



Medivation Announces European Initiation of Phase 3 Clinical Trial of MDV3100 in Advanced Prostate Cancer

SAN FRANCISCO, January 12 /PRNewswire/ -- Medivation, Inc. today announced treatment of the first European patient in a Phase 3 clinical trial of the investigational drug MDV3100 in advanced prostate cancer. The trial, known as AFFIRM, will evaluate the novel androgen receptor antagonist MDV3100 in men with castration-resistant prostate cancer who were previously treated with docetaxel-based chemotherapy.

"Late stage prostate cancer remains an obvious and large unmet clinical need," said Professor Johann de Bono, Medical Oncologist, Royal Marsden Hospital, UK, and Principal European investigator for the AFFIRM trial. "This study will provide an opportunity to test MDV3100, a promising developmental drug candidate for those men with the most advanced prostate cancer and in great need of a new therapeutic option."

Prostate cancer is the third leading cause of cancer deaths in men across Europe, with more than 300,000 cases being diagnosed each year and accounting for almost 25% of all cases of cancer in men living in Europe.^{1,2}

The randomized, placebo-controlled, double-blind, multi-national AFFIRM trial is expected to enroll approximately 1,200 patients at sites in Europe, the United States, Canada, South America, Australia and South Africa. The primary endpoint of the trial is overall survival; secondary endpoints include progression-free survival, safety and tolerability. This trial will evaluate MDV3100 at a dose of 160 mg taken orally once daily versus placebo.

For more information about the AFFIRM trial please go to <http://www.medivation.com>. Medivation, Inc. recently announced a global agreement with Astellas Pharma Inc. to develop and commercialize MDV3100. The companies will collaborate on a comprehensive development programme that will include additional studies to develop MDV3100 for both early- and late-stage prostate cancer.

Notes to Editor

About MDV3100

MDV3100 is an investigational therapy in clinical development for the treatment of advanced prostate cancer. The first triple-acting, oral anti-androgen, 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* earlier this year demonstrated that MDV3100 is superior to bicalutamide in each of these three actions.

Medivation previously announced interim safety and efficacy results from an ongoing Phase 1-2 clinical trial of MDV3100. The interim results showed that MDV3100 was associated with anti-tumor activity in patients who had become resistant to bicalutamide or other standard anti-androgen treatments, including both patients who had failed prior chemotherapy and patients who were chemotherapy naive. Anti-tumor activity was demonstrated by reductions in prostate-specific antigen levels, improvement or stabilization in tumors that had spread to soft tissue or bone, and a decrease in circulating tumor cells, which has been associated in published literature with improved survival in patients with castration-resistant prostate cancer. MDV3100 was generally well tolerated in this trial at doses up to and including 240 mg/day, with fatigue being the most frequently reported adverse event.

About Prostate Cancer

Prostate tumors that have stopped responding to, or are growing despite the use of, active hormone treatment strategies are characterized as castration-resistant. Patients with castration-resistant prostate cancer have a poor prognosis and few treatment options.

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 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 <http://www.medivation.com>.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the 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 <http://www.astellas.com/en>

References:

1. <http://www.europa-uomo.org/> (last accessed 17 November 2009)
2. <http://info.cancerresearchuk.org/cancerstats/types/prostate/incidence/> (last accessed 17 November 2009)

This press release contains forward-looking statements, including statements regarding the potential clinical benefits of MDV3100 in various patient populations, and development plans and goals for MDV3100, 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 progress, timing and results of Medivation's clinical trials, including the risk that positive results in earlier clinical trials may not be repeated in subsequent clinical trials and the risk that interim results from ongoing clinical trials may not be predictive of the final results of any such trial, difficulties or delays in obtaining regulatory approval, enrollment of patients in Medivation's clinical trials, partnering of Medivation's product candidates, manufacturing of Medivation's product candidates, competition with Medivation's product candidates should they receive marketing approval, 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, 2009, filed November 4, 2009, 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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