Press release, April 5, 2018

Results showing GABA's relevance for diabetes, patent filed by Diamyd Medical and Uppsala University scientist, published in eBioMedicine

Diamyd Medical holds, in collaboration with Professor Bryndis Birnir at Uppsala University, patent pending new GABA results. The results, now published in the scientific journal eBioMedicine, supports GABA's role as a therapeutic important signal substance in the insulin producing beta cells and in immune cells from healthy humans as well as from patients with type 1 and type 2 diabetes.

The results, published in two separate articles, identify new biomarkers and support the therapeutic effect of GABA treatment in humans. In the first article, an international research team lead by Professor Bryndis Birnir have identified and studied two unique GABA A receptors in the insulin producing beta cells and demonstrated that the receptors' expression and reactivity differ between healthy humans and patients with type 2 diabetes. They have also shown that GABA affects the process when insulin is secreted by the insulin producing cells. The results form the basis of a patent application describing the preventive treatment and the treatment with GABA alone or in combination with other substances, as well as the use of the two identified receptors as a platform to develop new pharmaceuticals specifically binding to or affecting the receptors.

In the second article, the scientists describe GABA's effect on the immune cells, showing that the growth of these immune cells in patients with type 1 diabetes is suppressed by GABA. The scientists also identified that the T lymphocytes, a type of immune cells, were similarly affected by GABA in a subgroup of healthy individuals. GABA also decreased the secretion of a large number of inflammatory molecules. The results form the basis of a patent application describing the use of specific biomarkers for GABA treatment and identification of individuals that may respond to preventive treatment with GABA.

"The results published in eBiomedicine provide strong support for the relevance of GABA in type 1 and type 2 diabetes," says Ulf Hannelius, CEO of Diamyd Medical. "The patent pending findings further support our investment in GABA and are of interest for the development of our proprietary GABA based study drug Remygen™."

The articles are available on:
https://doi.org/10.1016/j.ebiom.2018.03.019
https://doi.org/10.1016/j.ebiom.2018.03.014

About GABA and Diamyd Medical's patent rights
GABA (gamma-aminobutyric acid) is known for being a signaling substance in the central nervous system. In preclinical trials, the molecule has been shown to enhance the function of the beta cells and contribute to a reconstruction of the insulin producing tissue, which may lead to improved glucose control. Research has shown that GABA may increase the insulin sensitivity and control inflammation in metabolic syndrome as well as in type 2 diabetes and mitigate the disease process in other inflammatory diseases such as rheumatoid arthritis.

In addition to the two pending patents based on the current published findings, Diamyd Medical's IP rights within GABA comprise two exclusive licenses from UCLA. One of the licenses is for a key patent expiring 2031 for a combination treatment for type 1 diabetes with GABA and GAD65. Within the same patent family, a patent covering diabetes treatment with GABA and preproinsulin or an immunogenic fragment thereof has been granted. These IP rights comprise the rights to GABA for treatment and the prevention of inflammatory diseases including type 2 diabetes and rheumatoid arthritis.

The second license comprises pending patents for the therapeutic use of GABA with positive allosteric modulators of the GABAA receptor to enhance beta cell regeneration, survival and immunomodulation. The Company has an additional pending patent for the cultivation of tolerogenic dendritic cells with GABA and a pending patent for the formulation of the proprietary study drug Remygen™.

About Diamyd Medical
Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in studies with more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase-II trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, there are four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen™, an oral GABA-based study drug. An investigator-initiated placebo controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham. Exclusive licenses for GABA and positive allosteric modulators of GABA receptors for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen™ key assets. Diamyd Medical is also one of the major shareholders in the stem cell company NextCell Pharma AB and has holdings in the medtech company Companion Medical, Inc., San Diego, USA and in the gene therapy company Periphagen, Inc., Pittsburgh, USA.

Diamyd Medical's B-share is traded on Nasdaq First North under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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