

## GeNeuro's temelimab shows extended neuroprotective effects in relapsing-remitting MS

- Further evidence adds to already strong set of positive clinical data
- Data presented atECTRIMS 2019 Congress in Stockholm, Sweden

**Geneva, Switzerland, September 16, 2019 – 7:30 am CEST** – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurodegenerative and autoimmune diseases, such as multiple sclerosis (MS) and type-1 diabetes (T1D), today announced that the neuroprotective effects of temelimab in MS patients extend to 96 weeks and that it is safe to use and well tolerated for a prolonged period. These data, from ANGEL-MS, an extension of the Phase 2 CHANGE-MS trial in relapsing-remitting MS (RRMS), were presented at the European Committee for Treatment and Research in Multiple Sclerosis ([ECTRIMS 2019](#)) Congress in Stockholm, Sweden.

Temelimab is a monoclonal antibody designed to neutralize a pathogenic envelope protein, pHERV-W Env, which is encoded by a member of the Human Endogenous Retrovirus W family. This protein plays a causal role in the development of MS and is thought to also be a key factor in the onset and development of T1D.

Patients with RRMS who completed the CHANGE-MS study were included in the ANGEL-MS study, from 43 centers across 12 countries. Overall, 220 patients from CHANGE-MS (95% of those who completed the study) entered the extension, with 75 patients, 68 patients and 77 patients enrolled to receive temelimab 6 mg/kg, 12 mg/kg and 18 mg/kg monthly IV infusions, respectively.

The data showed that, after two years of treatment, patients originally randomized to temelimab (18 mg/kg) in CHANGE-MS show evidence in ANGEL-MS for continued relative improvements in MRI-based neurodegenerative outcomes, such as brain volumes, magnetization transfer ratio (MTR) and black holes during ANGEL-MS up to 96 weeks compared to all other groups. In the combined CHANGE-MS and ANGEL-MS treatment periods (total of 96 weeks), the reduction in the atrophy rate of the cerebral cortex between patients treated at 18mg/kg over the entire period versus the control group was 42% (dose effect<sup>1</sup>  $p=0.058$ ) and the reduction in the atrophy rate of the thalamus was of 43% (dose effect<sup>1</sup>  $p=0.038$ ). Temelimab also had a marked effect on myelin integrity, as measured by Magnetization Transfer Ratio (MTR), with an increase in MTR values by >1.5% over the period, both in cortical ( $p<0.03$  in all bands) and normal appearing white matter ( $p<0.02$  in all bands). Importantly, these effects were not driven by an anti-inflammatory effect. These data supplement the initial findings from ANGEL-MS announced in March 2019: <http://www.geneuro.com/data/news/P1379-Ectrims-2019.pdf>

By targeting fundamental underlying mechanisms of neurodegeneration in MS, such as neutralizing microglial-mediated damage, as well as restoring OPC remyelination capacity, temelimab may address the critical unmet medical need of blocking disease progression in MS. As the study showed, temelimab continued to be safe and well tolerated over this extended treatment period, which allows to consider new therapeutic solutions for the different forms of MS. Temelimab could be used as a monotherapy for patients in progressive phases without relapses, a poorly served patient population, as well as in

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<sup>1</sup> Dose-effect analyzed by linear regression on all groups

combination with existing disease modifying drugs targeting inflammation in relapsing patients, thus bringing new benefits against disease progression across all forms of MS.

*“We are excited to see that the long term data confirm the neuroprotective effect of temelimab in MS, and demonstrate its potential to make significant improvements in the lives of patients with MS against disease progression,”* said **Jesús Martin-Garcia, CEO of GeNeuro**. *“These clinical results confirm the recent advances in the understanding HERV biology, and warrant the continued clinical development of temelimab in multiple sclerosis. “*

### About Temelimab

The development of temelimab (GNbAC1) is the result of more than 25 years of research into human endogenous retroviruses (HERVs), including 15 years within Institut Mérieux and INSERM before GeNeuro was founded in 2006. HERVs are present in the human genome and some have been associated with various auto-immune diseases. The viral envelope protein encoded by a HERV in the HERV-W family (pHERV-W Env) has been found in the brains MS patients, and particularly in active lesions, as well as in the pancreas of patients with type-1 diabetes on pathological examination. By neutralizing pHERV-W Env, temelimab could simultaneously block a pathological, neurodegenerative process and help to restore myelin integrity in MS patients, as well as to maintain insulin production in T1D patients. Given that the pHERV-W Env protein has no known physiological function, temelimab was expected to have a good safety and tolerability profile, with no effect on the patient’s immune system, and importantly this has been borne out by all clinical trials carried out to date.

### About GeNeuro

GeNeuro’s mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis, by neutralizing causal factors encoded by HERVs, which represent 8% of human DNA.

GeNeuro is based in Geneva, Switzerland and has R&D facilities in Lyon, France. It has 24 employees and rights to 17 patent families protecting its technology.

For more information, visit: [www.geneuro.com](http://www.geneuro.com)

### Contacts

<b>GeNeuro</b>	<b>NewCap (France)</b>	<b>Halsin Partners</b>	<b>LifeSci Advisors</b>
Jesús Martin-Garcia	Mathilde Bohin / Louis-Victor Delouvrier (investors)	Mike Sinclair (media)	Chris Maggos (investors)
Chairman and CEO	+33 1 44 71 98 52	+44 20 7318 2955	+1 646 597 6970
+41 22 552 48 00	Arthur Rouillé (media)	<a href="mailto:msinclair@halsin.com">msinclair@halsin.com</a>	+41 79 367 6254
<a href="mailto:investors@geneuro.com">investors@geneuro.com</a>	+33 1 44 71 94 98		<a href="mailto:chris@lifesciadvisors.com">chris@lifesciadvisors.com</a>
	<a href="mailto:geneuro@newcap.eu">geneuro@newcap.eu</a>		

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