



Medivation Announces Positive New Efficacy Data From Phase 1-2 Trial of MDV3100 in Advanced Prostate Cancer Patients

-- Findings Presented at American Society of Clinical Oncology 2009 Annual Meeting and Included in Best of ASCO(R) Educational Program --

SAN FRANCISCO, June 2, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Medivation, Inc. (Nasdaq: MDVN) today announced the presentation of new clinical results from a Phase 1-2 trial evaluating MDV3100, a next-generation androgen receptor antagonist, in castration-resistant prostate cancer (CRPC) patients. The new findings, which include data from all 140 enrolled patients, confirm previously reported results that MDV3100 consistently demonstrated anti-tumor activity in both chemotherapy-naive and post-chemotherapy CRPC patients across dose levels and endpoints, as evaluated by reductions in prostate specific antigen (PSA) levels, radiographic findings and circulating tumor cell (CTC) counts.

New findings include the median time to PSA progression, which was 6.1 months for post-chemotherapy patients, with the median time not yet reached for chemotherapy-naive patients. In addition, the median time to radiographic progression was 6.6 months for post-chemotherapy patients, with the median time not yet reached for chemotherapy-naive patients.

"These new clinical data in the post-chemotherapy setting are encouraging because these patients have a poor prognosis, surviving on average a year or less -- with no approved treatment options," said Howard Scher, M.D., principal investigator of the trial and chief of the Genitourinary Oncology Service and the D. Wayne Calloway Chair in Urologic Oncology at Memorial Sloan-Kettering Cancer Center in New York. "These findings suggest that MDV3100, with its unique mechanism of action, provides beneficial clinical effects in contrast to those achieved with first-generation androgen receptor antagonists."

In vitro data recently published in Science provide evidence that MDV3100's novel mechanism of action is unlike that of the leading androgen receptor antagonist, bicalutamide. Specifically, MDV3100:

- blocks the androgen receptor with greater binding affinity than bicalutamide;
- impairs nuclear translocation and blocks DNA binding of the androgen receptor, one of the key steps required for androgen-dependent prostate cancer growth and a step not blocked by bicalutamide; and,
- induces death in prostate tumor cells that were previously resistant, an effect not seen with bicalutamide.

Additional Trial Results

The Phase 1-2 data presented at ASCO demonstrated that MDV3100 has anti-tumor activity across a variety of endpoints:

	PSA declines (50% or more from baseline)	Radiographic control in soft tissue lesions (partial response or stable disease)	Radiographic control in bony lesions (stable disease)	CTC count conversion (from unfavorable to favorable status)
Chemotherapy-naive	62 percent	80 percent	63 percent	75 percent
Post-chemotherapy	51 percent	65 percent	51 percent	37 percent

MDV3100 has been generally well tolerated at doses up to and including 240 mg/day.

Medivation plans to initiate a pivotal Phase 3 clinical trial of MDV3100 later this year. The primary endpoint of the trial will be overall survival.

"We believe that the benefit-risk ratio for MDV3100 is highly favorable, and we are working diligently to initiate the Phase 3 clinical trial later this year," said David Hung, M.D., president and chief executive officer of Medivation. "The clinical results to date suggest that MDV3100 is not only a promising medication for men with CRPC, but that it may also be useful earlier in the disease state, for patients whose prostate cancer is still hormone sensitive."

The data were presented by Dr. Scher in an oral session at the American Society of Clinical Oncology's (ASCO) 2009 Annual Meeting in Orlando, Fla. (abstract #5011). Additionally, ASCO selected the MDV3100 abstract for inclusion in its Best of ASCO (R) program, an educational initiative covering highlights from the ASCO Annual Meeting to increase global access to cutting-edge science.

About Prostate Cancer and MDV3100

Prostate cancer is the most common non-skin cancer in the United States and the third most common cancer worldwide. More than 1 million men in the United States have prostate cancer, and it is the second leading cause of cancer death among men after lung cancer(1). In 2009, an estimated 192,280 new cases are expected to be diagnosed and approximately 27,360 men are expected to die from the disease. Patients with castration-resistant (also known as hormone-refractory) prostate cancer have few treatment options and a poor prognosis.

Overexpression of the androgen receptor is believed to contribute to the progression of CRPC. MDV3100 is a next-generation androgen receptor antagonist that inhibits androgen receptor function by blocking nuclear translocation of the androgen receptor and DNA binding.

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 for the treatment of Alzheimer's and Huntington's diseases. With Pfizer, the Company 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 medication in patients with mild, moderate or severe Alzheimer's disease. Further development of Dimebon in patients with Huntington's disease is also planned. In addition, a Phase 1-2 clinical trial of MDV3100 in patients with castration-resistant (also known as hormone-refractory) prostate cancer is ongoing. For more information, please visit us at <http://www.medivation.com>.

This press release contains forward-looking statements, including statements regarding the timing and potential results of Phase 3 trials of 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 progress, timing and results of Medivation's clinical trials, 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 March 31, 2009, filed on May 11, 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.

(1)American Cancer Society

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