CHURCHILL PHARMACEUTICALS ANNOUNCES NDA FILING ACCEPTANCE FOR YONSA™ BY THE U.S. FDA

The NDA contains data to support approval for YONSA, (abiraterone acetate) ultramicrosize tablets, for the treatment of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Churchill Pharmaceuticals also announces positive results from the pivotal STAAR Study evaluating serum testosterone levels in patients with mCRPC in a head-to-head comparison trial of Yonsa to Zytiga®

THURSDAY, JULY 20, 2017 8:00 AM EDT

KING OF PRUSSIA, PA – Churchill Pharmaceuticals, LLC (Churchill), a privately held company devoted to expanding treatment options with oral oncology agents, announces that the New Drug Application (NDA) for YONSA™ (abiraterone acetate) ultramicrosize tablets has been accepted for filing by the U.S. Food and Drug Administration (FDA). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of March 19, 2018 to complete its review.

The submission was based primarily on the final results of the **STAAR* Study, a randomized, open label patient trial in the U.S. comparing YONSA 500mg once daily plus methylprednisolone 4 mg twice daily, to another formulation of abiraterone acetate (Zytiga) 1000 mg once daily plus prednisone 5 mg twice daily. *STAAR* was an evaluation of 53 male patients with metastatic castration-resistant prostate cancer (mCRPC), a mean age of 75 years and a majority of whom had Gleason scores >7. Over 90% of patients treated with YONSA achieved absolute testosterone levels of <1 ng/dL at each time point, while non-detectable testosterone levels (≤0.1 ng/dL) were achieved in a higher percentage of patients treated with YONSA versus patients treated with the comparator.

“We are pleased that the NDA for YONSA has been accepted. The notification from the FDA indicated that the application is sufficiently complete to permit a substantive review and that no potential review issues have been identified. Our team looks forward to working closely with the FDA throughout the review process,” stated Scott Megaffin, President, Churchill.

“YONSA represents a new potential treatment option for the nearly 30,000 men diagnosed annually in the U.S. with mCRPC,” stated Ben Steinmetz, Senior Vice President, Commercial, Churchill. “YONSA sets the stage in our initial commercial approach with an exciting and innovative opportunity to deliver on the Churchill commitment to responsibly enhance product access to critical therapies.”

About **YONSA™ (a**birateronе acetate) ultramicrosize tablets

YONSA is an investigational oral agent, formulated as abiraterone acetate ultramicrosize tablets. YONSA is a CYP17 inhibitor being developed 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). This enzyme is expressed in testicular, adrenal and prostatic tumor tissues and is required for androgen biosynthesis. YONSA ultramicrosize tablets have double the bioavailability of the comparator formulation of abiraterone acetate. YONSA has been formulated using the SoluMatrix Fine Particle Technology™.

The *STAAR Study

The *STAAR* Study (CHL-AA-201, A Randomized, Open-Label, Active-Controlled, Multi-Center Study to Evaluate Serum Testosterone Levels in Patients with Metastatic Castration-Resistant Prostate Cancer) was an 84-day study in the U.S. comparing YONSA in combination with methylprednisolone against Zytiga® in combination with prednisone. The primary endpoint was comparative lowering of serum testosterone at pharmacodynamic steady-state. Additional secondary endpoints included safety assessments, PSA and pharmacokinetic measurements. The full results of the *STAAR* Study will be presented at a future scientific meeting.

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™.

For more information, please visit www.churchillpharma.com and www.iceutica.com

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