

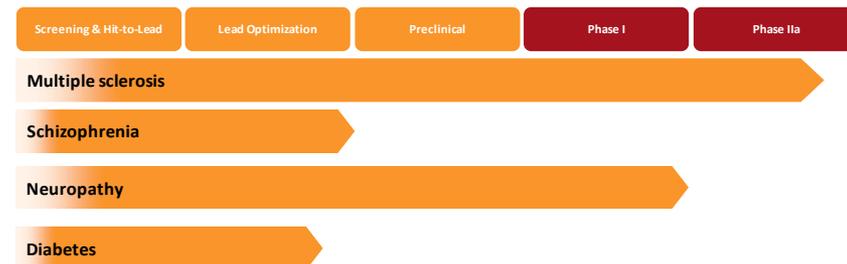
# Newsletter

## October 2013

GeNeuro is a privately held biotech company that is focused on developing a pioneering approach for the therapy and diagnosis of diseases associated with human endogenous retrovirus (HERV) expression with a primary focus on Nervous System diseases. GeNeuro builds a therapeutic product pipeline for disorders with high unmet medical needs. The company's goal is to optimize the management of the disease, including the treatment, the diagnostic tools and the patient's follow-up.

GeNeuro's lead compound GNbAC1 is an investigational therapeutic monoclonal antibody for the treatment of Multiple Sclerosis. GNbAC1 is targeting a HERV protein, neutralizing a potential key factor in the inflammatory process without modifying the human immune system. By acting upstream of the pathological process, GeNeuro's product could stop the progression of Multiple Sclerosis.

GeNeuro is also investigating therapeutic approaches for other diseases such as Schizophrenia, CIDP and Diabetes.



The first clinical Phase I trial took place in Switzerland and focused on drug safety in healthy volunteers. The randomized, double-blind, placebo-controlled, phase I study tested single ascending intravenous doses of GNbAC1 in healthy volunteers and the results showed that GNbAC1 is very well tolerated.

GeNeuro SA launched a phase IIa clinical study with GNbAC1 in Autumn 2012, at the University Hospitals of Basel and Geneva, in Switzerland. The randomized placebo-controlled phase IIa study tested single ascending doses of GNbAC1 in patients with multiple sclerosis for the first time. The main objectives of the study were the safety and pharmacokinetics of the monoclonal antibody in patients. A 6-months extension followed until last September.

For the clinical Phase IIa trial, GNbAC1 was tested for the first time in MS patients, 90% suffering from chronic progressive MS (6/10 with SPMS, 3/10 with PPMS):

- GNbAC1 was very well tolerated in all patients after repeated administrations at doses 2 mg/kg and 6 mg/kg.
- No induction of immunogenicity, suggesting a low risk of neutralisation of therapeutic effect by anti-drug antibodies.
- Dose-linear pharmacokinetics with elimination half-life of 15-17 days, compatible with a 4-week administration schedule.
- Both dose cohorts are now treated in an extension phase up to 12 months.

These positive results open the way for a multicentric Phase IIb clinical trial to test the efficacy of GNbAC1 in MS next year. Information about the clinical trials conducted in patients are posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), identifier NCT01639300.

GeNeuro SA has launched longitudinal epidemiological studies to follow the evolution of the HERV proteins in populations of MS patients and healthy controls. The LOMBARD & CONTROL studies are recruiting participants at the University Hospital of Lausanne, in Switzerland, at the Hospitals of Lyon and Marseille in France and at the Hospital of Barcelona in Spain. The recruitment is still ongoing in the centers of Lyon, Marseille and Barcelona.

Information are posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), identifiers NCT01804660 & NCT01804647.

GeNeuro has validated its early stage development in Chronic inflammatory demyelinating polyneuropathy (CIDP) during a Scientific Advice Meeting with the European Medicines Agency (EMA).

GeNeuro is working with French academic groups to launch a clinical trial in Schizophrenia.

GeNeuro will present its scientific developments at the following meetings:

BioEurope, 4-6 November 2013, Vienna