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FDA broadens US indication for once-yearly Reclast® as only osteoporosis treatment approved for prevention of fractures after a hip fracture

- *Revised label includes data showing 35% reduction in new clinical fractures in patients treated with Reclast following recent hip fracture¹*
- *Few patients currently receive osteoporosis treatment following hip fracture despite high risk of morbidity and mortality²*
- *Safety and efficacy profile of Reclast, already approved for treatment of postmenopausal osteoporosis¹, reinforced in revised label*

Basel, June 5, 2008 – The US Food and Drug Administration (FDA) has broadened the US indication for once-yearly Reclast® (zoledronic acid) Injection 5 mg* to include the prevention of new clinical fractures in patients who have recently had a low-trauma hip fracture¹.

No other osteoporosis treatment has demonstrated a reduction of new clinical fractures in patients who have recently had a low-trauma hip fracture (e.g. due to a fall from standing height or less).

The FDA decision is based on safety and efficacy data from the landmark Recurrent Fracture Trial, published in *The New England Journal of Medicine*, showing a significant 35% reduction in the risk of new clinical fractures in patients treated with Reclast³.

“The consequences of osteoporosis can be devastating, particularly hip fractures. However, few patients actually receive treatment for the prevention of additional fractures after a hip fracture²,” said Kenneth G. Saag, MD, MSc, Professor of Medicine and Epidemiology, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham. “In the first large-scale clinical trial of its kind, these data support an efficacious therapeutic option for patients after a hip fracture.”

Osteoporosis is a condition in which the bones become weak and can break more easily⁴. Around 10 million people in the US are affected by osteoporosis and another 34 million are at risk from the disease, which caused an estimated 297,000 hip fractures in the US in 2005⁴. Of those patients who experience a hip fracture, almost a quarter of people over the age of 50 die from complications within one year⁴.

Among those who survive a year after experiencing a hip fracture, 50% need help walking, 25% require long-term nursing care, and all remain at high risk of further fracture⁵. Yet few hip fracture patients are currently treated for osteoporosis².

* The tradename outside the US is Aclasta®

The Recurrent Fracture Trial involved more than 2,100 men and women aged 50 and older³ with osteoporosis who had experienced a hip fracture. Results showed that Reclast increased bone mineral density (BMD) and reduced the risk of new clinical fractures by 35% compared to patients treated with placebo³. The risk of new spine fractures was reduced by 46% and new non-spine fractures (e.g. hip, wrist and rib) by 27%³.

In the Recurrent Fracture Trial, the incidence of all-cause mortality was 9.6% in the Reclast group versus 13.3% in the placebo group³. This reduction in mortality is multifactorial and the groups were not randomized for risk of mortality at entry into the study³.

The updated US label further reinforces the safety and efficacy of Reclast, the only once-yearly treatment for postmenopausal osteoporosis approved in the US and EU (under the name Aclasta[®]) to reduce the risk of fractures in all key areas of the body typically affected by this disease, including the hip, spine and non-spine¹. Regulatory approval is also being sought for Aclasta in the European Union for the prevention of clinical fractures after a recent low-trauma hip fracture.

Unlike oral bisphosphonate therapies that are taken daily, weekly or monthly, Reclast/Aclasta is given as a once-yearly 15-minute intravenous infusion¹. This means with a single treatment, along with daily calcium and vitamin D supplements, a patient can receive a full year's fracture protection against the consequences of osteoporosis.

“The new label reinforces the potential of Reclast/Aclasta for treating a range of osteoporosis patients,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. “These data support the clear need to treat patients after hip fracture who are at risk of the potentially devastating and life-threatening consequences of osteoporosis.”

Reclast/Aclasta is already approved in more than 50 countries for the treatment of postmenopausal osteoporosis and in more than 70 countries for the treatment of Paget's disease of bone, the second most common metabolic bone disorder⁶.

Reclast/Aclasta has a demonstrated tolerability profile. The most common adverse events associated with Reclast/Aclasta were transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occurred within the first three days following Reclast/Aclasta administration and resolved within three days. The incidence of post-dose symptoms can be reduced with the administration of paracetamol or ibuprofen shortly after Reclast/Aclasta infusion.

The active ingredient in Reclast/Aclasta is zoledronic acid, which is also available in a different dosage under the brand name Zometa[®] (zoledronic acid) Injection 4 mg for use in certain oncology indications.

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trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis AG'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 is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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