US FDA Grants Priority Review to Bayer’s NDA for Radium Ra 223 Dichloride for Castration-Resistant Prostate Cancer with Bone Metastases

Oslo, Norway, 13 February 2013 - Algeta ASA (OSE: ALGETA) announces that Bayer has received notification that the New Drug Application (NDA) for the investigational compound Radium Ra 223 Dichloride (radium-223) has been accepted for filing and granted priority review by the US Food and Drug Administration (FDA). The application is currently under review for the treatment of castration-resistant prostate cancer (CRPC) patients with bone metastases.

Andrew Kay, Algeta’s President & CEO, said: “With the granting of priority review for the NDA for Radium Ra 223 dichloride (radium-223) in the US, there is recognition that Radium Ra 223 dichloride (radium-223) has the potential to offer a treatment option for CRPC patients with bone metastases where little or no therapy exists. While we await the final decision from the regulators later this year, and together with Bayer, we continue with our commercialization planning and look forward to a potential approval, and to making this compound available to patients.”

The FDA grants priority review to medicines that provide a treatment where little or no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete its review within six months of the 60-day filing receipt of the NDA submission (eight months total), rather than the standard 12-month review cycle.

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.

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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.

In January 2013, the US Nuclear Regulatory Commission (NRC) issued a licensing decision on the medical use of radium-223. The decision states that US medical sites can procure and administer radium-223 under 10 CFR Part 35, Subpart E, which includes 10 CFR § 35.300.
About CRPC and Bone Metastases

Prostate cancer is the most common cancer among men in the United States (other than skin cancer)\(^1\). 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)\(^2\).

A majority of men with CRPC have radiological evidence of bone metastases\(^3\). Bone metastases secondary to prostate cancer typically target the lumbar spine, vertebrae and pelvis\(^4\). In fact, bone metastases are the main cause of morbidity and death in patients with CRPC\(^5\).

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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

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\(^2\) National Cancer Institute, Surveillance Epidemiology and End Results (SEER). SEER Stat Facts: Prostate; Survival & Stage, 2002-2008


to be correct. These forward looking statements include statements regarding the potential timeline of FDA approval of radium-223 and 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.