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Astellas Highlights Progress to Advance Care of Patients with Genitourinary Cancers at ASCO-GU Annual Meeting

NORTHBROOK, IL – February 13, 2013 -- Astellas Pharma US, Inc., a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), today announced that more than 10 abstracts from Astellas oncology pipeline agents and marketed products will be presented at the 2013 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO-GU), to be held February 14-16 in Orlando, Florida.

"We're committed to delivering new treatment options for patients with GU cancers," said Mark Reisenauer, vice president, Astellas Oncology. "The data to be presented at ASCO GU further illustrates the potential role our products can play."

Key presentations to be made at ASCO-GU include:

Enzalutamide
Data from a 25-week, open label, single-arm phase 2 study highlighting the effect of enzalutamide on prostate-specific antigen (PSA) response in men with hormone-naïve prostate cancer will be presented. Five additional abstracts will highlight outcomes from a phase 1 study of enzalutamide in combination with docetaxel chemotherapy, as well as additional findings from the randomized, global, placebo-controlled phase 3 AFFIRM study of enzalutamide in men with metastatic castration resistant prostate cancer. XTANDI was approved by the FDA on August 31, 2012 for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel (chemotherapy). A Marketing Authorization Application for XTANDI is currently under review by the European Medicines Agency (EMA).

Tivozanib
Additional secondary analysis results from the Phase 3 TIVO-1 (tivozanib versus sorafenib in 1st line advanced RCC) trial will be presented. Reported data will include overall survival (OS) results for metastatic renal cell carcinoma (mRCC) patients who received tivozanib versus patients who received sorafenib in the TIVO-1 study. Additionally, four posters with tivozanib data regarding the safety and efficacy profile of tivozanib will also be presented at the meeting. A new drug application (NDA) for tivozanib, an investigational agent, is currently under review by the FDA for the treatment of patients with advanced renal cell carcinoma.

"We applaud companies such as Astellas that are committed to developing medicines for difficult-to-treat cancers," said Helen Miller, LCSW, CancerCare CEO. "We share their commitment to put cancer patients first."

About Astellas
Astellas Pharma US, Inc., located in Northbrook, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in oncology, and has several oncology products on the market and compounds in development. Astellas is proud to be an award recipient of the CEO Gold Standard Accreditation from the CEO Roundtable on

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Cancer. For more information on Astellas Pharma Inc., please visit our website at www.astellas.us.

About XTANDI
XTANDI is an oral, once-daily androgen receptor inhibitor. XTANDI was approved by the FDA on August 31, 2012 for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel (chemotherapy). A Marketing Authorization Application for XTANDI is currently under review by the European Medicines Agency (EMA).

The recommended dose of XTANDI is 160 mg (four 40 mg capsules) administered orally once daily. XTANDI can be taken with or without food and does not require concomitant steroid (e.g., prednisone) use.

The efficacy and safety of XTANDI were assessed in the randomized, placebo-controlled, global phase 3 AFFIRM clinical trial. A total of 1,199 patients with mCRPC who had previously received docetaxel were randomized 2:1 to receive either XTANDI orally at a dose of 160 mg once daily (N = 800) or placebo (N = 399). Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. The primary endpoint of the trial was OS.

In the phase 3 clinical trial, 48% of XTANDI patients and 46% of patients in the placebo arm were treated with glucocorticoids.

XTANDI-treated patients had a statistically-significant improvement in median OS compared to the placebo group: 18.4 months in the XTANDI group versus 13.6 months in the placebo group ($P < 0.0001$). XTANDI provided a 37% reduction in risk of death compared to placebo (hazard ratio = 0.631). Seizure occurred in 0.9% of patients on XTANDI and 0% of the placebo-treated patients. The most common adverse reactions (≥ 5%) are asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients.

Important Safety Information for XTANDI
Contraindications- XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Warnings and Precautions- In the randomized clinical trial, seizure occurred in 0.9% of patients on XTANDI. No patients on the placebo arm experienced seizure. Patients experiencing a seizure were permanently discontinued from therapy. All seizures resolved. Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.

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Adverse Reactions- The most common adverse drug reactions (≥ 5%) reported in patients receiving XTANDI in the randomized clinical trial were asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and in 6% on placebo (no Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients and 2% on placebo. One percent of XTANDI patients compared to 0.3% on placebo died from infections or sepsis. Falls or injuries related to falls occurred in 4.6% of XTANDI patients vs 1.3% on placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients and included non-pathologic fractures, joint injuries, and hematomas. Grade 1 or 2 hallucinations occurred in 1.6% of XTANDI patients and 0.3% on placebo, with the majority on opioid-containing medications at the time of the event.

Drug Interactions- Effect of Other Drugs on XTANDI: Administration of strong CYP2C8 inhibitors can increase the plasma exposure to XTANDI. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI cannot be avoided, reduce the dose of XTANDI. Co-administration of XTANDI with strong or moderate CYP3A4 and CYP2C8 inducers can alter the plasma exposure of XTANDI and should be avoided if possible. **Effect of XTANDI on Other Drugs:** XTANDI is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. Avoid CYP3A4, CYP2C9 and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

For Full Prescribing Information, please visit www.XtandiHCP.com.

About Tivozanib
Tivozanib is a potent, selective and long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor for which positive results from a Phase 3 clinical study in advanced RCC have been reported, and is being evaluated in other tumors.

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