Study Shows Once-Yearly Reclast Better than Risedronate at Increasing Bone Mass in Patients with Osteoporosis Caused by Glucocorticoids

Study of more than 800 men and women shows higher bone mineral density with Reclast than with risedronate, a current established therapy. Regulatory approval sought for treatment and prevention of glucocorticoid-induced osteoporosis in US.

East Hanover, NJ (PRWEB) April 11, 2008 -- New data show that a once-yearly infusion of Reclast® (zoledronic acid) Injection 5mg was significantly better than risedronate at increasing bone mass in patients with osteoporosis caused by glucocorticoids, commonly known as steroids. These medications are widely used to treat inflammatory conditions but can cause bone loss and osteoporosis.

Up to 50% of patients receiving long-term glucocorticoid therapy are at increased risk of fracture due to osteoporosis. Glucocorticoid-induced osteoporosis (GIO) is the most prevalent form of "secondary osteoporosis," which is characterized by low bone mass that results directly from specific diseases or medications.

Results of a clinical study in 833 men and women were presented today at the European Congress on Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ECCEO) in Istanbul, Turkey.

"Recognizing and treating GIO is an important need, as glucocorticoid therapy is widely used and presents an ongoing challenge for physicians," said Professor David M. Reid, Head of the Division of Applied Medicine at University of Aberdeen, UK. "The significant efficacy of this once-yearly treatment, offering year-long bone protection, will provide a valuable treatment option for healthcare professionals treating and managing osteoporosis induced by glucocorticoids."

The trial investigated both prevention (n=288) and treatment (n=545) of GIO in patients. Results demonstrated that a single yearly infusion of Reclast significantly increased bone mineral density (BMD) in the lumbar spine at 12 months compared to risedronate in both the treatment group (Reclast 4.1%, risedronate 2.7%; P=0.0001) and prevention group (Reclast 2.6%, risedronate 0.6%; P < 0.0001).

Risedronate is one of the established treatments for GIO. Like Reclast, risedronate is a member of the bisphosphonate class of drugs. Risedronate is taken in the form of a daily pill for the indication of GIO, whereas Reclast was studied as a once-yearly 15-minute infusion.

Novartis is applying for an indication with the U.S. Food and Drug Administration (FDA) for the treatment and prevention of GIO. Reclast is already approved for the treatment of postmenopausal osteoporosis and for the treatment of Paget's disease of bone in men and women, the second most common metabolic bone disorder.

"These new data reinforce the efficacy of this novel once-yearly treatment and confirm Reclast's ability to increase bone mineral density significantly in different populations," said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. The primary objective of the GIO study was to demonstrate non-inferiority of Reclast to risedronate in percentage change in lumbar spine BMD from baseline at 12 months.

Secondary endpoints included percentage change in lumbar spine BMD at six months, and in the BMD of
femoral neck and total hip at six and 12 months.

Results from the study confirm the demonstrated safety profile of Reclast. The most common adverse events associated with Reclast were transient post-infusion symptoms such as fever and muscle pain. The majority of these symptoms occurred in the first three days after Reclast administration and resolved within three days. Post-infusion symptoms can be reduced by taking acetaminophen or ibuprofen shortly after the Reclast infusion.

Analysis of key safety parameters, including osteonecrosis of the jaw, atrial fibrillation, renal impairment and delayed fracture healing, found Reclast was comparable to risedronate.

The active ingredient in Reclast 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.

Patients should not take Reclast if they're on Zometa as it contains the same ingredient; if they have low blood calcium, kidney problems, or are allergic to Reclast or Zometa; or they're pregnant, plan to become pregnant or nursing.

It's important for patients to drink fluids before getting Reclast to help prevent kidney problems. The most common side effects are flu-like symptoms, fever, muscle or joint pain and headache. Patients should tell their doctor if they have dental problems because rarely, problems with the jaw have been reported with Reclast. Patients should tell their doctor if they have low blood calcium or cannot take calcium and vitamin D, had surgery involving the neck or intestines. In patients with Paget's disease of bone, it is especially important for them to take 1500 mg of calcium and 800 IU of vitamin D daily, particularly during the first 2 weeks after getting Reclast. Patients should discuss all medicines they're taking, including prescription and non-prescription, vitamins and herbal supplements. Patients should contact their doctor if they develop severe bone, joint or muscle pain, numbness, tingling or muscle spasms.

For more information about Reclast, visit Reclast or call 866-RECLAST (866-732-5278).

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as "can", "will", should", or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Reclast or regarding potential future revenues from Reclast. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Reclast to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Reclast will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Reclast will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Reclast could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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.

About Novartis
Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, metabolic, cancer, organ transplantation, central nervous system, dermatological, GI and respiratory areas. The company's mission is to improve people's lives by pioneering novel healthcare solutions. Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

# # #
Contact Information
Tina Tuttle
Novartis Pharmaceuticals Corporation
http://www.reclast.com
862-778-1625

Online Web 2.0 Version
You can read the online version of this press release here.