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Medivation and Astellas Announce Positive Results from the Phase 3 AFFIRM Trial of MDV3100 in Prostate Cancer Patients Who Received Prior Chemotherapy

--MDV3100 prolonged life by 4.8 months compared to placebo and met all secondary endpoints--

--Medivation to host conference call at 4:30PM Eastern time on Thursday, February 2--

SAN FRANCISCO, CA and TOKYO -- January 31, 2012 -- Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (Tokyo: 4503) announced positive results on all efficacy endpoints from the Phase 3 AFFIRM trial of the investigational drug MDV3100 in men with prostate cancer previously treated with chemotherapy. Data will be highlighted in a late-breaking oral presentation at the upcoming 2012 Genitourinary Cancers Symposium in San Francisco, CA on Thursday, February 2.

"MDV3100 outperformed our expectations in the AFFIRM trial by meeting the primary and secondary endpoints with strong statistical significance and demonstrating a favorable safety profile," 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. "These results, together with its convenient once-daily oral dosing regimen, should make MDV3100 a promising option for men with prostate cancer who have received prior hormones and chemotherapy."

Of particular note:

- Men taking MDV3100 lived for a median of 18.4 months, compared with 13.6 months for men taking placebo ($p < 0.0001$; HR=0.631).
- MDV3100 also met all secondary endpoints, including radiographic progression-free survival (8.3 versus 2.9 months; $p < 0.0001$; HR=0.404), soft tissue response rate (28.9% versus 3.8%; $p < 0.0001$) and time to prostate-specific antigen (PSA) progression (8.3 versus 3.0 months; $p < 0.0001$; HR=0.249).

- PSA declines of 50% or greater were more common in the MDV3100 group than in the placebo group (54.0% versus 1.5%; $p < 0.0001$), as were PSA declines of 90% or greater (24.8% versus 0.9%; $p < 0.0001$).
- MDV3100 was well tolerated. Common side effects included fatigue, diarrhea and hot flush. Serious adverse events, adverse events causing patients to stop treatment, and adverse events causing death all were lower in the MDV3100 group than in the placebo group. Grade 3 or greater side effects of interest were fatigue (6.3% in the MDV3100 group versus 7.3% in the placebo group), cardiac disorders (0.9% versus 2.0%) including myocardial infarction (0.3% versus 0.5%), seizure (0.6% versus 0.0%) and liver function test abnormalities (0.4% versus 0.8%).

“The almost five-month overall survival benefit MDV3100 showed over placebo in this trial is noteworthy, as is the fact that men with post-chemotherapy prostate cancer taking MDV3100 lived for a median of a year and a half,” 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. “As a practicing oncologist, I am hopeful that I may be able to offer MDV3100 as a life-prolonging option to these very ill patients.”

“The robust overall survival data produced in the AFFIRM trial by MDV3100, the first androgen receptor signaling inhibitor, clinically validate this novel mechanism of action in treating men with prostate cancer who have received prior chemotherapy,” said David Hung, M.D., president and CEO, Medivation. “We and our colleagues at Astellas are committed to working diligently to bring MDV3100 to patients as quickly as possible.”

“First of all, we’d like to thank both the investigators and patients for their contributions to the AFFIRM trial, as these results are an important step toward making this potential new treatment available to patients with prostate cancer,” said Steven Ryder, M.D., president, Astellas Pharma Global Development. “MDV3100 is a significant contributor to our strategy of becoming a global category leader in oncology. We’re delighted to be collaborating with Medivation on MDV3100 at this critical juncture.”

Details of the presentation are as follows:

Abstract title: Effect of MDV3100, an androgen receptor signaling inhibitor (ARSI), on overall survival in patients with prostate cancer postdocetaxel: Results from the phase III AFFIRM study

Presenter: Howard I. Scher, M.D., chief, Genitourinary Oncology Service at Memorial-Sloan Kettering Cancer Center, and the co-principal investigator of the AFFIRM study

- Thursday, February 2 from 10:15-11:45am PT
General Session II: Castration-Resistant Prostate Cancer -- Treatment Sequencing and Implementation

Conference Call Information

Medivation will host a conference call on February 2, 2012 at 4:30pm ET to discuss the results. Drs. Howard Scher of Memorial Sloan-Kettering Cancer Center and Neal Shore of the Carolina Urologic Research Center will participate in the call. To access the call, please dial 877-303-2523 from the United States or +1-253-237-1755 internationally.

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 prostate cancer previously treated with chemotherapy, MDV3100 is also being studied in the Phase 3 PREVAIL trial and the Phase 2 TERRAIN trial in men with prostate cancer who have failed hormonal therapy but have not yet received chemotherapy, and in a Phase 2 study in men with prostate cancer who have not yet received hormonal therapy.

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 partner Astellas, Medivation currently has the investigational drug MDV3100 in Phase 3 development for prostate cancer. For more information, please visit us at www.medivation.com.

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 www.astellas.com/en.

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 September 30, 2011, filed with the SEC on

November 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.