FDA Approves SyneuRx' IND Application for Late Phase Clinical Development of a Mild Dementia Treatment

Germantown, MD, USA (April 4, 2016) - SyneuRx announced today, the U.S. FDA's approval of their newest IND program for SND14 as a treatment for mild dementia. SyneuRx will go directly to late phase clinical development with a PII/III adaptive design trial for this mild dementia indication.

SyneuRx' CEO, Professor Emil Tsai, noted "Early intervention is a must for dementia therapy, which is why we decide on the indication of mild dementia. The SND14 mild dementia protocol has potential for double benefit to the patient, first for substantial cognitive improvement and second, more importantly, to confirm a disease course improvement of the dementia process by use of randomized start design. Findings from a preliminary proof of concept study demonstrated that patients with mild dementia can return to normal cognitive capacity following treatment by SND14; while existing treatments only modestly improve cognition and have no impact on the disease progression. We are not only seeking cognitive improvement, we also want to confirm a fundamental improvement in the disease progression. If confirmed, this will be unprecedented in dementia treatment."

Mild dementia is the fourth late phase IND program for SyneuRx. The API of SND14 is undergoing parallel clinical trials by SyneuRx for 1) pediatric, 2) adult schizophrenia, and 3) refractory schizophrenia. The adult and refractory schizophrenia indications have been awarded the Breakthrough Therapy designation by the FDA.

Breakthrough designations in CNS indications are very rare. The Breakthrough designation is a FDA program for expedited development which provides SyneuRx and Amarex Clinical Research (authorized CRO representative) additional access to the FDA in order to support a quicker path to a NDA application. For Breakthrough designation, the FDA provides 1) consultation to ensure clinical studies are designed as efficient as possible, 2) extra meetings to discuss the development program's progress, 3) a special scientific liaison to facilitate communication and 4) accelerated review of clinical trial results.

Amarex CEO, Dr. Kazem Kazempour, added "The Breakthrough designation is a validation that existing clinical evidence indicates the drug has potential to provide substantial improvement of a clinically significant endpoint over available therapies."

Professor Tsai added, "SyneuRx and Amarex have been collaborating with great success for several years on multiple CNS indications and will continue to work together with the FDA to get to NDA applications as effectively as possible for these much needed therapies for the patients with CNS disorders."

About SyneuRx International (Taiwan) Corp.
SyneuRx is a global biotech company listed at the Emerging Board of Taiwan, undergoing clinical development of new classes of drugs for multiple major CNS disease conditions, most of which are lacking adequate medical treatments. Several late phase clinical trials are presently in process for multiple indications globally

About Amarex Clinical Research

Amarex is a global full service Contract Research Organization (CRO) that provides complete regulatory and clinical development services to take client's products from laboratory proof of concept to achieving FDA approval of new or re-purposed medical products. Amarex creates regulatory approval plans for their clients and executes those plans through clinical research up to and including NDA, BLA, PMA, or 510(k) applications. Amarex works with all types of medical products in all therapeutic indications. The leadership team's experience spans 30+ years of clinical research in Phase 1-4 trials, for over 300 projects, in more than 60 countries. www.amarexcro.com

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