



Draft #9, 4/12/10

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MEDIVATION AND ASTELLAS ANNOUNCE PUBLICATION IN THE LANCET OF POSITIVE EFFICACY DATA FROM PHASE 1-2 TRIAL OF MDV3100 IN ADVANCED PROSTATE CANCER PATIENTS

-- Novel, Triple-Acting Oral Androgen Receptor Antagonist Currently in Phase 3 Development for Advanced Prostate Cancer --

SAN FRANCISCO, CA and TOKYO, JAPAN -- April 15, 2010 -- Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. today announced publication of positive results from their previously reported Phase 1-2 trial of the novel triple-acting oral androgen receptor antagonist MDV3100 in men with progressive, metastatic castration-resistant prostate cancer in the April 15 online version of *The Lancet*. According to the published results, MDV3100 demonstrated antitumor activity in patients with late-stage prostate cancer as evaluated by reductions in prostate specific antigen (PSA) levels, radiographic findings and circulating tumor cell (CTC) counts. Antitumor effects were observed in patients who were resistant to standard anti-androgen treatments, as well as in patients who had progressed following chemotherapy. MDV3100 is currently in Phase 3 development for the treatment of advanced prostate cancer.

"MDV3100, with its unique mechanism of action, could offer an important new treatment option to men with prostate cancer that is resistant to currently available anti-androgens," said Howard Scher, M.D., lead author of *The Lancet* article and chief of the Genitourinary Oncology Service at Memorial Sloan-Kettering Cancer Center in New York. "It is particularly encouraging that antitumor activity was seen on all outcomes assessed in patients who had failed chemotherapy because their survival times are one year or less, on average, and their treatment options are limited."

Phase 1-2 Trial Design and Results

All patients in the open-label, dose-escalation, U.S. Phase 1-2 clinical trial had progressive disease upon enrollment and were heavily pretreated, with 77 percent having failed at least two lines of prior hormonal therapy and 54 percent having failed one or more chemotherapy regimens. A total of 140 men were enrolled in the trial, which evaluated MDV3100 doses between 30 and 600 mg/day. Patients could remain on treatment for as long as they continued to tolerate the drug and

their disease did not progress. Efficacy endpoints included CTC counts, serum PSA levels, soft tissue and bony metastases, and time on treatment.

Results showed that MDV3100 was associated with anti-tumor activity across a variety of endpoints in patients who had become resistant to bicalutamide (Casodex[®]) or other standard anti-androgen treatments, including patients who had failed prior chemotherapy (n=75) and those who were chemotherapy-naïve (n=65). Anti-tumor activity was demonstrated by:

- Substantial reductions in PSA levels, including declines in serum PSA of 50 percent or more in 56 percent of patients.
 - The PSA responses lasted for a median of 41 weeks for chemotherapy-naïve patients, 32 weeks for all patients and 21 weeks for post-chemotherapy patients.
- Improvement or stabilization in tumors that had spread to soft tissue or bone. Treatment with MDV3100 was associated with tumor regressions (22 percent of all patients -- both chemotherapy-naïve and post-chemotherapy patients) and stable disease in soft tissue (49 percent of all patients) and stable disease in bone (56 percent of all patients).
 - The median time to radiographic progression was not reached for chemotherapynaïve patients; it was 47 weeks in all patients combined and 29 weeks for postchemotherapy patients.
- A conversion from unfavorable to favorable CTCs in 49 percent of patients (75 percent of the chemotherapy-naïve and 37 percent of the post-chemotherapy groups). Of patients who initiated therapy with favorable counts, 91 percent retained favorable counts during treatment.

MDV3100 was generally well tolerated in the trial at doses up to and including 240 mg/day. Fatigue was the most frequently reported adverse event.

"Based on the favorable benefit-risk ratio for MDV3100 observed in the Phase 1-2 trial, we initiated the randomized, placebo-controlled Phase 3 AFFIRM trial in men with progressive advanced prostate cancer following chemotherapy, as new treatments are urgently needed for this patient group," said Lynn Seely, M.D., chief medical officer of Medivation. "We also plan to evaluate MDV3100 in earlier stages of prostate cancer, as those patients also are in need of new treatment options."

Phase 3 Trial of MDV3100 Underway

Medivation and Astellas are enrolling patients in a Phase 3 clinical trial of MDV3100 in men with progressive disease following docetaxel treatment. Known as AFFIRM, the randomized, placebocontrolled, double-blind, multi-national trial is evaluating MDV3100 at a dose of 160 mg taken orally once daily in men with metastatic prostate cancer who were previously treated with docetaxel-based chemotherapy. The primary endpoint of the trial is overall survival; secondary endpoints include progression-free survival, safety and tolerability. The AFFIRM study is being conducted at sites in Argentina, Austria, Australia, Belgium, Canada, Chile, France, Germany, Italy, Netherlands, Poland, South Africa, Spain, UK and U.S. Information about patient eligibility and enrollment can

be obtained by visiting <u>www.affirmtrial.com</u> or calling the AFFIRM study hotline toll-free in the U.S. and Canada at 1-888-782-3256.

About the Medivation/Astellas Collaboration

In October 2009, Medivation, Inc. entered into a global agreement with Astellas Pharma Inc. to develop and commercialize MDV3100. The companies will collaborate on a comprehensive development program that will include additional studies to develop MDV3100 for both early- and late-stage prostate cancer. Astellas is a recognized global category leader in the field of urology, focusing its R&D and marketing resources in areas where there are unmet medical needs. The company has developed pioneering treatments for prostate cancer, benign prostatic hyperplasia and overactive bladder. Through its commitment to research, support and understanding, the company continues working to identify and develop innovative solutions for better patient outcomes across the field of urology with a particular focus on broadening its expertise and product delivery in oncology.

About MDV3100

MDV3100 is an investigational therapy in clinical development for the treatment of advanced prostate cancer. The first triple-acting, oral androgen receptor antagonist, MDV3100 has been shown in preclinical studies to provide more complete suppression of the androgen receptor pathway than bicalutamide, the most commonly used anti-androgen. MDV3100 slows growth and induces cell death in bicalutamide-resistant cancers via three complementary actions - MDV3100 blocks testosterone binding to the androgen receptor, impedes movement of the androgen receptor to the nucleus of prostate cancer cells (nuclear translocation), and inhibits binding to DNA. Preclinical data published in *Science* in April 2009 demonstrated that MDV3100 is superior to bicalutamide in each of these three actions.

About Prostate Cancer

Prostate cancer is the second most common non-skin cancer among men in the world and it is the sixth leading cause of cancer death among men worldwide. Prostate tumors that have stopped responding to, or are growing despite the use of, active hormone treatment strategies are characterized as castrate-resistant. Patients with castrate-resistant prostate cancer have a poor prognosis and few treatment options.

About Astellas Pharma Inc.

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology & Infectious Diseases, Neuroscience, DM complications & Metabolic Diseases and Oncology. For more information on Astellas Pharma Inc., please visit our website at www.astellas.com.

In Europe, Astellas is responsible for 20 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 3,400 staff across these regions.

Headquartered in Deerfield, Illinois, Astellas Pharma US, Inc. employs more than 2,000 people in the U.S., Canada and Brazil.

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. In September 2008, Medivation announced a global agreement with Pfizer, Inc to develop and commercialize dimebon (latrepirdine) for the treatment of Alzheimer's and Huntington diseases. With Pfizer, Medivation is conducting a broad dimebon clinical development program that includes several Phase 3 trials assessing the efficacy and safety of dimebon taken alone or in combination with other Alzheimer's medications in patients with mild, moderate and severe Alzheimer's disease. The companies are also conducting a Phase 3 trial of dimebon in Huntington disease. In October 2009, Medivation entered a global agreement with Astellas Pharma Inc. to develop and commercialize MDV3100 for both early- and late-stage prostate cancer. The first Phase 3 clinical trial in the MDV3100 development program, known as the AFFIRM trial, is under way in patients with castration-resistant prostate cancer who have previously been treated with docetaxel-based chemotherapy. For more information, please visit us at www.medivation.com.

This press release contains forward-looking statements, including statements regarding the continued clinical development of Medivation's product candidates, the therapeutic and commercial potential of Medivation's product candidates, and the continued effectiveness of, and continuing collaborative activities under, Medivation's collaboration agreements with Pfizer and 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 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, enrollment of patients in Medivation's clinical trials, partnering of Medivation's product candidates, including Medivation's dependence on the efforts of and funding by Pfizer and Astellas for the development of dimebon and MDV3100, respectively, including the risk that Pfizer could elect to unilaterally terminate the dimebon collaboration agreement with Medivation at its election at any time, the achievement of development, regulatory and commercial milestones under Medivation's collaboration agreements, manufacturing of Medivation's product candidates, including Medivation's dependence on Pfizer for the manufacture of all clinical requirements of dimebon, 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 annual report on Form 10-K for the year ended December 31, 2009, filed on March 15,2010 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.		
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