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## Investor News

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### **Bayer and Orion Expand Clinical Development Program With New Phase III Study ARASENS for BAY-1841788 (ODM-201) in Prostate Cancer**

- Phase III study ARASENS to be initiated in metastatic hormone sensitive prostate cancer assessing the novel androgen-receptor antagonist in combination with standard androgen deprivation therapy and the chemotherapy docetaxel
  - Start of patient enrolment expected towards the end of 2016
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**Leverkusen, Germany, June 3, 2016** – Bayer and Orion Corporation today announced the expansion of the global clinical development program for the investigational androgen receptor (AR) antagonist BAY-1841788 (ODM-201) in the area of prostate cancer. A new Phase III study ARASENS will evaluate the compound in combination with standard androgen deprivation therapy (ADT) and the chemotherapy docetaxel in men with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC), who are starting first line hormone therapy. BAY-1841788 (ODM-201) is an investigational oral AR-antagonist that has a unique chemical structure designed to block the growth of cancer cells through binding to the AR with high affinity and inhibiting the receptor function. The compound is currently in Phase III development ARAMIS study for high-risk non-metastatic castration-resistant prostate cancer (nmCRPC). The new trial ARASENS is expected to start the enrolment of patients towards the end of 2016.

“Although the treatment options for patients with advanced prostate cancer who are castration-resistant have evolved considerably in recent years, there were only few advances in the earlier, hormone-sensitive stage of metastatic disease. Novel treatment approaches are urgently needed for patients to delay the progress of the cancer and improve survival,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “Bayer's commitment to prostate cancer research runs deep, and the initiation of ARASENS is the latest in a long

line of studies designed to evaluate treatment options for patients with advanced disease.”

Bayer and Orion have recently expanded the 2014 agreement to include the joint development of BAY-1841788 (ODM-201) for mHSPC. Under that agreement, Bayer will commercialize the product globally; Orion has the option to co-promote BAY-1841788 in Europe, and is responsible for the manufacturing of the product.

“We believe that the profile of ODM-201 makes it an excellent treatment candidate for patients with metastatic hormone-sensitive prostate cancer. This is another example of how Orion’s oncology research is aiming to contribute to the benefit of patients. We are also happy to see Bayer’s continuous commitment to ODM-201”, said Dr. Reijo Salonen, Senior Vice President of R&D at Orion.

### **About ARASENS**

ARASENS (A Randomized, double-blind, placebo-controlled Phase III study of ODM 201 versus placebo in addition to standard Androgen deprivation therapy and docetaxel in patients with metastatic castration SENSitive prostate cancer) is planned to be initiated towards the end of 2016. Approximately 1,300 patients will be randomized (1:1 ratio) to receive either BAY-1841788 or placebo in combination with an ADT of investigator’s choice (LHRH agonist/antagonists or orchiectomy), started ≤12 weeks before randomization. Six cycles of docetaxel will be administered after randomization. The primary endpoint of the study is overall survival, and secondary endpoints include time to castration-resistant prostate cancer (time to CRPC), time to initiation of subsequent antineoplastic therapy, symptomatic skeletal event free survival (SSE-FS), time to first symptomatic skeletal event (time to SSE), time to initiation of opioid use, time to pain progression, time to worsening of physical symptoms of disease and safety.

ARASENS adds to the ongoing clinical development program for BAY-1841788, which includes ARAMIS (NCT02200614), a randomized, Phase III, multicenter, double-blind, placebo-controlled trial evaluating patients with non-metastatic CRPC who are at high risk for developing metastatic disease. ARAMIS is currently enrolling patients.

### **About Metastatic Hormone-Sensitive Prostate Cancer**

Prostate cancer (PC) is the second most common form of cancer worldwide and the fifth leading cause of cancer-related death in men. More than 1.1 million men worldwide were diagnosed with the disease in 2012.

At the time of diagnosis, most men have localized prostate cancer, meaning their cancer is confined to the prostate gland and can be treated with curative surgery or radiotherapy. Upon relapse when the disease will metastasize or spread, androgen deprivation therapy (ADT) is the cornerstone of treatment for this hormone-sensitive disease. Approximately five percent of men will already suffer from prostate cancer with distant metastases when first diagnosed. Men with newly diagnosed metastatic hormone-sensitive prostate cancer (HSPC) will start their treatment with hormone therapy, such as ADT or a combination of the chemotherapy docetaxel and ADT. Despite this first line treatment, most men with metastatic HSPC will eventually progress to castration-resistant prostate cancer (CRPC), which can impact survival and quality of life.

#### **About BAY-1841788 (ODM-201)**

BAY-1841788 (ODM-201) is an investigational oral androgen receptor (AR) antagonist that has a unique chemical structure designed to block the growth of cancer cells through binding to the AR with high affinity and inhibiting the receptor function. In preclinical studies, BAY-1841788 and its main circulating metabolite are active also in known AR mutants (ex W742L, F877L), and have been found to have negligible blood-brain barrier penetration.

BAY-1841788 (ODM-201) is not approved by the U.S. Food and Drug Administration, the European Medicines Agency or any other health authority.

#### **About Oncology at Bayer**

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

#### **Bayer: Science For A Better Life**

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of

sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to [www.bayer.com](http://www.bayer.com).

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