



PRESS RELEASE

AB SCIENCE SUMMARIZES KEY MESSAGES FROM ITS PARTICIPATION TO A PANEL DISCUSSION AT THE 2023 ALS DRUG DEVELOPMENT SUMMIT (BOSTON, USA)

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AB Science SA (Euronext – FR0010557264 – AB) today summarizes the key messages delivered to an audience of key opinion leaders and decision-makers in the field of ALS research and healthcare policy, during an Panel Discussion at the ALS Drug Development Summit in Boston, USA (May 16-18, 2023).

The Annual ALS Drug Development Summit is the only industry-focused conference dedicated to overcoming preclinical and clinical challenges currently facing ALS pipelines.

Alain Moussy (CEO and co-founder of AB Science) was an invited panel member for a session entitled 'A Year in Review: Showcasing the Breakthrough Developments in ALS Drug Development'. The themes of this Panel Discussion included reviewing the ground-breaking developments in ALS drug development in the past year, the impact on people living with ALS, clinicians, drug developers and regulatory bodies, and the implications for the next generation of ALS therapeutics.

The Summit highlights the implication of the entire ALS community to work together to advance the availability of new therapies for ALS sufferers.

Highlights from the discussion included:

- Two drugs have recently been registered in ALS by the US Food and Drug Administration (FDA), indicating that the ALS drug development landscape is gaining some long-awaited positive momentum.
- In the context of ALS being an incurable and fatal degenerative disease, it is encouraging to see a certain degree of flexibility from regulatory agencies regarding registration based on a single pivotal trial and conditional approval pathways. It is hoped that such flexibility is adopted by regulatory agencies worldwide.
- As more drugs become available to ALS patients it will be important to assess if combined therapies offer increased benefit.
- On the topic of treatment combinations, Alain Moussy discussed how there should be a particular emphasis on combining drugs with different mechanisms of action. This strategy has previously proved successfully in treating cancer and HIV.
- Patients are requesting expanded access (or compassionate use) programs as a way to access investigational drugs under certain conditions outside of a clinical trial.
- ALS advocacy groups and patient support has played a critical role in facilitating drug approvals and will continue to do so.
- One challenge presented by the increased availability of approved therapies is the emergence of internationally dissimilar standards of care, which will complicate clinical trial design.
- Handling of missing data in ALS studies, especially those using the ALSFRS-R endpoint, is complex with no consensus between regulatory agencies, FDA recommending using CAFS calculation whereas EMA favors a penalty in case of discontinuation called *jump to reference*. Alain Moussy suggested a harmonized approach across agencies.
- Surrogate endpoints based on biomarkers are of interest but further research is necessary to establish correlation with meaningful functional benefit and survival.

- On the topic of ALS clinical endpoints, Alain Moussy suggested the development of a new clinical endpoint inspired by oncology, such as progression free survival (PFS) to facilitate registration of new drugs in a timely manner, since PFS will lead to more events than OS and so reduce the number of patients needed in a clinical study for an orphan disease.

Additional information on the ALS Drug Development Summit can be found at the meeting website: <https://www.als-drug-development.com/>.

About amyotrophic lateral sclerosis

Amyotrophic lateral sclerosis (ALS) is a fatal motor neuron disorder that is characterized by progressive loss of the upper and lower motor neurons at the spinal or bulbar level. The disease belongs to a group of disorders known as motor neuron diseases, which are characterized by the gradual degeneration and death of motor neurons. In ALS, both the upper motor neurons and the lower motor neurons degenerate or die, and stop sending messages to muscles. The prevalence of ALS in western countries is fairly uniform at 6 per 100,000 persons, corresponding to around 30,000 cases in Europe and 20,000 in the USA. The first drug treatment for ALS, riluzole (Rilutek), was approved in 1995. In Europe, there has been no new treatment approved since riluzole.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a class of targeted proteins whose action are key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, often lethal with short term survival or rare or refractory to previous line of treatment. AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine and is developed in human medicine in oncology, neurological diseases, inflammatory diseases and viral diseases. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

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

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