

Sage Therapeutics, Shionogi ink deal for MDD treatment

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The collaboration aims to accelerate development of SAGE-217 in key Asian markets



US-based Sage Therapeutics, and Japan's Shionogi recently announced they have entered into a strategic collaboration for the clinical development and commercialization of SAGE217 for the treatment of major depressive disorder (MDD) and other indications in Japan, Taiwan and South Korea.

Earlier, Sage had received Breakthrough Therapy Designation from the USFDA for SAGE-217 in MDD in February 2018, and recently announced an expedited development plan for SAGE-217 in the US with a pivotal Phase 3 placebo-controlled trial in patients with MDD expected to commence this year, and an ongoing placebo-controlled trial in women with PPD, now also designated a pivotal trial.

The goal of the collaboration is to accelerate development of a potentially groundbreaking medicine to patients in key Asian markets. Under the terms of the agreement, Shionogi will be responsible for all clinical development, regulatory filings and commercialization of SAGE-217 for MDD, and potentially other indications, in Japan, Taiwan and South Korea.

Shionogi will make an upfront payment to Sage of \$90 million, and Sage will be eligible to receive additional development and commercial milestones of up to \$485 million. Sage will receive tiered royalties on sales of SAGE-217 in Japan, Taiwan and South Korea, if development efforts are successful, with tiers averaging in the greater than 20 percent range, subject to other terms of the agreement. Shionogi has also granted Sage certain rights to co-promote SAGE-217 in Japan across all indications. Sage maintains exclusive rights to develop and commercialize SAGE-217 outside of Japan, Taiwan and South Korea.

"We are pleased to collaborate with Shionogi, a company that shares our excitement at the opportunity to work together to accelerate development and broaden geographic access to a potentially paradigm-shifting treatment for depression," said Jeff Jonas, M.D., chief executive officer of Sage. "Shionogi is a well-regarded commercial leader in mood disorders in the Asian market. By working together, we believe we can expand the global footprint for SAGE-217 alongside our ongoing efforts in the U.S. and E.U. As we have always said, our goal is to build a fully-integrated, multi-national biopharmaceutical

company and this collaboration moves us another step closer to achieving the goal.”