



NEWS RELEASE

## Merck Researchers Present BMD Data from a Phase II Study of Odanacatib, Merck's Investigational Cat-K Inhibitor for Post-Menopausal Osteoporosis

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Odanacatib Significantly Increased BMD Following Prior Alendronate Treatment

Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced results from a Phase II trial for odanacatib, an investigational cathepsin K (cat-K) inhibitor in development for the treatment of osteoporosis in post-menopausal women. The results were presented today at the 34th Annual Meeting of the American Society for Bone and Mineral Research.

In the study, treatment with odanacatib (compared to placebo) significantly increased Bone Mineral Density (BMD) over a two-year period in post-menopausal osteoporotic women who previously had three or more years of treatment with alendronate. Patients were allowed to have been off alendronate therapy for up to three months immediately prior to enrollment in the study.

"Odanacatib works differently than other treatments for osteoporosis by targeting cat-K, a specific enzyme within bone cells," said Albert Leung, M.D., Ph.D., executive director, clinical research, Merck Research Laboratories. "We're excited about these results because understanding the effects of odanacatib in a population of post-menopausal women previously treated for osteoporosis is important to clinicians."

**Study evaluated efficacy and safety of odanacatib following treatment with alendronate**

This study was a randomized, double-blind, placebo-controlled, multi-center, 24-month trial of odanacatib in 243



women with post-menopausal osteoporosis who had been previously treated with alendronate (dosed daily or weekly) for  $\geq 3$  years. Participants were at least 60 years of age with low BMD T-scores ( $\leq -2.5$  and  $> -3.5$ ) at any hip site (femoral neck, trochanter, or total hip) without a history of fragility fracture, or had BMD T-scores  $\leq -1.5$  and  $> -3.5$  at any hip site, with a history of fragility fracture (except hip fracture). The patients were randomized in a 1:1 ratio to receive odanacatib 50 mg once weekly or placebo for 24 months. All patients received vitamin D3 (5600 IU/week) and also calcium supplementation, if needed.

The study evaluated the effects of odanacatib 50 mg once weekly on the following:

- Femoral neck BMD change from baseline compared to placebo over 24 months (primary endpoint)
- Femoral neck BMD compared to baseline over 24 months (key secondary endpoint)
- BMD at hip trochanter, total hip, lumbar spine and distal forearm
- Biochemical markers of bone resorption and formation at months 12 and 24
- Clinical and laboratory assessment of safety and tolerability

BMD was assessed by DXA at baseline, 6, 12 and 24 months. This study was not designed to evaluate the effect of odanacatib on fractures.

## Results showed odanacatib significantly increased BMD compared to placebo

In the odanacatib group, BMD changes from baseline at 24 months were significantly different versus placebo at all three hip sites (+1.73%, +1.83%, +0.83% for the femoral neck, hip trochanter, and total hip, respectively, vs. -0.94%, -1.35%, -1.87% with placebo), and the lumbar spine (+2.28% vs. -0.30% change with placebo). At the distal forearm, BMD changes from baseline at 24 months were -0.92% and -1.14%. The difference versus placebo at the distal forearm (+0.22%) was not statistically significant.

The overall incidence of adverse events, including those that were considered drug-related or serious, were similar between treatment groups. Treatment discontinuations due to adverse events were 9.0 percent for patients receiving odanacatib and 3.3 percent for patients receiving placebo. The most common clinical adverse events in patients receiving odanacatib and placebo, respectively, were urinary tract infection (11.5%, 16.5%), back pain (11.5%, 9.9%), arthralgia (9.0%, 9.9%), fractures (4.9%, 13.2%), bronchitis (5.7%, 4.1%), nasal pharyngitis (3.3%, 5.8%), and upper respiratory infection (4.1%, 0.8%).

## About Odanacatib

In osteoporosis, bone loss occurs because of an imbalance in bone remodeling (the rate of bone resorption exceeds that of bone formation). Osteoclasts, cells that resorb bone, secrete signaling factors to stimulate

osteoblasts, cells that form bone. Odanacatib selectively inhibits cat-K, the primary enzyme in the osteoclasts that digests proteins during bone resorption. Progressive increases in bone mineral density have been demonstrated with odanacatib.

In July 2012, Merck announced it planned to begin closing the Phase III trial assessing fracture risk reduction with odanacatib, at the recommendation of the study's Data Monitoring Committee (DMC), after its first planned interim analysis showed robust efficacy and a favorable benefit-risk profile. The DMC noted that safety issues remain in certain selected areas and made a recommendation with respect to following up on them. Merck's previously announced plan to conduct a blinded extension trial will allow further monitoring of the issues. The extension trial will also continue to measure efficacy.

Final results of the study will be submitted for presentation and publication in 2013 once the data analysis is complete. Merck anticipates submitting regulatory applications for odanacatib in the United States and European Union (EU) in the first half of 2013, and in Japan in the second half of 2013.

## About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on Twitter, Facebook and YouTube.

## Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that all of the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry

regulation and health care legislation in the United States and internationally; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2011 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

Merck

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