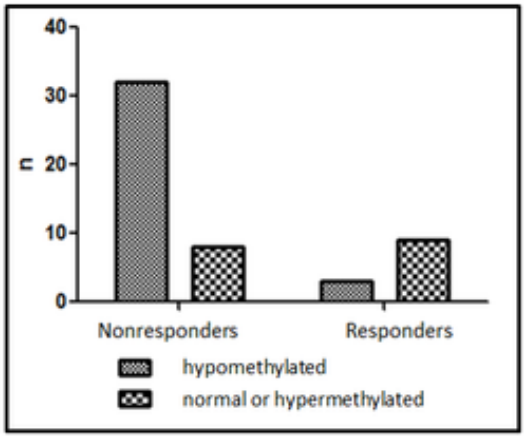
Technology Offer

# Methylation biomarker to predict the response to monoaminergic antidepressants

Reference Number 15-00247

## Challenge

Depression is a common mental disorder which often becomes chronic or recurrent, substantially impairing an individual's ability to cope with daily life. First-line pharmacotherapy most frequently prescribed are monoaminergic antidepressants, e.g. fluoxetine (Prozac®), of which there are dozens of products on the market. However, only 30-40% of the patients achieve a remission in response to the first chosen therapy. As a consequence, most patients require further pharmacotherapy and around 50% of these patients also fail to respond to a second antidepressant. Moreover, many products take weeks to show effectiveness. Early and effective therapy is of great importance in order to prevent patients from delayed treatment durations, chronic depression or recurrence. Therefore, there is an urgent need for a diagnostic tool that allows for rapid screening of patients to assess eligibility for a specific treatment and enables physicians to choose early on the appropriate therapy for each individual patient.




*High predictive value of the methylation status in responders and non-responders of monoaminergic antidepressants. The odd ratio for a non-response after six weeks of treatment in the case of hypomethylation of the exon prior to treatment is 12. (95% confidence interval: 2.63-54.82; p=0.002)*

## Technology

The technology is a new methylation biomarker to predict the response and remission to treatment with monoaminergic antidepressants such as Prozac®. The methylation status of an exon promoter region within a specific gene was found to be predictive for the response and remission of an individual patient to monoaminergic antidepressants, as patients with hypomethylated exon regions were more likely not to respond to such treatment. Patients identified as non-responders can thus be directly prescribed a more appropriate treatment regime such as non-monoaminergic drugs, a combination of different antidepressants, or the augmentation of monoaminergic antidepressants with lithium or electroconvulsive treatment (ECT). The new biomarker can help to reduce the time until remission for the individual patient and lower disease-associated risks such as suicide attempts. Furthermore, total health care costs for depression could be reduced since quick remission may lower overall medication costs and eliminate the need for long hospital stays.

## Commercial Opportunity

In-licensing or collaboration for further development is possible.

## Development Status

A discovery trial with n=41 patients was conducted, followed by a replication trial with n=126 severely depressed patients. In vitro evidence for the association of exon hypomethylation and non-responsiveness to monoaminergic antidepressants has been gathered.

## Patent Situation

European (EP2859353B1 - national validation in DE (60 2013 043 516.2), CH, FR. GB) and US (US10,059,996 B2) patents have been granted.

## Further Reading

Kleimann et al. (2015) BDNF serum levels and promoter methylation of BDNF exon I, IV and VI in depressed patients receiving electroconvulsive therapy. J Neural Transm (Vienna) Jun;122(6):925-8.
Tadic et al. (2014) Methylation of the promoter of brain-derived neurotrophic factor exon IV and antidepressant response in major depression. Molecular Psychiatry 19, 281–283.

Medizinische Hochschule Hannover

**Licensing Contact:**
Dr Dior Baumjohann
Technology Manager
T: +49 177 8367-212
baumjohann@ascenion.de

**Ascenion GmbH**
Herzogstraße 64
D-80803 München
T: +49 89 318814-0
info@ascenion.de
www.ascenion.de