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Establishment

JSW-Clinical Investigation

In the beginning of summer 2009, three well established and experienced clinical CROs: **Clinical Investigations**, **JSW Lifesciences** and **Ruslan Clinical Research**, decided to join forces for improved customer services in most relevant geographic areas of Europe. They founded the new **CRO - JSW-Clinical Investigations Ltd** based in the UK. The management of the three companies is now forming a board of directors consisting of **Prof. Dr. Gerhard Krejci** (Clinical Investigations), **Dr. Nik Nikitin** (Ruslan) and chaired by **Dr. Manfred Windisch** (JSW Lifesciences). The management team combines decades of experience in the field of clinical research and drug development and a profound understanding of how to organise and conduct clinical trials in a highly competitive environment.

The new company employs 131 well educated co-workers with a proven track record in clinical research and drug development, consisting of medical doctors, pharmacists, scientists and nurses. All of them have a full education in ICH-GCP and are aware of all regulatory requirements in the geographic area where they are located. The main offices are in the UK, Budapest, Bucharest, Sofia, Prague, Zagreb, Kharkov, Saint Petersburg, La Coruna, and in Austria. The JSW-CI facility in Grambach (Austria) has an area of 3600 square metres and also accommodates laboratory facilities for preclinical drug research, with a specific focus on neurological and psychiatric indications.

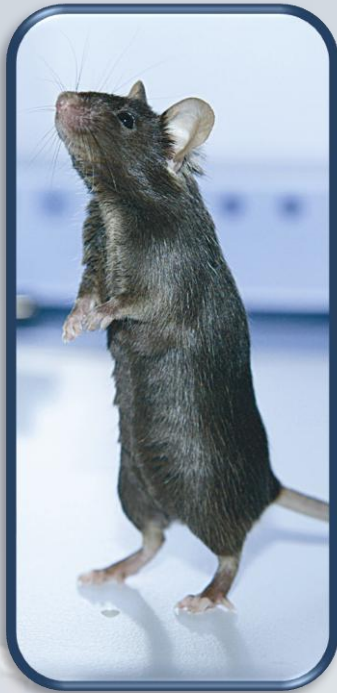
JSW-CI combines experience and expertise in a wide variety of indications, including CNS and psychiatric disorders (Alzheimer's disease, Parkinson's disease, stroke, depression and schizophrenia), oncology, cardiology, gastroenterology, endocrinology, infectious diseases, ophthalmology, immunology, nephrology, pulmonary diseases, transplantation medicine, and other indications. We perform clinical trial services for pharmaceuticals (small molecules and biologics), phytotherapeutics, medical devices, cosmetics and health care products.



The scope of services can start with forming a strategy of drug development for our customers and includes all further steps from protocol design, creation of case report forms and all documentations for regulatory submissions, organisation of clinical trial sites and their quality control, negotiations with investigative sites and investigators, set up of investigator meetings including training in GCP, site monitoring and auditing, organisation of additional services like clinical laboratory, drug supply and distribution, and finally, the whole procedure of data management, statistics and report writing.

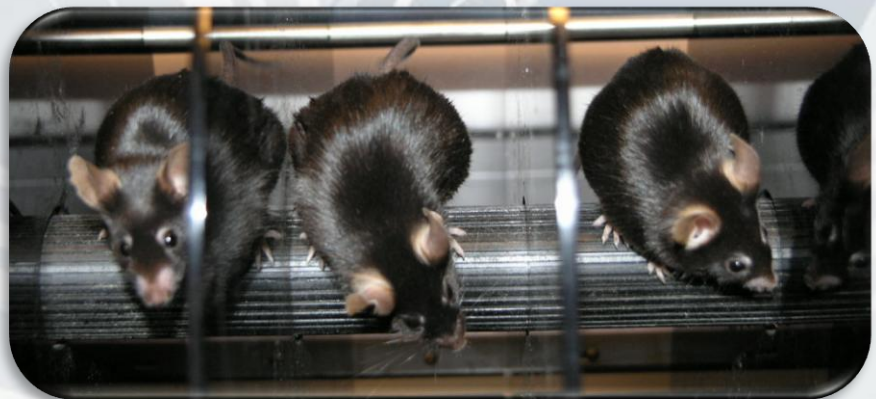
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Animal Models of Alzheimer s Disease - Do they have predictive value for drug development?



In spite of enormous research efforts during the last 20 years so far no cure of Alzheimer's disease has been developed and during the last years no new compounds have reached the market. A critical step in drug development is the prove of concept in reliable animal models closely reflecting the etiopathogenesis of the disease. Here due to the lack of complete clarifications of the etiology of AD all the models have some limitations which have to be carefully considered when they are used for assessing the therapeutic value of new treatments. The situation is complicated by the fact that practically no natural models of AD exist and so most of the research is either done in induced models trying to simulate disease conditions by an active manipulation of the animals, or in so called transgenic models. In the meanwhile an enormous number of different model systems are available, including non-mammal systems like C.elegans, drosophila or zebrafish.

Most of the transgenic models are based on the amyloid cascade theory of AD, few utilize the over expression of tau protein which forms the second hallmark of the disease, and there are also double and triple transgenic models available combining all of the pathologies.



All of these systems are artificial and they are not really reflecting what happens under human disease conditions because in most of the cases early onset, hereditary AD is modeled. But many therapeutic strategies have been developed based on such disease models, some of them reached in the meanwhile even the status of progressed clinical trials, but still the predictive value of the model remains unclear, in particular considering outcome of recent clinical trials compared to reported findings from the animal studies. Therefore careful selection of the right models and a thoughtful interpretation of data will be needed to utilize animal research in the most efficient way to facilitate drug development for more efficacious therapy of AD.

JSW-Lifesciences, as a leading expert in animal models of neurodegenerative diseases, has an enormous experience to help with the selection of the most relevant models and the best study design.

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The 6th International Winter Conference on Alzheimer's Disease in Zuers

Why do we have so few drugs for treatment of Alzheimer's disease? Was there something we did wrong for a long time, for example selecting the wrong patient population, designing the trials in a wrong way, or could it eventually be that most of the efforts were focusing on the wrong target?



It is reality that the first cholinesterase inhibitor has been approved now more than 15 years ago, and since then no new drugs with a better efficacy reached marketing approval. There are few hopes on the horizon, for example the very promising data from the phase II trial of Dimebon, there have been also positive data obtained with PBT2, a metal-chelator which is able to prevent abnormal aggregation of amyloid, and finally the data obtained in a study with a small peptide derived from activity dependent

neurotrophic factor which also achieved positive effects in an MCI population. Last year a big surprise which triggered a lot of discussion was the announcement of the data about Rember, Methylene Blue, as an agent preventing tau aggregation, showing quite promising data in a relatively large phase II clinical trial. Also immunotherapy of AD was in the focus of interest of the meeting and new, promising approaches for active and passive vaccination have been discussed. Attempt to influence the occurrence of truncated, pyro-glutamated Abeta is another alternative treatment idea. In spite of encouraging preclinical data and positive results from early phases of clinical trials, all of these approaches so far have not proven their efficacy in phase III clinical trials.

High level presentations by an international speaker's panel, were followed by lively discussions, giving opportunity to an exchange of opinions and experience in regard of all these questions and facts. This conference evolved to be an efficient and stimulating platform for all entities involved in AD drug development.

Upcoming Meetings 2010

01.-02. February	4th DRUG DISCOVERY FOR NEURODEGENERATION CONFERENCE Houston, TX - USA	http://www.worldeventsforum.com/ad/df/2010/
24.-27. March	11th International Geneva/Springfield Symposium on Advances in Alzheimer Therapy Geneva, Switzerland, EU	http://www.siumed.edu/cme/alzheimer/index.html
03.-07. July	7th FENS Forum of European Neuroscience Amsterdam, The Netherlands, EU	http://fens2010.neurosciences.asso.fr/index.html
10.-15. July	ICAD Alzheimer's Association – International Conference on Alzheimer's Disease Honolulu, Hawaii - USA	http://www.alz.org/icad/2010_icad.asp

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