

Buprenorphine / samidorphan helpful in refractory depression

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(HealthDay)—An adjunctive buprenorphine/samidorphan (BUP/SAM)

combination seems beneficial for patients with major depressive disorder (MDD) with inadequate response to antidepressant therapy (ADT), according to a study published online Oct. 29 in *Molecular Psychiatry*.

Maurizio Fava, M.D., from Harvard Medical School in Boston, and colleagues report on the efficacy and safety of BUP/SAM as adjunctive treatment in patients with MDD and inadequate response to ADT in two phase 3 randomized studies (FORWARD-4 and FORWARD-5). The Montgomery-Åsberg Depression Rating Scale (MADRS) was used to measure efficacy.

The researchers found that the primary end point was achieved in FORWARD-5; adjunctive BUP/SAM 2 mg/2 mg was demonstrated to be superior to placebo (average difference change from baseline to week three through end of treatment [EOT] in MADRS-6 and -10 versus placebo: -1.5 [$P = 0.018$] and -1.9 [$P = 0.026$], respectively); the primary end point was not achieved in FORWARD-4 (change from baseline in MADRS-10 at week five versus placebo: -1.8 ; $P = 0.109$). In pooled analyses of the two studies, consistently greater reduction was seen in MADRS scores from baseline for BUP/SAM 2 mg/2 mg versus [placebo](#) at multiple time points, including EOT and average change from baseline to week three through EOT. For MADRS-10 change from baseline to EOT, the overall effect size in the pooled analyses was 0.22.

"Having a new class of antidepressants with a novel mechanism of action could have significant impact for patients with persistent symptoms," Fava said in a statement.

Several authors disclosed financial ties to pharmaceutical companies, including Alkermes, manufacturer of ALKS 5461 (buprenorphine/samidorphan).

More information: [Abstract/Full Text](#)

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