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Abstracts #8021 and #533

Adding Novartis drug Zometa® to chemotherapy significantly improved overall survival in study of newly diagnosed multiple myeloma patients

- *Phase III data show Zometa, a bone-targeted agent, provided significant clinical anticancer benefit and significantly reduced risk of skeletal-related events*
- *Survival advantage observed with Zometa added to chemotherapy versus oral clodronate added to chemotherapy is independent of skeletal-related event benefit*
- *Results from a separate study in premenopausal early breast cancer confirmed significant anticancer benefit of Zometa in this patient population*
- *Data add to a growing body of clinical evidence suggesting potential anticancer activity of Zometa*

Basel, June 5, 2010 — New data to be presented tomorrow at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL, show that the addition of Zometa® (zoledronic acid) to first-line chemotherapy significantly improved overall survival for newly diagnosed multiple myeloma patients by 16% (P=0.0118) and progression-free survival by 12% (P=0.0179) compared with oral clodronate plus first-line chemotherapy[1]. The 5.5 month survival improvement demonstrated by Zometa in this study of nearly 2000 patients was independent of the drug's effect on bone complications (also known as skeletal-related events or SREs)[1]. Zometa was significantly superior to clodronate in the prevention of SREs associated with multiple myeloma, reducing the relative risk of SREs 24% more than clodronate (P=0.0004)[1].

Zometa is approved in more than 100 countries for the reduction or delay of bone complications in multiple myeloma and across a broad range of metastatic cancers (breast, prostate, lung and other solid tumors) involving bone, as well as for the treatment of hypercalcemia of malignancy (HCM)[2]. It is the most widely used bisphosphonate in the oncology setting and has been used to treat more than 3.5 million patients worldwide[3].

"This is the first time we have seen in a large, Phase III independent trial that the addition of zoledronic acid to chemotherapy significantly improves survival in patients with multiple myeloma," said Dr. Evangelos Terpos, Department of Clinical Therapeutics/Oncology Division, University of Athens School of Medicine, Alexandra General Hospital, Athens, Greece. "These data suggest that zoledronic acid has the potential to help multiple myeloma patients live longer."

Other Zometa data presented at ASCO include a five-year follow-up analysis from the Phase III Austrian Breast & Colorectal Cancer Study Group-12 (ABCSG-12) trial which showed that the addition of Zometa to hormonal therapy following surgery improved disease-free survival

by 32% (HR=0.68 [95%CI 0.51,0.91], P=0.009) in premenopausal women with hormone receptor-positive (HR+) early breast cancer[4]. These data confirm earlier results from ABCSG-12 presented at ASCO 2008[5]. Data from the ABCSG-12 study are the basis of the Company's US and European Union regulatory filings for Zometa in the treatment of adjuvant breast cancer.

"These five-year data are exciting for oncologists and patients alike because they confirm that adding zoledronic acid to a post-surgical hormonal treatment regimen can reduce the risk of cancer returning," said Michael Gnant, MD, lead investigator and Professor of surgery at the Medical University of Vienna. "If approved for this indication, zoledronic acid may offer early breast cancer patients the opportunity to further reduce the risk of breast cancer returning, when added to post-surgery hormone therapy."

Myeloma IX study details[1]

Myeloma IX is a Phase III, prospective, multicenter, randomized, controlled study to compare intravenous (IV) Zometa (4mg every 3-4 weeks) with oral clodronate (1600 mg daily) based on the severity of bone disease and in improving survival. A total of 1,960 evaluable patients from the United Kingdom with newly diagnosed International Staging System (ISS) Stage I, II or III multiple myeloma entered either an intensive or non-intensive treatment pathway, determined on the basis of performance status, informed decision and consent. Patients were randomized for type of bisphosphonate therapy and first-line therapy (induction chemotherapy) on a 1:1 basis.

The primary study endpoints were overall survival (OS), progression free survival (PFS) and response. OS was defined as the length of time after randomization to death from any cause. PFS was defined as the length of time from randomization to disease progression or death. Secondary endpoints included SREs (including bone fractures, radiation to bone, surgery to bone, bone lesions and/or spinal cord compression) and safety.

At a median follow-up of 3.7 years, risk of death was reduced by 16% (P=0.0118) and the risk of progression-free survival events fell by 12% (P=0.0179) with Zometa versus oral clodronate. The proportion of patients who experienced an SRE was reduced by 24% in those receiving Zometa versus clodronate (27.0% versus 35.3%; P=0.0004). The survival advantage demonstrated by Zometa was observed in patients with Stage I, II or III newly diagnosed multiple myeloma. This survival advantage was also observed in addition to and independent of the drug's effect on SREs.

The tolerability profile of Zometa is well-established and results from this study were found to be consistent with the known profile. The incidence of osteonecrosis of the jaw (ONJ) in the Zometa and clodronate treatment arms was 3.6% and 0.3%, respectively. Renal deterioration was reported to be similar between treatment groups.

ABCSG-12 study details[4,6]

ABCSG-12 is an open-label, multicenter, Phase III study that enrolled 1,803 premenopausal women with estrogen receptor-positive Stage I or II breast cancer, with fewer than 10 axillary lymph nodes involved. Patients were recruited for the study after surgery and initiation of goserelin treatment for ovarian suppression, and randomly assigned into one of four study groups: (1) anastrozole plus Zometa; (2) anastrozole alone; (3) tamoxifen plus Zometa; (4) tamoxifen alone. The treatment period was three years and the median follow-up period was 62 months.

The primary endpoint for all four study arms was disease-free survival. Recurrence-free survival, overall survival and bone-mineral density were secondary endpoints. Disease-free survival was defined as the length of time after randomization during which patients had no local recurrence, contralateral breast cancer, distant metastasis, secondary carcinoma and/or death from any cause. Recurrence-free survival was defined as the length of time after randomization during which patients had no local recurrence, contralateral breast

cancer, distant metastasis and/or secondary carcinoma. Bone-mineral density was a primary endpoint of the sub-study. Exploratory endpoints included bone metastasis-free survival.

At the median follow-up of 62 months, disease-free survival events were reduced by 32% (P=0.009) with Zometa added to hormone therapy versus hormone therapy alone. This updated analysis continues to show no difference between tamoxifen and anastrozole use, but that adding Zometa significantly improves disease-free survival (HR=0.68 for both arms). Overall, side effects were consistent with known drug profile. There were no cases of renal failure or confirmed cases of ONJ in the study.

ABOUT ZOMETA[2]

Zometa is indicated for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with advanced malignancies involving bone. An intravenous bisphosphonate, Zometa is the only therapy to demonstrate efficacy in reducing or delaying bone complications across a broad range of tumor types such as breast, prostate, lung and renal cell cancers, in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a 4 mg, 15-minute infusion.

Zometa is the world's leading treatment for the prevention or delay of skeletal-related events (SREs) in patients with advanced malignancies involving bone across a broad range of tumors. Laboratory research has suggested that Zometa may also help protect patients from the spread of cancer to other parts of the body (distant metastatic sites) and help keep patients recurrence-free.

IMPORTANT SAFETY INFORMATION

Zometa has been associated with reports of renal insufficiency. Patients should be adequately rehydrated and have their serum creatinine assessed prior to receiving each dose of Zometa. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes in 100 ml of dilutent. Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates including Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Zometa contains the same active ingredient (zoledronic acid) as found in Aclasta. Patients being treated with Zometa should not be treated with Aclasta concomitantly.

In clinical trials, the most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Osteonecrosis of the Jaw (ONJ): ONJ has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy, and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available to suggest whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures. A causal relationship between bisphosphonate use and ONJ has not been established.

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About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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