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Reclast Receives US Approval As A Highly Effective Treatment For Patients With Paget's Disease Of The Bone

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Reclast (zoledronic acid) has received US regulatory approval as the first new treatment in nearly a decade for patients with a bone condition known as Paget's disease, estimated to affect about one million people in the US alone[1].

Reclast, which is marketed as Aclasta in other countries, is the first approved treatment for Paget's disease patients to be given as a single-dose infusion compared to current oral therapies that must to be taken daily for up to six months. This medicine was first launched in Germany in May 2005 for Paget's disease and is now approved in more than 50 countries.

Paget's disease is a chronic, long-lasting and often painful bone disorder that causes abnormal bone growth due to a malfunction in the body's regular bone-building process[2]. An outcome can be weak and brittle bones, causing them to break more easily. Approximately four million people worldwide have the condition[3].

"The fact that Reclast is both highly effective and can last for several years in most patients could make this the new standard of care for Paget's patients," said Frederick R. Singer, MD, Director of the Endocrine/Bone Disease Program at John Wayne Cancer Institute in Santa Monica, California. "Current bisphosphonate therapy, while generally effective, does not induce similar long-term remissions."

Clinical studies show Aclasta/Reclast is more effective[4], starts working faster[5] and offers a longer period of remission than Actonel (risedronate sodium)*, the current treatment standard for patients with Paget's disease. Aclasta/Reclast is administered as a single 5 mg, 15-minute intravenous infusion by a healthcare professional.

"We believe Aclasta/Reclast provides a critical new treatment option for people who suffer from Paget's disease," said James Shannon, MD, Global Head of Development at Novartis Pharma AG. "Furthermore, we are exploring the full clinical potential of this agent in treating other metabolic bone diseases, including postmenopausal osteoporosis."

The approval by the US Food and Drug Administration (FDA) was based on efficacy and safety data comparing a single dose of Aclasta/Reclast with Actonel (30 mg risedronate) taken daily for 60 days in two identically designed six month trials. Results combined from both trials showed 96 percent of patients taking Aclasta/Reclast responded to treatment compared to 74 percent of patients taking Actonel at six months. Results of these head-to-head studies were published in the September 1, 2005 issue of the New England Journal of Medicine[6].

These studies also demonstrated that Aclasta/Reclast starts working faster, showing a significant difference as early as two months. Patients who took Aclasta/Reclast responded to treatment after an average of 64 days versus 89 days for those taking Actonel. Overall, the number of patients with adverse events was similar in the Aclasta/Reclast and Actonel groups.

About Paget's disease

In Paget's disease, the normal cycle of new bone replacing broken-down bone is disrupted: too much bone breaks down and the replacement bone is structurally weak. Patients may experience bone pain, skeletal deformity, pathological fractures, secondary arthritis, neurological complications and deafness that can impede their ability to perform routine activities such as walking and prolonged standing[7]. Paget's disease can be difficult to diagnose and may often be left untreated as not all patients experience noticeable symptoms[7].

"Paget's disease is a serious and commonly overlooked condition that can be very debilitating for some patients," said Charlene Waldman, executive director, The Paget Foundation. "This approval is an important milestone for people with Paget's disease because it has been more than nine years since a new treatment option has been made available."

About Aclasta/Reclast

HORIZON, the ongoing clinical program of Aclasta/Reclast, is one of the most comprehensive drug evaluation programs ever undertaken in the area of metabolic bone diseases. Approximately 13,000 patients worldwide have participated in the program in more than 400 centers. It is the first program to study a once-yearly dosing regimen for the prevention and treatment of postmenopausal osteoporosis. Other studies involved in the program include prevention of fractures following a hip fracture in men and women, and treatment of corticosteroid-induced osteoporosis and male osteoporosis.

The European Medicines Agency (EMEA) and FDA are currently reviewing submissions for the approval of Aclasta/Reclast as a once-yearly treatment for postmenopausal osteoporosis. Zoledronic acid, the active ingredient of Aclasta/Reclast, is also available under the brand name Zometa for use in other indications.

The US regulatory approval of Reclast in treating patients with Paget's disease comes after Novartis supplied responses to "approvable letters", which are issued when the FDA is prepared to approve an investigational medicine and contain conditions that must be met prior to final US approval.

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