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PRESS RELEASE

We read with great interest and concern the official announcement by the European Medicines Agency (EMA) regarding the refusal of the marketing authorization for romosozumab, which was issued on the 28th of June 2019.

The main reasons for the refusal according to the announcement were: the yet unexplained increase of cardiovascular events, the higher mortality observed in patients aged over 75 years treated with romosozumab, as well as the lack of convincing data regarding the benefit among patients with less severe disease. In the same announcement, romosozumab was reported to be effective in reducing the risk of fracture in patients with severe osteoporosis. In addition, measures to reduce the risk of cardiovascular events could not be readily applied as the mechanism for these events is not clear and a group of patients with a lower risk for these events has not been identified.

The concern of the board of trustees of HSSBM resides mainly on the recent approval of the same medication by the corresponding Medicines Agencies in a significant number of developed countries (U.S.A., Canada, Australia, Japan, S. Korea). The approval of the medication in these countries was based on the data obtained from the same clinical studies that were used for the EMA decision. Romosozumab has been approved for patients with severe osteoporosis and high fracture risk in these parts of the world.

The second in a row refusal, albeit based on different reasons, of an osteoporosis treatment in Europe with a concomitant approval of the same agent in other parts of the world, renders us considerably troubled and concerned. We fully acknowledge the need for a thorough review of all clinical data prior to the approval of any medication, as well as any country-specific restrictions resulting from the economic burden of pharmaceutical expenses. However, we find it difficult to comprehend how the same medication could be considered either "effective" or "dangerous" depending on the patient's residence.

The HSSBM has recently issued the "2018 Guidelines for the diagnosis and treatment of osteoporosis in Greece" which are now in use by all physicians dealing with osteoporosis in Greece. We are convinced that there are unmet needs in the treatment of patients with severe osteoporosis. New medications, which might fill this specific treatment gap are expected. HSSBM is definitely willing to contribute by offering its scientific point of view and critical thinking on these issues whenever asked for.

By articulating the above concerns, raised by physicians dealing with osteoporotic patients in everyday clinical practice, we expect with great interest the potential re-examination of the EMA opinion on romosozumab authorization, while waiting for new therapeutic solutions and anticipating the continuation of research in the field of osteoporosis treatment.

Board of trustees of H.S.S.B.M
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