

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Long-term data show Novartis once-yearly Aclasta preserves bone mass and provides fracture protection in postmenopausal osteoporosis**

- *Aclasta reduced the risk of new spine fractures by 52% over six years versus patients who stopped treatment after three years¹*
- *New data from six-year study validate Aclasta safety profile and support long-term use of annual infusions in patients with postmenopausal osteoporosis¹*
- *More than one million Aclasta infusions administered worldwide² for the treatment of early to advanced bone loss³*

Basel, October 16, 2010 – Novartis announced today that new six-year data reinforce the long-term efficacy and safety profile of once-yearly Aclasta* (zoledronic acid 5 mg) in postmenopausal women with osteoporosis¹. The study of more than 1,200 women was presented at the annual meeting of the American Society for Bone and Mineral Research (ASBMR) in Toronto, Canada.

The study showed that Aclasta preserved bone mass in postmenopausal osteoporotic patients who received annual infusions for six years¹. In patients who stopped Aclasta treatment after three years, the bone mineral density (BMD) decreased but remained well above the levels measured at the beginning of the study (difference between the two groups at six years: 1.04%, $p=0.0009$)¹.

Patients who stayed on Aclasta therapy for six years reduced their risk of new morphometric spine fractures by 52%, compared to those who stopped treatment at three years ($p=0.04$)¹, the study also showed. Morphometric fractures can occur unaccompanied by pain and therefore may not be diagnosed and treated⁴. Over time patients can experience these fractures in the form of back pain, loss of height, or stooped posture⁴.

"These new findings show that continued treatment with zoledronic acid for six years continues to maintain bone mass and reduces vertebral fractures risk with no change to its favorable safety profile compared to discontinuation of treatment after three years," said Dennis Black, PhD, the study's lead author and Professor of Epidemiology and Biostatistics at the University of California, San Francisco. "These new long-term data reconfirm Aclasta as an important therapeutic option for doctors when considering an osteoporosis medicine for their patients."

In both study groups, the bone markers were maintained over six years within the normal premenopausal range¹. In patients who discontinued Aclasta after three years, there was no evidence of accelerated bone loss¹. This builds upon existing data from extensive clinical studies and confirms that Aclasta helps preserve bone turnover, the balanced process by which the bone is constantly renewed and remodeled throughout adult life.

* The tradename in the US is Reclast®

"Aclasta is highly effective at protecting patients against osteoporotic fractures for a long period of time and its once-yearly dosing represents an important improvement for patients and doctors in terms of compliance for an entire year," said Trevor Mundel, MD, Global Head of Development at Novartis AG. "These long-term data affirm our confidence in the efficacy and safety profile of this medicine."

Osteoporosis is a condition in which bones become weak and break more easily⁴. According to the International Osteoporosis Foundation (IOF), an estimated 75 million people in Europe, USA, and Japan are affected by this disease⁵ and one in three women over the age of 50 as well as one in five men will suffer an osteoporotic fracture in their lifetime⁵.

This long-term study, which extended the HORIZON (Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly) Pivotal Fracture Trial by three years, is a multi-center, double-blind, randomized, placebo-controlled study to evaluate the long-term efficacy and safety of Aclasta in the treatment of postmenopausal osteoporosis¹. The extension study evaluated more than 1,200 women aged 68 years or older¹. After three years of therapy, participants were randomized to either receive an Aclasta infusion (n=616) or an annual placebo infusion (n=617) for additional three years¹.

The primary endpoint of the study was the percentage change in the BMD at the femoral neck at year six vs. year three¹. Secondary endpoints included evaluation of BMD at other sites, fractures, changes in bone turnover markers and overall safety¹. The incidence of adverse events was comparable between groups¹. There was no long-term effect on renal function or increase in risk of osteonecrosis of the jaw or atrial fibrillation¹.

Aclasta provides year-long bisphosphonate compliance with a single infusion. Aclasta is the only yearly treatment approved in US and EU to reduce the risk of fractures in areas of the body typically affected by osteoporosis, including the hip, spine and non-spine (e.g., wrist and rib)⁶. Additionally, it is also the only proven therapy to reduce new clinical fracture and all-cause mortality (28% reduction in death) after a recent low trauma hip fracture⁷.

Approved in more than 90 countries, Aclasta is approved for up to six indications to treat a broad spectrum of patients, from the newly diagnosed to those with more severe forms of osteoporosis². These include treatment of postmenopausal osteoporosis, prevention of postmenopausal osteoporosis, prevention of subsequent fractures after a low-trauma fracture, increase in bone mass in men with osteoporosis, treatment and prevention of glucocorticoid-induced osteoporosis in men and women, and treatment of Paget's disease of bone in men and women².

Aclasta is generally well tolerated. Given as an infusion, it by-passes the gastrointestinal tract and avoids the potential side-effects like upper gastrointestinal irritation. The most common adverse events associated with Aclasta are transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occur within the first three days following Aclasta administration and usually resolve within three days. The incidence of such post-dose symptoms can be reduced with the administration of paracetamol or ibuprofen shortly after Aclasta infusion. These data are based on one of the most extensive osteoporosis clinical trial programs involving over 14,000 men and women.

Zoledronic acid, the active ingredient in Aclasta, is also available in a different dosage under the trade-name Zometa for use in certain oncology indications.

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