

Algeta announces first patient treated in phase II trial of Alpharadin to treat bone metastases in breast cancer

Clinical study underway in second tumor type

Oslo, Norway, 2 February 2010 – Algeta ASA (OSE: ALGETA), the cancer therapeutics company, announces that it has treated the first patient in a phase II clinical study with Alpharadin for bone metastases resulting from endocrine-refractory breast cancer. This is the second tumor type under investigation with Alpharadin, the first being prostate cancer.

Algeta's lead product Alpharadin (based on radium-223) is a first-in-class, highly targeted alpha-pharmaceutical under clinical evaluation to improve survival in patients with bone metastases from advanced cancer. Its localized action helps preserve the surrounding healthy tissue thereby limiting side-effects.

The new trial (BC1-09) will recruit 20 women with breast cancer that has spread primarily to the bone and that no longer responds to endocrine therapy. It will be conducted at cancer centers in Oslo (Norway), Brussels (Belgium) and Sheffield (UK). Patients will receive one intravenous injection of Alpharadin (radium-223 chloride), 50 kBq/kg b.w., every four weeks for four cycles.

The objective of the study is to examine whether Alpharadin has a clinically relevant effect on several biomarkers for bone turnover during the 16-week treatment period.¹ The trial will also monitor the safety of Alpharadin treatment in these patients. In an earlier Phase I study, safety data were collected from women with bone metastases from breast cancer as part of the wider Alpharadin clinical program. The results showed that Alpharadin has a benign side-effect profile in these patients and were consistent with safety findings in men with prostate cancer.

Prof. Robert Coleman, a cancer specialist at the Weston Park Hospital in Sheffield and Principal Investigator for the trial, said "Bone metastases are a frequent and devastating development of breast cancer as it advances, leading to a dramatic deterioration in patient health. If Alpharadin can replicate the clinical benefits it has shown in men with prostate cancer then it may be an important new therapy for women with limited treatment options."

Andrew Kay, Algeta's President and CEO said: "We believe that Alpharadin's great potential lies in its mode of action that suggests it is likely to target and destroy bone metastases in several different tumor types from which bone metastases spread. We have seen highly encouraging results in our clinical studies with Alpharadin in men with prostate cancer that has spread to the bone, including improved survival benefit, pain relief and a benign side effect profile. Success in this new trial in women with breast cancer will address another unmet medical need in this large patient group as well as extending Alpharadin's commercial potential as a first-choice treatment for bone metastases."

Alpharadin is in a global phase III clinical trial (ALSYMPCA) to treat bone metastases resulting from prostate cancer. Recruitment of patients into this trial continues to progress very well and is expected to complete enrolment of 750 patients on schedule in the second half of 2010.

¹ The following markers of bone turnover will be measured to follow the effect of Alpharadin during the 16-week treatment period: urine N-Telopeptide (uNTX), urine C-Telopeptide (uCTX-1), bone specific alkaline phosphatase (bALP), N-terminal propeptide of procollagen type 1 (P1NP), pyridinoline cross-linked carboxyterminal telopeptide (ICTP).

In September 2009, Algeta entered into a \$800 million global agreement with Bayer Schering Pharma AG for the development and commercialization of Alpharadin. As part of the agreement, Algeta retains an option to co-promote Alpharadin in the United States and to share profits from future sales.

Bone Metastases and Breast Cancer

Sources: Cancer Research UK, American Cancer Society, World Health Organization

The development of bone metastases represents a serious development for cancer patients as they are associated with a dramatic decline in patient health and quality of life, ultimately leading to death. Bone metastases represent a major unmet medical need, occurring in up to 90% of certain late-stage cancers, e.g. prostate, breast and lung.

- Breast cancer is by far the most common cancer in females, accounting for around 31% of all female cancers
- Breast cancer accounted for more than half a million deaths worldwide in 2004
- Nearly 200,000 new cases of invasive breast cancer were diagnosed in the US in 2009 and around 40,000 women were expected to die as a result of breast cancer
- Only lung cancer accounts for more cancer deaths among women.
- As many as 75% of breast cancer patients with metastatic disease will have metastases in the bone (Harvey, H.A. and Cream, L.R. (2007) *Clin. Breast Cancer*. Jul;7 Suppl 1:S7-S13)

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About Algeta

Algeta ASA is a cancer therapeutics company built on world-leading, proprietary technology. Algeta is developing a new generation of targeted cancer therapeutics (alpha-pharmaceuticals) that harness the unique characteristics of alpha particle emitters and are potent, well-tolerated and convenient to use.

Algeta's lead alpha-pharmaceutical candidate, Alpharadin (based on radium-223), has blockbuster potential for treating bone metastases arising from multiple major cancer types, owing to its bone-targeting nature, potent efficacy (therapeutic and palliative) and benign safety profile. Development of Alpharadin is most advanced targeting bone metastases resulting from hormone-refractory prostate cancer (HRPC), and it entered an international phase III clinical trial (ALSYMPCA) in mid-

2008 based on compelling clinical results from a comprehensive phase II program. This trial is currently open for recruitment.

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Algeta is also developing other technologies for delivering alpha-pharmaceuticals. These include methods to enhance the potency of therapeutic antibodies and other tumor-targeting molecules by linking them to the alpha particle emitter thorium-227. The Company is headquartered in Oslo, Norway, and was founded in 1997. Algeta listed on the Oslo Stock Exchange in March 2007 (Ticker: ALGETA).

Alpharadin and Algeta are trademarks of Algeta ASA.

Forward-looking Statement

This news release contains forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on results of operations and the financial condition of Algeta. 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 associated with technological development, the risk that research & development will not yield new products that achieve commercial success, the impact of competition, the ability to close viable and profitable business deals, the risk of non-approval of patents not yet granted and difficulties of obtaining relevant governmental approvals for new products.

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