with LEVULAN KERASTICK + BLU-U to treat minimally to moderately thick actinic keratoses on the upper extremities, meaning the arms from elbows to base of the fingers:

- *Significantly Greater Clearance of Lesions* – At 12 weeks, the mean clearance rate of all lesions treated with PDT using LEVULAN KERASTICK + BLU-U was 80.6% after one or two treatments compared to 45.5% treated with placebo PDT

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- *Significantly Greater Clearance of Cumulative Disease Area* – Eight out of 10 patients (82.4%) treated with PDT using LEVULAN KERASTICK + BLU-U were 100% clear at 12 weeks after one or two treatments compared to four out of 10 patients (42.6%) treated with placebo PDT
- *Large Lesion Clearance* – More than half of patients treated with PDT using LEVULAN KERASTICK + BLU-U experienced complete clearance of larger lesions (70.6% with lesions 25–36 mm<sup>2</sup> and 59.5% with lesions ≥36 mm<sup>2</sup>)
- *No Safety Profile Concerns Raised* – PDT with LEVULAN KERASTICK + BLU-U was well tolerated, with no clinically significant adverse events reported or discontinuations due to adverse events<sup>6</sup>

LEVULAN KERASTICK is the only photodynamic therapy medicine approved by the US FDA for use on the upper extremities.

### **About the Analyses Presented at AAD Virtual Meeting Experience 2020**

#### *ODOMZO (sonidegib) Analyses*

Two post hoc analyses of the BOLT study assessed the response rates and duration of 66 patients with laBBC who were taking concomitant medications and ODOMZO and confirmed there was no impact on the efficacy and safety of ODOMZO 200 mg daily when taking common concomitant medications. These patients were taking ODOMZO as well as cardiovascular medicines such as statins (HMG-CoA reductase inhibitors), blood thinners (direct thrombin inhibitors) and high blood pressure medicines (angiotensin II receptor blockers or ACE inhibitors), as well as common medicines used to treat arthritis (NSAIDs) and inflammatory symptoms and autoimmune diseases (glucocorticoids or salicylic acid derivative). The safety profile of ODOMZO was manageable and consistent with previous analysis. At 42 months, 97% (64/66) of the patients experienced an adverse event with the majority of adverse events (AEs) being grade 1-2 in severity. The most frequent AEs were muscle spasms (56.1%), alopecia (51.5%), dysgeusia (47.0%) and nausea (37.9%).<sup>3,4</sup>

BOLT was a double-blind, randomized, controlled, 42-month study that evaluated ODOMZO 200 mg daily in 230 patients with locally advanced basal cell carcinoma (laBCC) and metastatic basal cell carcinoma (mBCC). Researchers evaluated objective response rate, which was defined as the proportion of patients with a best overall response of complete response or partial response.

Tumor response was evaluated using the BCC-modified Response Evaluation Criteria In Solid Tumors, which is the most stringent response criteria for studying treatment efficacy in laBCC. AEs were monitored 30 days after last dose.<sup>3,4</sup>

Through 42 months of the Phase 2 BOLT trial, ODOMZO (sonidegib) 200 mg once daily (QD) demonstrated durable efficacy and consistent/manageable toxicity.<sup>7,8,9</sup>

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### *LEVULAN KERASTICK (aminolevulinic acid HCl) + BLU-U Analyses*

A post hoc analysis of the Phase 3 trial supports the efficacy and safety benefits of photodynamic therapy (PDT) with LEVULAN KERASTICK + BLU-U to treat minimally to moderately thick actinic keratoses on the upper extremities compared to vehicle-controlled PDT (VEH-PDT). PDT with LEVULAN KERASTICK + BLU-U showed significantly greater clearance of lesions and significantly larger percent of cumulative disease area cleared (see chart below). There were no clinically significant AEs reported and no patients discontinued treatment due to AEs. Reactions to PDT were all expected, nonserious, and typically resolved within several weeks. Two (1.5%) patients treated with PDT using LEVULAN KERASTICK (aminolevulinic acid HCl) + BLU-U and one (0.7%) patient treated with VEH-PDT developed squamous cell carcinomas (SCCs) on treated extremities posttreatment. These patients all had a prior history of SCC.<sup>6</sup>

	Week 8 Results After 1 Treatment		Week 12 Results After 1 or 2 Treatments	
	PDT with LEVULAN KERASTICK + BLU-U	VEH-PDT	PDT with LEVULAN KERASTICK + BLU-U	VEH-PDT
Mean Clearance Rate of Treated Lesions	67.3%	37.2%	80.6%	45.5%
Cumulative Disease Area Cleared	67.8%	37.2%	82.4%	42.6%

$P < 0.0001$  using linear mixed model with fixed effects for treatment group, time point, and treatment group by time point interaction.

### **About ODOMZO (sonidegib)**

ODOMZO (sonidegib) is indicated for the treatment of adult 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. Recommended dose is 200 mg orally once daily taken on an empty stomach, at least one hour before or two hours after a meal.

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.

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**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

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. Report pregnancies to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

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.

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, which may be accompanied by serum creatine kinase (CK) elevations, occur with ODOMZO and other drugs which inhibit the hedgehog (Hh) pathway. Obtain serum CK and creatinine levels prior to initiating therapy, periodically during treatment, and as clinically indicated. Temporary dose interruption or discontinuation of ODOMZO may be required based on the severity of musculoskeletal adverse reactions.

ODOMZO is not indicated for use in pediatric patients. Premature fusion of the epiphyses has been reported in pediatric patients exposed to ODOMZO and other Hh pathway inhibitors. In some cases, fusion progressed after discontinuation.

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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.

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

The most common adverse reactions occurring in  $\geq 10\%$  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%), 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 LEVULAN KERASTICK (aminolevulinic acid HCl)**

LEVULAN KERASTICK (aminolevulinic acid HCl) for topical solution, 20%, plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratosis of the upper extremities.

### **IMPORTANT SAFETY INFORMATION**

Contraindicated in patients with cutaneous photosensitivity at wavelengths of 400–450 nm, porphyria, or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the LEVULAN KERASTICK topical solution.

Application of LEVULAN KERASTICK topical solution should involve lesions on the face or scalp, or upper extremities. Multiple lesions can be treated within a treatment region, but multiple treatment regions should not be treated simultaneously.

Do not apply to the eyes or to mucus membranes. Irritation may be experienced if LEVULAN KERASTICK topical solution is applied to eyes or mucous membranes. Treatment of upper extremities is approved after an incubation time of 3 hours under occlusion. Excessive irritation may be experienced if this product is applied under occlusion longer than 3 hours.

Transient amnesic episodes have been reported during postmarketing use of LEVULAN KERASTICK in combination with BLU-U Blue Light Photodynamic Therapy Illuminator. Inform patients and their



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caregivers that LEVULAN KERASTICK in combination with PDT may cause transient amnestic episodes. Advise them to contact the healthcare provider if the patient develops amnesia after treatment.

After LEVULAN KERASTICK topical solution has been applied, the treatment site will become photosensitive and patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) for 40 hours. To avoid unintended photosensitivity, LEVULAN KERASTICK topical solution should be applied by a qualified health professional to no more than 5 mm of perilesional skin surrounding each target actinic keratosis lesion.

Advise patients to wear a wide-brimmed hat or similar head covering of light-opaque material or a long-sleeved shirt and/or gloves to shade the treated actinic keratoses from sunlight or other bright light sources until at least 40 hours after the application of LEVULAN KERASTICK topical solution. Sunscreens will not protect against photosensitivity reactions caused by visible light. The patient should be advised to reduce light exposure if the sensations of stinging and/or burning are experienced.

LEVULAN KERASTICK topical solution has not been tested on patients with inherited or acquired coagulation defects.

It is possible that concomitant use of other known photosensitizing agents such as St. John's wort, griseofulvin, thiazide diuretics, sulfonyleureas, phenothiazines, sulfonamides and tetracyclines might increase the photosensitivity reaction of actinic keratoses treated with the LEVULAN KERASTICK topical solution.

During light treatment, both patients and medical personnel should be provided with blue blocking protective eyewear as specified in the BLU-U Blue Light Photodynamic Therapy Illuminator Operating Instructions.

The most common local adverse reactions (incidence  $\geq 10\%$ ) were erythema, edema, stinging/burning, scaling/crusting, itching, erosion, hypo/hyperpigmentation, oozing/vesiculation/crusting, scaling and dryness.

In clinical trials, severe stinging and/or burning was reported by at least 50% of face and scalp patients and 9% of upper extremity patients at some time during treatment. However, less than 3% of subjects receiving treatment for face or scalp lesions discontinued light treatment because of stinging/burning. No subjects discontinued light treatment in the trial for upper extremity lesions.

Please refer to the [Full Prescribing Information](#) for complete discussion of the risks associated with LEVULAN KERASTICK (aminolevulinic acid HCl) for topical solution, 20%.

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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 ILUMYA™, Sun Dermatology is comprised of several branded products with a focus on various dermatologic conditions.

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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](http://www.sunpharma.com) & follow us on Twitter [@SunPharma\\_Live](https://twitter.com/SunPharma_Live).

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### References

- 1) World Health Organization. [Skin Cancers](#). February 2020.
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