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AB Science announces the launch of a phase 3 clinical development program for the Treatment of Alzheimer's Disease

AB Science SA. (Euronext: AB), announces the launch of a phase 3 clinical development program in the treatment of Alzheimer's disease with its lead compound masitinib, following positive phase 2 study results.

Results from a randomised controlled phase 2 trial conducted by AB Science in patients with Alzheimer's disease has shown that the rate of cognitive decline of Alzheimer's disease slowed or even stopped in patients receiving masitinib over 24 weeks, with an acceptable tolerance profile observed. These results are considered positive by AB Science, having achieved statistical significance even in a relatively small patient cohort.

In parallel, AB Science announces having received a **positive scientific opinion from the European Medicines Agency (EMA) on the design of its pivotal phase 3 study in this indication.**

Following evaluation of a proposed pivotal phase 3 study in Alzheimer's disease, the EMA has given its approval on the study design. This study will support a future application for market authorisation of masitinib in the treatment of mild to moderate Alzheimer's disease.

Masitinib's mechanism of action in Alzheimer's disease
The brain and spinal cord constitute the central nervous system. They may be injured following inflammatory diseases (multiple sclerosis for example) and/or degenerative diseases (such as Alzheimer's disease). Experimental data suggests that there is an inflammatory component in Alzheimer's disease.

Mast cells[1] are relatively abundant in the brain and spinal cord, notably around the blood vessels. Some studies consider that mast cells play a key role in enabling the passage of inflammation cells from the blood to the brain, which may then cause tissue destruction. Mast cells may also be recruited in degenerative diseases and contribute to tissue destruction.

Furthermore, the activation of kinases (such as PDGF-R) could contribute to the degenerative process of Alzheimer's disease by increasing the expression of gamma-secretase, an enzyme participating in the production of amyloid fibrils which, by accumulating in the brain, are responsible for the disruption of the neural network.

If these mechanisms were proven, it is possible that the inhibition of the c-Kit, Lyn and PDGF-R kinases, which are all blocked by masitinib, could contribute to improving the condition of patients suffering from neuroinflammatory and neurodegenerative diseases.

Alain Moussy, Chairman and CEO of AB Science declared: *«These statistical significance results encourage us to pursue the development of masitinib in Alzheimer's disease, which remains today an unmet medical need. Given masitinib's selective targeting of mast cells and specific kinases, these preliminary findings also provide clinically relevant evidence of their involvement in neurodegenerative pathologies. As predicted, masitinib appears to offer an innovative therapeutic solution in those indications with high medical need. The positive scientific opinion from EMA on the phase 3 study design is an important step for the development of masitinib in Alzheimer's disease».*

[1] Mast cells are key components of the immune system, present in the brain and implicated in regulation of the blood-brain barrier's permeability.

Summary of the phase 2 study design and results

A double-blinded, randomised, placebo-controlled, parallel-group study with the objective to evaluate masitinib, administered orally over 24 weeks, in patients suffering from mild-to-moderate Alzheimer's disease. Response was measured by change in ADAS-Cog, ADAS-ADL and MMSE scores after 24 weeks of treatment. A total of 35 patients were included in this study.

The rate of clinically relevant cognitive decline according to the primary endpoint, ADAS-Cog response (increase >4 points), was significantly lower with masitinib treatment compared to placebo after 12 and 24 weeks (6% versus 50% for both; p=0.040 and p=0.046, respectively). Moreover, whilst the placebo treatment-arm showed worsening mean ADAS-Cog, ADCS-ADL, and MMSE scores, the masitinib treatment-arm reported improvements, with statistical significance between treatment-arms at weeks 12 and/or 24 (respectively, p=0.016 and 0.030; p=0.035 and 0.128; and p=0.047 and 0.031). Adverse events occurred more frequently with masitinib treatment (65% versus 38% of patients); however, the majority of events were mild or moderate and transient.

Summary of the phase 3 study design validated by EMA

A prospective, multicentre, randomised, controlled, double-blind, parallel-group, phase 3 study to compare the efficacy and safety of masitinib at 6 mg/kg/day versus placebo in the treatment of patients with mild to moderate Alzheimer's disease over a 24 week duration. A total of 300 patients will be enrolled with masitinib being administered orally as an add-on therapy to standard care.

The measure of response will be based upon the proportion of patients presenting:

- An effect on the rate of cognitive decline and memory as evaluated by the Alzheimer's Disease Assessment Scale (ADAS-Cog) at week 24;
- An effect on the functional autonomy and quality-of-life evaluated by the Alzheimer's Disease Cooperative Study Activities of Daily Living (ADCS-ADL) at week 24.

Positioning of masitinib in Alzheimer's disease

Alzheimer's disease affects more than four million people in industrialised countries.

Five products are registered, four of which belong to the pharmacological class of anticholinesterases, the fifth being an NMDA inhibitor. In spite of this, Alzheimer's disease does not currently have any satisfactory treatment.

Many products are under development, including notably one antibody that blocks the beta amyloid protein and is currently in phase 3 development; and two antibody inhibitors of anti-gamma secretase, which aim to block production of the beta amyloid protein, also in phase 3. These products, with one exception, are injectable.

It is worth noting that Lilly recently stopped the phase 3 development of Solanezumab, an antibody for blocking the beta amyloid protein. This interruption was due to the lack of benefit on disease progression and the worsening of clinical measures.

Masitinib is an oral tyrosine kinase inhibitor that effectively down-regulates mast cell functions, cells that play a prominent role in sustaining the inflammatory network of the central nervous system and participant in regulation of the blood-brain barrier's permeability, and therefore represents an original mechanism of action. Furthermore, masitinib inhibits the expression of the gamma secretase through the inhibition of certain kinases, including FYN and PDGFR.

Masitinib is currently positioned as a first line treatment, in competition with the gamma secretase and the beta amyloid substance inhibitors.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers.

Owing to its novel mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases and in certain diseases of the central nervous system. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumour regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodelling, masitinib may have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specialising in the research, development and commercialisation of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signalling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases and central nervous system diseases), in both human and veterinary medicines. Thanks to its extensive research and development capabilities, AB Science has its own portfolio of molecules. Masitinib, a lead compound, has already been registered in veterinary medicine in Europe and is pursuing seven phase 3 studies in human medicine, including three studies on-going in pancreatic cancer, GIST and mastocytosis.

Further information is available on AB Science's website: www.ab-science.com

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