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Medivation and Astellas Announce Positive Survival Data from Interim Analysis of Phase 3 AFFIRM Trial of MDV3100 in Men with Advanced Prostate Cancer

- Study will be stopped early and MDV3100 offered to all participants -

- Medivation to hold conference call at 8:30AM Eastern time today -

SAN FRANCISCO, CA and TOKYO -- November 3, 2011 -- Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. announced that the Independent Data Monitoring Committee (IDMC) has informed the companies of positive results from a planned interim analysis of the Phase 3 AFFIRM trial of MDV3100 in men with advanced prostate cancer previously treated with chemotherapy. MDV3100, the first androgen receptor signaling inhibitor, successfully met the study's pre-specified interim efficacy stopping criteria, demonstrating a clinically meaningful and statistically significant (p<0.0001) improvement in overall survival compared to placebo. As a result, the IDMC recommended that AFFIRM be stopped early and men who received placebo be offered MDV3100.

As reported by the IDMC, MDV3100 produced a 4.8-month advantage in median overall survival compared to placebo. The estimated median survival for men treated with MDV3100 was 18.4 months compared with 13.6 months for men treated with placebo. MDV3100 provided a 37 percent reduction in risk of death compared to placebo (Hazard Ratio=0.631). The IDMC further determined, considering the observed safety profile, that MDV3100 demonstrated a favorable risk-to-benefit ratio sufficient to stop the study. A full analysis of the results from AFFIRM, including safety data, will be submitted for presentation at an upcoming scientific congress.

"MDV3100 was rationally designed to target androgen receptor signaling, a key driver of prostate cancer growth, and the overall survival benefit the compound demonstrated in the AFFIRM interim analysis is significant," said Howard I. Scher, M.D., chief, Genitourinary Oncology Service at Memorial-Sloan Kettering Cancer Center, and the co-principal investigator of the AFFIRM study. "If approved, MDV3100 will be a welcome option for men with prostate cancers that have progressed on hormones and initial chemotherapy."

"MDV3100 has a novel mechanism of action, inhibiting androgen receptor signaling at three distinct points in the signaling pathway," said Professor Johann de Bono, M.D., MSc, Ph.D., FRCP, Honorary Consultant in Medical Oncology, Professor of Experimental Cancer Medicine, The Institute of Cancer Research and The Royal Marsden Hospital, and the co-principal investigator of the AFFIRM study. "I am thus particularly pleased with the results of the AFFIRM interim analysis, as there is a real need for new treatments in advanced prostate cancer that target the cancer in different ways."

The Phase 3 AFFIRM trial is a randomized, double-blind, placebo-controlled, multinational trial evaluating MDV3100 (160 mg/day) versus placebo in 1,199 men with advanced prostate cancer who were previously treated with docetaxel-based chemotherapy. Enrollment was completed in November 2010 and the interim analysis was triggered at 520 events.

Medivation and Astellas plan to hold a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) in early 2012 and will provide an update on regulatory timelines for MDV3100 subsequent to that meeting.

"We are very excited about these results and will work closely with our alliance partners at Medivation to pursue regulatory submissions in the United States, Europe and Japan," said Steven Ryder, M.D., president, Astellas Pharma Global Development. "This is consistent with our corporate commitment to pursue innovative approaches to improving patient care and our strategic intent to be a global category leader in oncology."

"These results are both an important step toward making this life-extending potential treatment available to the prostate cancer community and a significant milestone for our company," said David Hung, M.D., president and CEO, Medivation. "Because we continue to believe that MDV3100 may also benefit patients with earlier-stage disease, we plan to continue studying the compound in a broad array of earlier prostate cancer disease settings while we pursue initial regulatory approval in post-chemotherapy patients. We extend sincere thanks to all the patients, investigators and employees who helped make this possible."

Conference Call Information

Medivation will host a conference call today at 8:30 a.m. Eastern Time. To access the call, please dial 877-303-2523 from the United States or +1-253-237-1755 internationally. In addition, the live conference call is being webcast and can be accessed on the "Events and Presentations" page of the "Investor Relations" section of the Company's website at www.medivation.com. A replay also will be available for 30 days following the live call.

About MDV3100

MDV3100 is an investigational agent that is the first in a new class of medicines called androgen receptor signaling inhibitors. An oral, once-daily investigational drug, MDV3100 inhibits androgen receptor signaling in three distinct ways: it inhibits 1) testosterone binding to androgen receptors; 2) nuclear translocation of androgen receptors; and 3) DNA binding and activation by androgen receptors. In addition to the AFFIRM trial in men with advanced prostate cancer previously treated with chemotherapy, MDV3100 is also being studied in the Phase 3 PREVAIL trial in 1,700 men with advanced prostate cancer who have not received chemotherapy, the Phase 2 TERRAIN trial in nearly 400 men whose disease has progressed while on luteinizing hormone releasing hormone (LHRH) analogue or hormone therapy, and a Phase 2 study in hormone-naïve men.

About the Medivation/Astellas Collaboration

In October 2009, Medivation and Astellas entered into a global agreement to jointly develop and commercialize MDV3100. The companies are collaborating on a comprehensive development program that includes studies to develop MDV3100 across the full spectrum of advanced prostate cancer. Subject to receipt of regulatory approval, the companies will jointly commercialize MDV3100 in the United States and Astellas will have responsibility for commercializing MDV3100 outside the United States.

About Medivation

Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel small molecule drugs 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 caregivers. Together with its corporate partners Astellas and Pfizer, Medivation currently has investigational drugs in Phase 3 development to treat advanced prostate cancer and mild-to-moderate Alzheimer's disease. For more information, please visit us at <u>www.medivation.com</u>.

About Astellas Pharma Inc.

Astellas Pharma Inc. is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. The organization is committed to becoming a global category leader in Oncology, and has several oncology compounds in development in addition to MDV3100. For more information on Astellas Pharma Inc., please visit our website at <u>www.astellas.com/en</u>.

This press release contains forward-looking statements, including statements regarding the continued clinical development of MDV3100 and potential future progress related thereto, the therapeutic and commercial potential of MDV3100, the potential future clinical trial results, potential future regulatory approval and commercialization of MDV3100, and the continued effectiveness of, and continuing collaborative activities and benefits under, Medivation's collaboration agreement with Astellas, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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, risks related to the timing and potential regulatory approval and commercialization of MDV3100, the progress, timing and results of Medivation's clinical trials, including the risk that adverse clinical trial results could alone or together with other factors result in the delay or discontinuation of some or all of Medivation's product development activities, the risk that positive results seen in our clinical trials may not be predictive of the results of our ongoing or planned clinical trials and the risk that life-prolonging treatments could prevent ongoing or planned MDV3100 trials from succeeding or could reduce any potential survival benefit that may be shown in these trials even if they do succeed, partnering of Medivation's product candidates, including Medivation's dependence on the efforts of and funding by Astellas for the development of MDV3100, the achievement of development, regulatory and commercial milestones under Medivation's collaboration agreement with Astellas, the manufacturing of Medivation's product candidates, the industry and competitive market, the adequacy of Medivation's financial

resources, unanticipated expenditures or liabilities, intellectual property matters, and other risks detailed in Medivation's filings with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ended June 30, 2011, filed with the SEC on August 9, 2011. 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.