In Europe, CHMP missed an opportunity for osteoporosis patients at high risk of fracture

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Experts from the International Osteoporosis Foundation (IOF) and the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO) regret the recent decision by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) to reject the marketing application for abaloparatide, a potential new treatment option for postmenopausal women at high risk of fragility fracture.

Abaloparatide was previously approved for use in the USA, where it has been available to thousands of patients at a reasonable cost. It is the first new bone forming (anabolic) treatment approved for postmenopausal women with osteoporosis in close to 15 years. The therapy is targeted to patients who are at increased risk due to a history of previous osteoporotic fractures, for those who have multiple fracture risk factors, and for those who do not respond to, or are intolerant of, other available therapies.

There is a major gap in osteoporosis treatment, whereby as many as 80% of patients who have already sustained a first fracture are not identified and do not receive treatment to prevent secondary fractures. Given that currently available treatments are not optimal for all patients, the development of effective new therapeutic options is considered a major factor and key way to reduce the dangerous treatment gap.

Professor Cyrus Cooper, president of IOF, stated: "It is undisputed among experts and patients alike that there is a critical need for effective

treatments for those who are at high risk of sustaining serious and life-threatening fractures due to osteoporosis. Such patients urgently require new treatment options that address their individual needs, and for many, bone forming agents are the therapy of choice. There is only one comparable therapy currently available in Europe and this is currently accessible to few patients in a limited number of countries. It was therefore very disappointing to hear that a long-awaited new therapy, which is available in the USA, will not be available for European patients."

Professor Jean-Yves Reginster, president of ESCEO, commented: "For those of us who treat patients with osteoporosis and have been following the development of this new therapeutic option, this decision by EMA is frustrating to say the least. In published studies, abaloparatide was shown to be safe and effective for the management of osteoporosis, and at least as effective, if not more effective, than the currently available anabolic agent. Importantly, it was expected to be approximately 30-50 % less expensive - which would have given European patients access to an appropriate new medication at a lower cost, thus improving accessibility for thousands of patients. Given the current situation, it may be possible that no new safe and effective bone forming agent will be developed for many years, and many patients will continue to have very few, if any, treatment options."

IOF and ESCEO urge re-examination of the CHMP decision and encourage continued research into the development of safe and effective therapeutic options to meet patient needs in Europe.

Provided by International Osteoporosis Foundation