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™ 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 α-hydroxylase/C17,20-lyase (CYP17). The CYP17 enzyme is expressed in testicular, adrenal and prostatic tumor tissues and is required for androgen biosynthesis.

INDICATION

YONSA® (abiraterone acetate) in combination with methylprednisolone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Important Administration Instructions

To avoid substitution errors and overdose, be aware that YONSA tablets may have different dosing and food effects than other abiraterone acetate products. Patients receiving YONSA should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

YONSA® can cause fetal harm and potential loss of pregnancy.

WARNINGS AND PRECAUTIONS

Hypertension, Hypokalemia, and Fluid Retention Due to Mineralocorticoid Excess: YONSA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Monitor patients for hypertension, hypokalemia, and fluid retention at least once a month. Control hypertension and correct hypokalemia before and during treatment with YONSA®.

Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia or fluid retention, such as those with heart failure, recent myocardial infarction, cardiovascular disease, or ventricular arrhythmia. The safety of YONSA® in patients with left ventricular ejection fraction < 50% or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) was not established because these patients were excluded from these randomized clinical trials.

Adrenocortical Insufficiency (AI): AI was reported in patients receiving abiraterone acetate in combination with corticosteroid, following an interruption of daily steroids and/or with concurrent infection or stress. Monitor patients for symptoms and signs of AI, particularly if patients are withdrawn from corticosteroids, have corticosteroid dose reductions, or experience unusual stress. Symptoms and signs of AI may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with YONSA®. Perform appropriate tests, if indicated, to confirm AI. Increased dosages of corticosteroids may be used before, during, and after stressful situations.

Hepatotoxicity: In postmarketing experience, there have been abiraterone acetate-associated severe hepatic toxicity, including fulminant hepatitis, acute liver failure and deaths. Measure serum transaminases (ALT and AST) and bilirubin levels prior to starting treatment with YONSA®, every two weeks for the first three months of treatment and monthly thereafter. In patients with baseline moderate hepatic impairment receiving a reduced YONSA® dose of 125 mg, measure ALT, AST, and bilirubin prior to the start of treatment, every week for the first month, every two weeks for the following two months of treatment and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should

prompt more frequent monitoring. If at any time AST or ALT rise above five times the ULN, or the bilirubin rises above three times the ULN, interrupt YONSA® treatment and closely monitor liver function.

Re-treatment with YONSA® at a reduced dose level may take place only after return of liver function tests to the patient's baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN.

Permanently discontinue treatment with abiraterone acetate for patients who develop a concurrent elevation of ALT greater than 3 x ULN and total bilirubin greater than 2 x ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

The safety of YONSA® re-treatment of patients who develop AST or ALT greater than or equal to 20X ULN and/or bilirubin greater than or equal to 10X ULN is unknown.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

DRUG INTERACTIONS:
Based on *in vitro* data, YONSA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during YONSA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the YONSA® dosing frequency only during the co-administration period.

Abiraterone is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid coadministration of abiraterone acetate with substrates of CYP2D6 with a narrow therapeutic index (e.g., thioridazine). If alternative treatments cannot be used, exercise caution and consider a dose reduction of the concomitant CYP2D6 substrate drug.

In a CYP2C8 drug-drug interaction trial in healthy subjects, the AUC of pioglitazone (CYP2C8 substrate) was increased by 46% when pioglitazone was given together with an abiraterone acetate single dose equivalent to YONSA® 500 mg. Therefore, patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with abiraterone acetate.

USE IN SPECIFIC POPULATIONS

- **Females and Males of Reproductive Potential: Advise male patients with female partners of reproductive potential to use effective contraception**.
- Do not use YONSA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

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

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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.

About Sun Pharmaceutical Industries Inc., USA (SPII)

SPII is a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd, a global specialty generic company based in Mumbai, which provides innovative, high-quality, affordable medicines trusted by customers and patients in over 150 countries around the world. It fosters excellence through innovation, supported by strong R&D capabilities, with approximately 2,000 scientists on staff and R&D investments of approximately 8% of annual revenues. It has been marketing its products in the US market for more than 20 years, providing generics, branded generics and over-the-counter products, and has distribution and customer service teams throughout the US. For further information please visit www.sunpharma.com and follow us on Twitter at @SunPharma_Live

The corporate footprint of SPII is rapidly growing, with a newly established branded, specialty business headquartered in Princeton, NJ. The company is expanding its portfolio of products and technologies that offer unique formulations and novel delivery systems of common therapies, across various disease areas.

This newly formed branded specialty business is also growing its oncology division, as evidenced by its portfolio of oncology products, including YONSA® (abiraterone acetate) – which is manufactured in the U.S - and Odomzo® (sonidegib). SPII is committed to enhancing patient access to innovative cancer therapies.

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™, 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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