Human Metabolome Technologies

PRESS RELEASE

The First diagnostic plasma metabolite biomarker for Major Depression Disorder (MDD) has been published in *Psychiatry and clinical Neurosciences.*

Boston, MA - On January 24, 2018, Human Metabolome Technologies, Inc. (hereinafter referred to as HMT, Head office: Tsuruoka City, Yamagata Prefecture, President: Ryuji Kanno,) have announced that a biomarker for the diagnosis of Major Depression Disorder (MDD), which is being developed collaboratively with the Medical Corporation Association Gyo-ki kai, Kawamura general clinic (Tokyo, Japan, Representative: Noriyuki Kawamura, MD), has been published in *Psychiatry and Clinical Neurosciences.*

1. Background

For psychiatric disorders, such as MDD, precise diagnosis is still difficult because no effective blood test has yet been established. In this research, biomarker discovery was performed by comparing plasma from MDD patients and healthy subjects using HMT's metabolome analysis system.

MDD patients were diagnosed with a structured interview method (SCID) based on the Diagnostic and Statistical Manual of Mental Disorders 4th edition text revised edition (DSM-IV-TR). Plasma samples were collected from 34 MDD patients and 31 normal subjects and analyzed by using HMT's capillary electrophoresis-mass spectrometry (CE-MS) profiling method. Statistical analysis revealed that ethanolamine phosphate (PEA) among 23 plasma metabolites was significantly reduced in MDD patients.

To repeat the discovery of PEA as MDD diagnostic biomarker using an orthogonal quantitative method, the concentration of PEA in blood of another 34 MDD patients and 43 non-MDD patients were compared by using ion chromatography fluorescence detection (IC - FLD) method. The area under the curve (AUC) in the receiver operation characteristic curve (ROC) was 0.92. The sensitivity of the diagnostic performance was 88.1%, and the specificity was 88.6% when the PEA threshold concentration was set as 1.46 uM, demonstrating high discrimination performance for the diagnosis of MDD. To validate the reproducibility, a cohort study with 10 MDD patients and 13 non-MDD patients was performed, which was based on the calculation for sample size of achieving 0.85 in AUC. The result of this reproducibility study was an AUC of 0.89 demonstrating the reproducibility in the discrimination of MDD patients. These results suggest that plasma PEA concentration is a tentative MDD biomarker candidate.

2. Manuscript

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Title: Plasma metabolome analysis of patients with major depressive disorder.

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3. Future prospects

HMT and its relating company, Human Metabolome Technologies Biomedical Inc., is developing a PEA assay kit which will provide a non-invasive and low-cost measurement of the biomarker. This publication is expected to establish the recognition of PEA as potential biomarker candidate and accelerate the process to obtain legal permission to use PEA kit as *in vitro* diagnostic for MDD.

About Human Metabolome Technologies

Human Metabolome Technologies, Inc., (HMT) was founded in 2003 by Professor Masaru Tomita, Ph.D., Director of the Institute for Advanced Biosciences (IAB), Keio University, Japan, and by IAB's Professor Tomoyoshi Soga, Ph.D. A Japan-based biotechnology company, HMT provides capillary electrophoresis mass spectrometry-based metabolomics services, aiming to provide complete solutions for metabolomics research in biomarker discovery, drug design, diagnostic technology and food production.

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