

# **Press Release**

# Astellas and Medivation Enter Into Worldwide Agreement to Co-Develop and Co-Commercialize MDV3100 for the Treatment of Prostate Cancer

Medivation to Receive \$110 Million Upfront Cash Payment and Eligible to Receive \$655 Million in Milestone Payments, 50 Percent of U.S. Profits and Double-Digit Royalties on Ex-U.S. Sales Medivation to Host Conference Call/Webcast Today at 8:30 a.m. Eastern Time

**TOKYO, JAPAN and SAN FRANCISCO, CA, October, 27, 2009 -** Astellas Pharma Inc. ("Astellas") and Medivation, Inc. (Nasdaq: MDVN) announced today that they have entered into a global agreement to develop and commercialize MDV3100, Medivation's investigational drug for the treatment of prostate cancer. MDV3100 is currently being evaluated in the Phase 3 AFFIRM clinical trial in men with castration-resistant prostate cancer who were previously treated with docetaxel-based chemotherapy.

Under the terms of the agreement, Medivation will receive an up-front cash payment of \$110 million. Medivation is also eligible to receive payments of up to \$335 million upon the attainment of development and regulatory milestones plus up to an additional \$320 million in commercial milestone payments. The companies will collaborate on a comprehensive development program that will include additional studies to develop MDV3100 for both late- and early-stage prostate cancer. Subject to receipt of regulatory approval, the companies will jointly commercialize MDV3100 in the U.S. The companies will share equally all U.S. development costs, commercialization costs, and profits. Astellas will have responsibility for developing and commercializing MDV3100 outside the U.S. and will pay Medivation tiered double-digit royalties on ex-U.S. sales.

"We are pleased to initiate a great partnership with Medivation," stated Masafumi Nogimori, president and chief executive officer of Astellas. "We believe that MDV3100 has the unique potential to establish a new treatment approach for prostate cancer. Astellas already has the global expertise in urology and the strong commitment to focus on oncology. This partnership is a significant milestone to further expand our business in urology and to establish our franchise in oncology."

"We are excited to be working with Astellas to develop MDV3100 for a broad spectrum of prostate cancer disease states," said David Hung, M.D. president and chief executive officer of Medivation. "Astellas is an ideal partner for MDV3100 given its global reach, leading commercial presence in the urology space, and strategic focus on oncology. Astellas is the second major collaboration we have completed in the past year, and we are confident we have the right partners in place for each of our late-stage programs— Astellas for MDV3100 and Pfizer, Inc for dimebon (latrepirdine\*).

"According to the American Cancer Society, prostate cancer is the most common non-skin cancer among men in the United States. More than 2 million American men have prostate cancer, and it is the second leading cause of cancer death among men after lung cancer. In 2009, an estimated 192,000 new cases are expected to be diagnosed, and approximately 27,000 men are expected to die from the disease.

MDV3100, a new generation of oral anti-androgen, which shows different pharmacological profiles from current anti-androgens, 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.



# **Press Release**

Preclinical data published in Science earlier this year demonstrated that MDV3100 is superior to bicalutamide in each of these three actions.

The agreement is not subject to approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and becomes effective immediately. Medivation's legal and financial advisers on the transaction were Cooley Godward Kronish LLP and Aquilo Partners, L.P. Astellas' legal adviser on the transaction was Covington & Burling LLP.

\*Latrepirdine is the proposed generic (nonproprietary) name for dimebon.

#### **Conference Call Information**

Medivation will hold a conference call today at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss this announcement. To participate in the conference call, please dial 888-280-4443 for domestic callers and 1-719-457-2638 for international callers. In addition, this call is being Webcast and can be accessed at Medivation's website at www.medivation.com.

## **About MDV3100's Clinical Program**

In September 2009, Medivation began enrolling patients in a randomized, placebo-controlled, double-blind, multi-national Phase 3 clinical trial known as AFFIRM. This trial is evaluating MDV3100 at a dose of 160 mg taken orally once daily versus placebo in men with castration-resistant 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. This trial is expected to enroll approximately 1,200 patients at sites in the United States, Canada, Europe, South America, Australia and South Africa.

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 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 14,000 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 <a href="http://www.astellas.com">http://www.astellas.com</a>.

#### **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



# **Press Release**

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.

## **Medivation Forward Looking Statement**

This press release contains forward-looking statements, including statements related to future clinical development of and ongoing clinical trials evaluating MDV3100, the therapeutic and commercial potential of MDV3100, and potential future development and regulatory milestone payments, commercial milestone payments and royalty payments under the 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 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, enrollment of patients in Medivation's clinical trials, difficulties or delays in obtaining regulatory approvals, Medivation's dependence on Astellas for aspects of the development, regulatory approval, manufacturing and commercialization of MDV3100, manufacturing of MDV3100, competition with MDV3100 should it receive marketing approvals, 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 (SEC), including its guarterly report on Form 10-Q for the quarterly period ended June 30, 2009, filed with the SEC on August 5, 2009. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Medivation disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.

#### For further information:

#### Theravance Inc.:

Michael W. Aguiar, Senior Vice President and Chief Financial Officer, 650) 808-4100 investor.relations@theravance.com

### Astellas Pharma Canada, Inc.:

Michelle Reale, Corporate Communications, (905) 946-5621 michelle.reale@ca.astellas.com