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**CELECOXIB ADD-ON TO SERTRALINE IN THE THERAPY OF MAJOR DEPRESSION: CLINICAL OUTCOME**

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B. Leitner<sup>1</sup>, E. Weidinger<sup>1</sup>, S. Fischer<sup>1</sup>, D. Krause<sup>1</sup>, A.M. Myint<sup>1</sup>, P. Zill<sup>1</sup>, M.J. Schwarz<sup>2</sup>, N. Müller<sup>1</sup>

<sup>1</sup>Department of Psychiatry and Psychotherapy, Ludwig-Maximilians-University, München, Germany ; <sup>2</sup>Department of Laboratory Medicine, Ludwig-Maximilians-University, München, Germany

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### Introduction

A proinflammatory state in a subgroup of depressed patients has been reported repeatedly, for example an increase in interleukin-6 and tumour necrosis factor- $\alpha$  is well documented. Treatment with COX-2 inhibitors down-regulate increased inflammatory markers. Therefore an adjunctive treatment of depression with COX-2 in combination with an antidepressant might lead to a better clinical outcome.

### Objectives

To prove or disapprove the hypothesis of a better clinical outcome in the group with add-on celecoxib to sertraline in terms of improvement of HamD-17 and MADRS scores from baseline to endpoint.

### Design

This is a dual-center, randomized, double-blind, placebo-controlled, parallel group phase IIa study to investigate the mean change in clinical outcome and in serum expression of inflammation markers from baseline to endpoint (week 6) in patients with major depression (HAMD-17  $\geq$  22) treated with celecoxib in combination with sertraline compared to sertraline combined with placebo. 51 depressed patients of both gender, aged between 18 and 60 without any recent inflammatory related disease were enrolled. The study comprises six study visits (6x ratings including HAMD-17 and MADRS, 3x blood collections) during six weeks of treatment and a follow-up visit 10 weeks after baseline.

### Results and Conclusion

The study was completed quite recently and the results are in progress.