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## Medivation and Astellas Provide Update on PREVAIL

# -Companies Announce Phase 3 PREVAIL Interim Analysis Expected to Occur in 2013-

San Francisco, CA and Tokyo, Japan – April 1, 2013 – Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (TSE: 4503) today announced that the companies have established an updated interim analysis plan for the PREVAIL trial, a global Phase 3 clinical trial evaluating XTANDI® (enzalutamide) capsules in men with metastatic castration-resistant prostate cancer (mCRPC) who have not yet received chemotherapy. The planned interim analysis for the PREVAIL trial is expected to occur in 2013. In addition, the protocol-specified number of radiographic progression-free survival (PFS) events has been exceeded, and the primary PFS analysis will occur at the time of the interim analysis for overall survival. Medivation is conducting this study under its agreement with Astellas.

"As we did with our AFFIRM trial, we have evaluated recent industry data announced in the prostate cancer disease area and updated our analysis plan for the PREVAIL trial," said Lynn Seely, M.D., chief medical officer of Medivation, Inc. "We've shared our updated plan with the U.S. Food and Drug Administration who are in agreement with our approach. We plan to conduct the PREVAIL interim analysis in 2013."

The randomized, double-blind, placebo-controlled, multi-national Phase 3 PREVAIL trial met its enrollment goals in May 2012 at sites in the United States, Canada, Europe, Australia, Russia, Israel and Asian countries including Japan. The PREVAIL trial includes 1,717 patients who have progressed following treatment with a luteinizing hormone releasing hormone (LHRH) analog drug only, as well as patients who have progressed following treatment with both an LHRH analog drug and an anti-androgen drug. The study co-primary endpoints are radiographic progression-free survival and overall survival; secondary endpoints include time to first skeletal-related event and time to initiation of chemotherapy. The trial is designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily plus standard of care versus placebo plus standard of care.

### **About XTANDI®**

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

# 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.

Warning and Precautions - In the randomized phase 3 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.

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.

Drug Interactions - XTANDI is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. 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. 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 Medivation**

Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel therapies to treat serious diseases for which there are limited treatment options. Medivation aims to transform the treatment of these diseases and offer hope to critically ill patients and their families. For more information, please visit us at <a href="https://www.medivation.com">www.medivation.com</a>.

#### **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 Cancer. For more information on Astellas Pharma Inc., please visit our website at <a href="https://www.astellas.us">www.astellas.us</a>.

## **Forward-looking Statements**

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the potential timing of analyses of data from the PREVAIL trial. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Medivation's actual results to differ significantly from those projected, including, without limitation, those detailed in Medivation's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2012, filed on February 28, 2013 with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Medivation disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.