

New Targets for the Osteoporosis Market

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Bagrat Lalayan presents an overview of osteoporosis market and offers vision for future business strategies.

During 15+ years professional career I have been lucky enough to be responsible for marketing almost all best-selling brands in the treatment of osteoporosis. This is a unique medical field, recently developed and still not crowded by different drug classes.

From the medical point of view, postmenopausal osteoporosis, which literally means porous bone, is a disease in which the density and quality of bone are reduced. As bones become more porous and fragile, the risk of fracture is greatly increased. The loss of bone occurs silently and progressively. Often there are no symptoms until the first fracture occurs.

Despite of the fact that this bone pathology has been recognized and developed relatively recently, the market of osteoporosis is really huge as it is estimated that over 200 million people worldwide suffer from this disease. Approximately 30% of all postmenopausal women have osteoporosis in the US and in Europe. At least 40% of these women and 15–30% of men will sustain one or more fragility fractures in their remaining lifetime.

The market of osteoporosis, then, is bigger than markets of hypertension, diabetes or cancer. However, this serious healthcare issue had not received attention from pharmaceutical companies, mainly because of the lack of diagnosed patients, absence of evidence-based diagnostic tools, limited knowledge about the disease among healthcare specialists, and the myth that calcium food supplements are the only established treatment strategy.

Nevertheless, the huge competition in traditional markets has now led companies to focus their attention to new growing medical fields like osteoporosis. The success story started in 1995 when Merck (Merck, Sharp & Dohme [MSD] outside the US) launched Fosamax (alendronate), a first-in-class bisphosphonate, approved for the treatment of PMO (postmenopausal osteoporosis). Merck's strategy was to focus on the problem itself, and to enlarge the market instead of promoting the drug alone. As mentioned, osteoporosis was not widely accepted as a life-threatening and socially important disease; even the International Osteoporosis Foundation, the leading international society regulating management of osteoporosis, had been established only few years earlier before the launch of Fosamax.

For a period, Merck played an important role in development of osteoporosis market by building awareness among different healthcare specialists, funding the National Osteoporosis Risk Assessment program (significantly increasing number of early diagnosed women with low bone mass) and stimulating growth of diagnostic sites using DEXA technology. Sales of Fosamax finally reached over \$2 billion in 2002, a fantastic performance for a new medical field.

The positive example of Merck led other companies to step in osteoporosis market and new bisphosphonates (Roche [Boniva], P&G [Actone]) arrived. Later, Eli Lilly launched the first-in-class SERM, Evista, an anabolic teriparatide. After years of proclaiming bisphosphonates as the "gold standard" in management of osteoporosis, the era of biologics arrived with Amgen's first monoclonal product, Prolia (denosumab), and Radius's Tymlos, which is expected to be the most effective anabolic anti-osteoporotic drug.

The growing worldwide awareness has significantly increased the market and the number of diagnosed and treated patients. However, despite active development of new classes of anti-osteoporotic drugs, the key marketing message of “high anti-fracture efficacy” has remained the same. Thus, majority of clinical trials targeted prevention of primary and secondary, major and minor fractures. From one side, this has led to the development of specific clinical diagnostic tools such as FRAX and global awareness among doctors and patients about necessity in prevention of fractures. On the other hand, modern medicines have not proven significant superiority over “old” drugs in terms of prevention of fractures or the first generation of bisphosphonates in clinical head-to-head trials.

Certainly, the new generation of medicines has some advantages related to convenience of use or patient adherence, but the “anti-fracture efficacy” priority has prevailed over other benefits. The logic of healthcare professionals is “why should we prescribe expensive brands instead of cheap bisphosphonate generics if prevention of major fractures is achievable in both cases? Besides, “old” drugs such as alendronate have additional indications compared with Prolia or Tymlos, in conditions such as glucocorticoid-induced osteoporosis, Paget’s Disease or male osteoporosis.

So, how can the new generation of anti-osteoporotic drugs achieve a bigger market share and enlarge the number of prescriptions of brand products? I’m confident that new players should move away from the 30-year-old message of anti-fracture effectiveness unless they have data that their drug has significant superior efficiency in reducing the risk of fractures, especially of hip fractures. The time has arrived to develop new targets within osteoporosis market. Taking into account the epidemiology of PMO, it is not rational to limit promotional targets to highly specialized groups like endocrinologists, family doctors or orthopedists. It is known that osteoporosis itself is a risk factor for complications of other concomitant diseases. Companies are recommended to conduct new trials on the effectiveness of modern anti-osteoporotic drugs in the treatment of patients with osteoporosis and concomitant diabetes, cardiovascular, autoimmune and metabolic diseases, hepatitis, cancer or neurological disorders.

This strategy will prove the global importance of prevention and treatment of osteoporosis, and increase prescriptions from new groups of physicians like cardiologists, oncologists, neuropathologists, dermatologists, virologists and other specialists. Also, it could dramatically differentiate modern drugs from the previous generation of medicines and significantly expand the market for branded products.

Replacing the long-term marketing message of anti-fracture efficacy with the idea of evidence-based prescription of anti-osteoporotics to patients with osteoporosis and variety of other disorders could lead to a boost of sales, as occurred at the end of 20th century. It will also increase awareness of this social problem among other healthcare specialists to and benefit patients, who could be diagnosed at the early stage of the disease.

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