Sun Pharmaceutical Industries Ltd., SUN HOUSE, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India

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CIN: L24230GJ1993PLC019050

www.sunpharma.com



# 23 May 2018.

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 USFDA Approval of YONSA®, 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

Ashok I. Bhuta Compliance Officer

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Encl: as above





## **FOR IMMEDIATE RELEASE**

# Sun Pharma Announces USFDA Approval of YONSA® (abiraterone acetate) To Treat Metastatic Castration-Resistant Prostate Cancer In Combination With Methylprednisolone

YONSA® was shown in clinical studies to be an effective form of abiraterone acetate, and can be taken with or without food, in combination with methylprednisolone

Sun Pharma had acquired YONSA® from Churchill Pharmaceuticals and will commercialize YONSA® in the U.S.

Mumbai India, Princeton NJ, and King of Prussia, May 23, 2018 – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) and Churchill Pharmaceuticals, LLC. (Churchill) today announced that one of Sun Pharma's wholly owned subsidiary companies has received approval from the U.S. Food and Drug Administration (FDA) for YONSA® (abiraterone acetate), a novel formulation in combination with methylprednisolone, for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

Churchill is eligible to receive upfront and sales-linked milestone payments, and royalties on sales from Sun Pharma pursuant to an agreement between the two companies to commercialize YONSA® in the U.S.

"We are pleased to add YONSA® to our growing oncology portfolio and continue to deliver on Sun Pharma's commitment for enhanced patient access to innovative cancer therapies," said Abhay Gandhi, CEO - North America, Sun Pharma.

YONSA® in combination with methylprednisolone was filed as a New Drug Application (NDA) under the 505(b)(2) regulatory pathway and will be promoted as a branded product in the U.S.

# About YONSA® (abiraterone acetate) tablets

YONSA® is a CYP17 inhibitor which uses proprietary SoluMatrix Fine Particle Technology<sup>TM</sup> to create a micronized (smaller particle size) formulation of abiraterone acetate tablets - for the treatment of metastatic castration-resistant prostate cancer, in combination with methylprednisolone. The active ingredient is converted *in vivo* to abiraterone, an androgen biosynthesis inhibitor that inhibits 17  $\alpha$ -hydroxylase/C17,20-lyase (CYP17). The CYP17 enzyme is expressed in testicular, adrenal and prostatic tumor tissues and is required for androgen biosynthesis.

Please see Full Prescribing Information for YONSA® at www.YonsaRx.com/Yonsa-pi





#### Disclaimer:

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.

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 41 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 13 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 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.

### **About Sun Oncology**

Sun Oncology is the branded oncology division of a wholly owned subsidiary of Sun Pharma with focus on enhancing patient access to innovative cancer therapies. Sun Oncology is comprised of branded cancer products like Odomzo<sup>®</sup> (sonidegib) and YONSA<sup>®</sup> (abiraterone acetate).

## About Churchill Pharmaceuticals, LLC

Churchill is focused on providing value to cancer care by developing quality orally delivered oncology products with optimized clinical profiles. Our commitment to responsibly deliver these products to the patients, payers and healthcare communities we serve is at the core of our business. Churchill has a license from iCeutica to the SoluMatrix Fine Particle Technology $^{\text{TM}}$ , a proprietary manufacturing process that may unlock the potential of certain oral drugs by changing how well they dissolve and how efficiently they are absorbed. For more information, please visit https://www.churchillpharma.com and http://www.iceutica.com





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