Algeta announces that Xofigo® (radium Ra 223 dichloride) injection has been approved by the US FDA as Treatment for Castration-Resistant Prostate Cancer with Bone Metastases

- Algeta to host international conference call scheduled for tomorrow at 08:00 CET, 02:00 Eastern time – details below

Oslo, Norway, 15 May 2013 - Algeta ASA (OSE: ALGETA) announces that Bayer has received US Food and Drug Administration (FDA) approval for Xofigo® (radium Ra 223 dichloride) injection for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease. Xofigo is the first alpha particle-emitting radioactive therapeutic agent approved by the FDA. It has demonstrated improvement in overall survival (OS) and delay in time to first symptomatic skeletal event (SSE) compared to placebo in the pivotal phase III ALSYMPCA trial1.

The commercial production of Xofigo is underway, and first doses are expected to be ready for patient treatment within a few weeks. Bayer has worldwide exclusive marketing rights for Xofigo. Algeta US, LLC and Bayer Healthcare will co-promote the product in the US.

Andrew Kay, Algeta’s President & CEO, said: “We are delighted that the FDA has taken the decision to approve Xofigo so quickly. We are extremely pleased to be able to make Xofigo available to US patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. We will now finalize our launch preparations in the US, with the intention of launching Xofigo, with Bayer, as soon as possible. This approval is a major milestone for Algeta and puts us firmly on the path to deliver on our vision to be a world-class oncology company bringing medicines to cancer patients through our leadership in alpha particle-emitting pharmaceuticals.”

“Most men with castration-resistant prostate cancer develop bone metastases, which can decrease overall survival,” said Oliver Sartor, MD, North American Principal Investigator for the pivotal trial and medical director of the Tulane Cancer Center (New Orleans, LA). “Xofigo has demonstrated an anti-tumor effect on bone metastases and will be an important addition to the treatment of this cancer.”

Bone is the most common site in the body to be affected by metastatic cancer, and bone metastases are particularly prevalent in patients with prostate cancer2. Approximately 90% of patients with metastatic prostate cancer show evidence of bone metastases3,4,5,6 Bone metastases can lead to an increase in frequency of skeletal events7 and are shown to be the main cause of morbidity and death in patients with CRPC8.

Jan Manarite, senior educational facilitator for the Prostate Cancer Research Institute also added, “It is encouraging to have a new treatment for men with castration-resistant prostate cancer, who are dealing with bone metastases. Xofigo provides another new option to treat this cancer using a different approach.”
Efficacy and Safety Data Supporting Xofigo® (radium Ra 223 dichloride) Approval

The approval of Xofigo is based on data from the pivotal phase III ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) trial. At the interim analysis, Xofigo significantly improved OS [HR=0.695 (95% CI 0.552-0.875), p=0.00185]; median OS was 14.0 months with Xofigo plus best standard of care vs. 11.2 months with placebo plus best standard of care. Additionally, at the interim analysis there was a delay in the time to first symptomatic skeletal event (SSE) for patients treated with Xofigo vs. placebo.

An updated analysis, conducted after the study was unblinded, showed improvement in overall survival with a median OS of 14.9 months vs. 11.3 months; HR=0.695 (95% CI 0.581-0.832).

The most common adverse reactions (greater than or equal to 10%) in patients receiving Xofigo in the ALSYMPCA trial were nausea, diarrhea, vomiting and peripheral edema. The most common hematologic laboratory abnormalities (greater than or equal to 10%) were anemia, lymphocytopenia, leukopenia, thrombocytopenia and neutropenia.

About Xofigo® (radium Ra 223 dichloride)

Xofigo is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

Xofigo is an alpha particle-emitting radioactive therapeutic agent with an anti-tumor effect on bone metastases. The active ingredient in Xofigo is the alpha particle-emitting isotope radium-223, which mimics calcium and forms complexes with the bone mineral hydroxyapatite at areas of increased bone turnover, such as bone metastases. The high linear energy transfer of Xofigo may cause double-strand DNA breaks in adjacent cells, resulting in an anti-tumor effect on bone metastases. The alpha particle range from radium-223 dichloride is less than 100 micrometers which may limit the damage to the surrounding normal tissue.

In September 2009, Algeta signed an agreement with Bayer for the development and commercialization of Xofigo. Under the terms of the agreement, Bayer will develop, apply for health authority approvals worldwide and commercialize Xofigo globally. Algeta US, LLC will co-promote Xofigo with Bayer in the US.

Important Safety Information for Xofigo (radium Ra 223 dichloride)

Xofigo is contraindicated in women who are or may become pregnant. Xofigo can cause fetal harm when administered to a pregnant woman.

In the randomized trial, 2% of patients in the Xofigo arm experienced bone marrow failure or ongoing pancytopenia, compared to no patients treated with placebo. There were two deaths due to bone marrow failure. For 7 of 13 patients treated with Xofigo, bone marrow failure was ongoing at the time of death. Among the 13 patients who experienced bone marrow failure, 54% required blood transfusions. Four percent (4%) of patients in the Xofigo arm and 2% in the placebo arm permanently discontinued therapy due to bone marrow suppression. In the randomized trial, deaths related to vascular hemorrhage in association with myelosuppression were observed in 1% of Xofigo-treated patients compared to 0.3% of patients treated with placebo. The incidence of infection-related deaths (2%), serious infections (10%), and febrile neutropenia (less than 1%) was similar for patients treated with Xofigo and placebo.
Myelosuppression – notably thrombocytopenia, neutropenia, pancytopenia, and leukopenia – has been reported in patients treated with Xofigo.

Monitor patients with evidence of compromised bone marrow reserve closely and provide supportive care measures when clinically indicated. Discontinue Xofigo in patients who experience life-threatening complications despite supportive care for bone marrow failure.

Monitor blood counts at baseline and prior to every dose of Xofigo. Prior to first administering Xofigo, the absolute neutrophil count (ANC) should be greater than or equal to $1.5 \times 10^9/L$, the platelet count greater than or equal to $100 \times 10^9/L$, and hemoglobin greater than or equal to $10 \text{ g/dL}$. Prior to subsequent administrations, the ANC should be greater than or equal to $1 \times 10^9/L$ and the platelet count greater than or equal to $50 \times 10^9/L$. Discontinue Xofigo if hematologic values do not recover within 6 to 8 weeks after the last administration despite receiving supportive care.

Safety and efficacy of concomitant chemotherapy with Xofigo have not been established. Outside of a clinical trial, concomitant use of Xofigo in patients on chemotherapy is not recommended due to the potential for additive myelosuppression. If chemotherapy, other systemic radioisotopes, or hemibody external radiotherapy are administered during the treatment period, Xofigo should be discontinued.

Xofigo should be received, used, and administered only by authorized persons in designated clinical settings. The administration of Xofigo is associated with potential risks to other persons from radiation or contamination from spills of bodily fluids such as urine, feces, or vomit. Therefore, radiation protection precautions must be taken in accordance with national and local regulations.

The most common adverse reactions (greater than or equal to 10%) in patients receiving Xofigo were nausea, diarrhea, vomiting, and peripheral edema. Grade 3 and 4 adverse events were reported in 57% of Xofigo-treated patients and 63% of placebo-treated patients. The most common hematologic laboratory abnormalities in Xofigo-treated patients (greater than or equal to 10%) were anemia, lymphocytopenia, leukopenia, thrombocytopenia, and neutropenia.

For full prescribing information visit www.xofigo-us.com.

About the ALSYMPCA Trial

The ALSYMPCA trial was a phase III, randomized, double-blind, placebo-controlled international study of Xofigo with best standard of care vs. placebo with best standard of care in symptomatic CRPC patients with bone metastases. The trial enrolled 921 patients in more than 100 centers in 19 countries. The study treatment consisted of up to six intravenous injections of Xofigo or placebo each separated by an interval of four weeks.

The primary endpoint of the study was overall survival (OS). A key secondary endpoint was time to first symptomatic skeletal event (SSE), as defined as external beam radiation therapy (EBRT) to relieve skeletal symptoms, new symptomatic pathologic bone fracture, occurrence of spinal cord compression, or tumor-related orthopedic surgical intervention.

About CRPC and Bone Metastases

Prostate cancer is the most common cancer among men in the United States (other than skin cancer). Approximately 4% of prostate cancer cases are considered distant, which means that the cancer has spread beyond the prostate to distant areas of the
body (metastasized)\textsuperscript{10}. If prostate cancer starts to spread to other areas of the body, it most commonly goes to the bones\textsuperscript{7}.

**About the Patient Assistance Program**

Bayer and Algeta offer patient assistance through Xofigo Access Services\textsuperscript{SM} which will assist with obtaining coverage and patient support of Xofigo. Patients and providers may contact the program at 1-855-6XOFIGO (1-855-696-3446) for additional information.

**Details of international conference call**

A conference call for investors, analysts and the press, and hosted by Algeta's senior management team, will take place tomorrow at 08:00 CET, 02:00 Eastern time. To participate in the conference call, please dial the appropriate number below five minutes prior to the call:

- **US**: +1 866 966 5335
- **UK**: +44 20 3003 2666 (toll free 0808 109 0700)
- **Norway**: +47 21 56 33 18 (toll free 800 19 457)

Password: Algeta

To access the replay (available for seven days), please dial:

- **US**: +1 866 583 1035
- **UK**: +44 20 8196 1998
- **Norway**: toll free 800 19 101

Participant pin code: 9227182

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**For further information, please contact:**

- **Mike Booth**
  Communications & Corporate Affairs  
  +47 2202 4510  
  ir@algeta.com

*Media enquiries:*
- **Mark Swallow**
  Citigate Dewe Rogerson  
  +44 207 638 9571  
  mark.swallow@citigatedr.co.uk

- **Kari Watson**
  MacDougall Biomedical Communications  
  +1 781 235 3060  
  kwatson@macbiocom.com

*US investor enquiries:*
- **Tricia Swanson**
  The Trout Group  
  +1 646 378 2953  
  tswanson@troutgroup.com
About Algeta

Algeta is a company focused on developing novel targeted therapies for patients with cancer based on its alpha-pharmaceutical platform. The Company is headquartered in Oslo, Norway, and has a US subsidiary, Algeta US, LLC, based in Cambridge, MA performing commercial marketing operations in the US. Algeta is listed on the Oslo Stock Exchange (Ticker: ALGETA). For more information please visit www.algeta.com.

Forward-looking Statements

This news release contains certain forward-looking statements that are based on uncertainty, as they relate to events and depend on circumstances that will occur in the future and which, by their nature, may have an impact on results of operations and the financial condition of Algeta. Such forward-looking statements reflect our current views and are based on the information currently available to Algeta. Algeta cannot give any assurance as to whether such forward looking statements will prove to be correct. These forward looking statements include statements regarding our anticipated co-promotion of Xofigo in the US. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements. These factors include, among other things, risks or uncertainties associated with the ability to identify and hire a sufficient number of qualified employees in the US, growth management, general economic and business conditions and the pricing environment, the impact of competition, the ability to successfully commercialize Xofigo, the risk that costs associated with the co-promotion of Xofigo may be greater than anticipated, manufacturing capacity, the risk of non-approval of patents not yet granted, risks in obtaining additional regulatory approvals for radium-223 and the other risks and uncertainties described in our annual report.

Xofigo® is a registered trademark of Bayer. Xofigo Access Services® is a service mark of Bayer.

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1 XOFIGO Prescribing information. May 2013
8 Lange PH, Vasella RL. "Mechanisms, hypotheses and questions regarding prostate cancer metastatic to bone.” Cancer & Metastasis Reviews.1999;17:331-336
10 National Cancer Institute, Surveillance Epidemiology and End Results (SEER). SEER Stat Facts: Prostate; Survival & Stage, 2002-2008