**Agomelatine Effective for Children, Adolescents With Depression**

By Chris Berrie

CEPAGATTI, Italy -- September 15, 2020 -- Agomelatine safely reduces symptoms of depression in children and adolescents with major depressive disorder (MDD), according to a study presented at the Virtual 33rd European College of Neuropsychopharmacology Congress (ECNP).

Françoise Picarel-Blanchot, PhD, Servier Medical Affairs, Suresnes Cedex, France, and colleagues conducted a 12-week, randomised, double-blind, placebo-controlled trial comparing agomelatine with placebo and fluoxetine in children aged 7 to 12 years and adolescents aged 12 to 18 years. All patients had Major Depressive Disorder (MDD), as assessed on the Children Depression Rating Scale-Revised (CDRS-R) scale, and all patients received psychosocial counselling during the full study period.

Randomised patients having at least 1 post baseline assessment (n = 396) were considered in the efficacy analyses, and included 102 patients who received agomelatine 10 mg/day, 94 patients who received agomelatine 25 mg/day, 101 patients who received placebo, and 99 patients who received fluoxetine 10 to 20 mg/day.

For the total efficacy population, patients in the agomelatine 25 mg group and the fluoxetine 20/25 mg group showed significantly greater improvements in CDRS-R total score at 12 weeks -- the primary endpoint -- compared with placebo (4.22, *P* = .040; 3.74, *P* = .039; respectively).

The efficacy on the CDRS-R score was confirmed in the adolescent subgroup (n = 317) only for agomelatine 25 mg/day (5.22; *P* = .028). In the agomelatine 10 mg/day and fluoxetine 10 to 20 mg/day groups, the improvement observed on the CDRS-R score versus placebo after 12 weeks did not reach statistical significance.

More premature study withdrawals were observed in the placebo group (15.5%) compared with the agomelatine 10 mg/day group (7.8%), agomelatine 25 mg/day group (11.6%), and the fluoxetine group (13.0%).

One case of reversible transaminases increase (>3 upper limit of normal range) was reported in each agomelatine arm, and 2 cases were reported in the fluoxetine arm.

“Agomelatine might be a beneficial treatment option in the paediatric population and especially in adolescents suffering from MDD,” said Dr. Picarel-Blanchot.

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*[Presentation title: Efficacy and Safety of Agomelatine Given Orally in Children and Adolescents With Major Depressive Disorder: a Randomized Controlled Trial. Abstract P.322]*

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