Sun Pharmaceutical Industries Ltd., SUN HOUSE, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343 CIN: L24230GJ1993PLC019050 www.sunpharma.com



# 22 December 2016.

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

We are pleased to enclose herewith our Press Release relating to acquisition of branded oncology product  $Odomzo^{\text{®}}$  (sonidegib) for global markets, 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 Bbe

Ashok I. Bhuta Compliance Officer

Encl: as above

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## FOR IMMEDIATE RELEASE

# Sun Pharma to acquire branded oncology product Odomzo<sup>®</sup> (sonidegib) for global markets

- Transaction gives Sun Pharma its first branded oncology product
- Odomzo<sup>®</sup> extends Sun Pharma's commitment in dermatology
- Odomzo<sup>®</sup> has marketing approval in over 30 countries globally including US, Europe and Australia

MUMBAI (INDIA) & PRINCETON NJ (USA) – 22 December 2016: Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies today announced its plans to acquire a branded oncology product, Odomzo, from Novartis. The agreement has been signed between subsidiaries of both the companies and will close following anti-trust clearance and further closing conditions. The agreement has been signed for an upfront payment of US\$ 175 million and additional milestone payments.

Odomzo<sup>®</sup> (Sonidegib) was approved by the US FDA in July 2015. Odomzo is a hedgehog pathway inhibitor 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. Approximately 70% of the prescribers are dermatologists and rests are oncologists for this class of drug. According to IMS Health, the hedgehog inhibitor class grew by 40% Oct 2016 YTD versus prior year. Importantly new data supporting the use of Odomzo<sup>®</sup> were presented at ASCO in June 2016. Data from the BOLT trial showed continued antitumor activity for more than 26 months in patients treated with Odomzo<sup>®</sup> with no new safety concerns. At the 30-month follow-up, patients with locally advanced BCC had an overall response rate (ORR) as per central review of 56% with Odomzo<sup>®</sup> 200 mg.<sup>1</sup> The most frequent grade 3 and 4 adverse reactions occurring in more than 2% of patients were fatigue, decreased weight and muscle spasms.<sup>2</sup>

According to Mr Kirti Ganorkar, Global Head – Business Development – Sun Pharma, "Odomzo gives us an opportunity to meaningfully expand our already established branded dermatology business and support our expansion into Branded Oncology with a launched brand. We see meaningful global potential for Odomzo by leveraging Sun Pharma's existing dermatology and oncology infrastructure to provide an innovative product to BCC patients worldwide."

**According to Mr Jesper Jensen, Head – Biologics and Dermatology, Sun Pharma,**"We look forward to collaborating with the medical community to bring this novel therapy to the market to patients suffering from locally advanced basal cell carcinoma. Odomzo complements and enhances our existing Dermatology franchise. This acquisition has the potential to leverage and expand the relationships that our Levulan sales team have with the Dermatologists that treat common pre-cancerous skin conditions."

## About Basal Cell Carcinoma (BCC)

Non-melanoma skin cancer is the most common form of skin cancer globally. BCC accounts for approximately 80% of non-melanoma skin cancers, accounting for over 2 million estimated cases in the US alone. BCC consists of abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the outermost layer of the skin. It occurs most frequently on the head and neck, with the nose being the most common site. BCC that spreads from where it started to nearby tissue is called locally advanced and can be highly disfiguring. Advanced

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BCC is thought to represent roughly 1-10% of all cases of BCC. Worldwide incidence of BCC is rising by 10% each year due to factors such as an aging population and increased ultraviolet exposure.

### About BOLT TRIAL

BOLT was a multicentre, randomised, double-blind, phase-2 trial. Eligible patients had locally advanced basal cell carcinoma not amenable to curative surgery or radiation or metastatic basal cell carcinoma. Patients were randomised to receive 200 mg or 800 mg oral sonidegib once daily, until disease progression or intolerable toxicity. The primary efficacy outcome measure of the trial was objective response rate (ORR) as determined by blinded central review according to modified Response Evaluation Criteria in Solid Tumors (mRECIST) for patients with laBCC or RECIST version 1.1 for patients with mBCC. Duration of response (DoR), determined by blinded central review, was a key secondary outcome measure. The 30-month follow-up safety and efficacy data was presented at the 2016 ASCO Annual Meeting.

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

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 47 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2016 are approximately US\$ 4.3 billion, of which US contributes US\$ 2.1 billion. In India, the company enjoys leadership across 12 different classes of doctors with 32 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 8% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma\_Live

**Safe Harbor**: Statements in this document describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

<u>1 Dummer R et al, ASCO 2016</u> <u>2 Odomzo EU SmPC</u>

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