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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

Data Show Novartis drug Zometa® offers important advance as first bisphosphonate to significantly reduce bone complications common in kidney cancer

Zometa, a bisphosphonate with demonstrated safety and efficacy across a broad range of solid tumors, may also delay progression of bone lesions in renal cell carcinoma; Data presented at European Association of Urology annual congress

Basel, 14 March 2003 – Treatment with Zometa® (zoledronic acid) reduced by 58% the risk of painful and potentially crippling bone complications in patients with renal cell carcinoma, a type of kidney cancer. In addition, treatment with Zometa significantly delayed onset of the first bone complications. The data, presented at the annual congress of the European Association of Urology (EAU) in Madrid today, are long-term results from a retrospective subset analysis of a larger study, that was included in the dossier given marketing approval in Europe and in the US in 2002.

" Bone complications from kidney cancer can be so crippling that they not only can prevent patients with late stage disease from doing routine, daily activities but may also cause them to be bedridden, " said Alan Lipton, MD, key investigator and professor, Department of Medicine, Division of Oncology at the Milton S. Hershey Medical Center, Pennsylvania State University, US. " Zometa can reduce and delay the onset of these common complications -- helping patients maintain as normal a lifestyle as possible for a longer period of time. "

Bone complications, or skeletal related events, are a serious problem for advanced stage cancer patients. They result from the metastases (spread) of cancer to the bone, and include bone pain, pathologic fractures, need for radiation or surgery to bone, spinal cord compression and hypercalcemia. Renal cell carcinoma is the most common type of adult kidney cancer, accounting for 90-95% of tumors arising from the kidney. Approximately 35% of patients with metastatic renal cell carcinoma develop bone complications during the course of their disease.

Zometa is a new generation intravenous bisphosphonate. It is the first therapy of its kind to demonstrate efficacy in prevention of bone complications across a broad range of tumor types including renal cell, breast, prostate, and lung cancers, as well as multiple myeloma. Further, Zometa offers patients and clinicians a convenient 4 mg, 15-minute infusion time.

Study Details
The data stem from a retrospective subset analysis of a randomized, placebo controlled study designed to evaluate the efficacy and safety of Zometa in patients with bone metastases from renal cell carcinoma, non-small cell lung cancer and other solid tumors. The primary efficacy endpoint was the proportion of patients who experienced a bone complication. Secondary endpoints included time to first bone complication, skeletal morbidity rate, multiple event analysis, and time to progression of bone lesions. Monitoring of these endpoints helps determine the severity of skeletal complications and how quickly bone metastases are progressing. A total of 773 patients were enrolled in the study. Of these patients, 74 had renal cell carcinoma. Participants were randomized to 4 mg Zometa or placebo via 15-minute infusion every three weeks for 21 months.

In the subset of renal cancer patients, the data showed that significantly fewer patients in the group treated with Zometa (41%) experienced a bone complication compared with those in the placebo group (79%; P=0.011), and that Zometa significantly delayed the time to first bone complication (median 424 days vs. 72 days for placebo, P=0.007). Also in comparison to placebo, Zometa significantly reduced the annual event rate by about 20% (P=0.009) and the risk of developing a bone complication by 58% (P=0.010). Additionally, Zometa appears to have delayed the progression of disease in the bone, with a median time to progression of bone lesions at 586 days for the Zometa group, compared with 89 days for the placebo group (P=0.014).

About Zometa
Novartis has received marketing authorization for Zometa in more than 60 countries, including the United States and the member states of the European Union, for the prevention of skeletal related events in patients with advanced malignancies involving bone. These malignancies include multiple myeloma, prostate cancer, breast cancer, lung cancer, renal cancer and other solid tumors. Novartis also has received marketing clearance for Zometa in the treatment of hypercalcemia of malignancy (HCM), also known as tumor-induced hypercalcemia (TIH) in more than 80 countries throughout the world. The proven safety and efficacy of this treatment has resulted in more than 300,000 patients worldwide receiving Zometa to date.

Contraindications and adverse events
In this study, the incidence of renal adverse events was similar between treatment groups. The most common adverse events reported were bone pain (52% Zometa vs. 68% placebo); nausea (52% vs. 37%); fatigue (33% vs. 16%) and pyrexia (fever; 33% vs. 16%). Based on these results, the authors conclude that Zometa is well tolerated and significantly reduces the risk of skeletal complications in renal cell carcinoma patients with bone metastases, and may also delay disease progression in this population.

In clinical trials in patients with bone metastases, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events in bone metastases clinical trials, regardless of causality with Zometa, included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anaemia, weakness, cough, dyspnoea and oedema.

Zometa is contraindicated during pregnancy, in breast-feeding women and in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa. Zometa and other bisphosphonates have been associated with reports of renal insufficiency. Patients should have 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. Since safety and pharmacokinetic data are limited in patients with severe renal impairment, Zometa is not recommended in patients with bone metastases with severe renal impairment. In the clinical studies, patients with serum creatinine >3.0 mg/dL were excluded.

The foregoing release contains forward-looking statements that can be identified by terminology such as “offers important advance,” “demonstrate, ” “reduces, ” “may also delay” or similar expressions, or by discussions regarding potential new indications for Zometa, or regarding the long-term impact of a patient's use of Zometa. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Zometa will be approved for any additional indications in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Zometa. In particular, management's ability to ensure satisfaction of the health authorities'

further requirements is not guaranteed and management's expectations regarding commercialization of Zometa could be affected by, among other things, additional analysis of Zometa clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 900 people and operate in over 140 countries around the world. For further information please consult http://www.novartis.com.

Additional information on Novartis Oncology and Zometa can be found at www.novartisoncology.com or www.zometa.com . Additional media information can be found at www.novartisoncologyvpo.com.

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