Further sub-analyses of ALSYMPCA phase III study presented at 2013 Genitourinary Cancers Symposium

Oslo, Norway, 15 February 2013 - Algeta ASA (OSE: ALGETA) announces that further sub-analyses of data from the phase III ALSYMPCA study of radium Ra 223 dichloride (radium-223) in castration-resistant prostate cancer (CRPC) patients have been presented at the 2013 Genitourinary Cancers Symposium1 (14-16 February 2013, Orlando, FL, USA).

Radium-223 is an investigational alpha particle-emitting pharmaceutical in development for CRPC patients with bone metastases and is not approved by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) or other health authorities.

Gillies O’Bryan-Tear, Algeta’s Chief Medical Officer, said: “These additional analyses from ALSYMPCA continue to support radium-223’s potential in the treatment of men with CRPC that has metastasized to the bone.”

Abstract #11 by Vogelzang et al. found that radium-223 treatment significantly delayed time to first skeletal-related event (SRE) versus placebo by a median increase of 5.8 months (median time to SRE: 15.6 vs 9.8 months; HR=0.66; P<0.001).

Abstract #19 by Nilsson et al. described an analysis of pain parameters in ALSYMPCA. The analysis showed that, compared to placebo in CRPC patients with bone metastases, patients treated with radium-223 had significantly prolonged median time to first palliative external beam radiotherapy (EBRT) (HR=0.670, P=0.00117).

In the ALSYMPCA trial the most common hematologic adverse events for patients treated with radium-223 and best standard of care (BSoC) included anemia (31% vs. 31%), neutropenia (5% vs. 1%) and thrombocytopenia (12% vs. 6%). With respect to Grade 3 and 4 adverse events, the most common events included anemia (13% vs. 13%), neutropenia (2% vs. 1%) and thrombocytopenia (6% vs. 2%). The most common non-hematologic adverse events in patients treated with radium-223 and BSoC compared to placebo and BSoC included bone pain (50% vs. 62%), nausea (36% vs. 35%), diarrhea (25% vs. 15%) and vomiting (19% vs. 14%). With respect to Grade 3 to 4 adverse events, the most common events included bone pain (21% vs. 26%).

In September 2009, Algeta signed an agreement with Bayer Pharma AG (Berlin, Germany) for the development and commercialization of radium-223. Under the terms of the agreement, Bayer will develop, apply for global health authority approvals, and commercialize radium-223 globally. Algeta will co-promote radium-223 with Bayer in the US, and is eligible for milestones as well as royalties on Bayer’s sales outside the US. The ALSYMPCA trial was initiated by Algeta in June 2008.

References

Abstract #11 – Vogelzang, N. et al. Updated analysis of radium-223 dichloride (Ra-223) impact on skeletal-related events (SRE) in patients with castration-resistant

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1The 2013 Genitourinary Cancers Symposium is co-sponsored by the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO) and the Society of Urologic Oncology (SUO).
prostate cancer (CRPC) and bone metastases from the phase III randomized trial (ALSYMPCA).

Abstract #19 – Nilsson, S. et al. Pain analysis from the phase III randomized ALSYMPCA study with radium-223 dichloride (Ra-223) in castration-resistant prostate cancer (CRPC) patients with bone metastases.

### About the ALSYMPCA Trial

The ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) trial was a phase III, randomized, double-blind, placebo-controlled international study of radium-223 with best standard of care (BSoC) vs placebo with BSoC 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 administrations of radium-223 or placebo each separated by an interval of four weeks.

The primary endpoint of the study was overall survival. Secondary endpoints included time to occurrence of skeletal-related events (SRE), time to total alkaline phosphatase (ALP) and prostate-specific antigen (PSA) progression, total ALP response and normalization, safety, and quality of life.

### About CRPC and Bone Metastases

Prostate cancer is the most common cancer among men in the United States (other than skin cancer)\(^2\). Approximately 16% of prostate cancer cases are considered regional or distant, which means that the cancer has spread beyond the prostate to nearby or distant areas of the body (metastasis)\(^3\).

A majority of men with CRPC have radiological evidence of bone metastases\(^4\). Bone metastases secondary to prostate cancer typically target the lumbar spine, vertebrae and pelvis\(^5\). In fact, bone metastases are the main cause of morbidity and death in patients with CRPC\(^6\).

### About Radium Ra 223 Dichloride

Radium Ra 223 dichloride (radium-223), formerly referred to as radium-223 chloride, is an investigational alpha particle-emitting pharmaceutical in development for CRPC patients with bone metastases.

Radium-223 is an investigational agent and is not approved by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) or other health authorities. Bayer submitted a Marketing Authorization Application to the EMA and a New Drug Application to the FDA for radium-223 in December 2012 for the treatment of CRPC patients with bone metastases.

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\(^3\) National Cancer Institute, Surveillance Epidemiology and End Results (SEER). SEER Stat Facts: Prostate; Survival & Stage, 2002-2008


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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 radium-223 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 for the US field force, growth management, general economic and business conditions and the pricing environment, the impact of competition, the ability to successfully commercialize radium-223, the risk that costs associated with the co-promotion of radium-223 may be greater than anticipated, manufacturing capacity, the risk of non-approval of patents not yet granted, risks in obtaining regulatory approvals for radium-223 and the other risks and uncertainties described in our annual report.