



SUMMARY OF THE WEBCAST HELD ON MARCH 4, 2024 PROVIDING AN UPDATE ON AB SCIENCE DEVELOPMENT

Paris, March 7, 2024, 3pm CET

AB Science SA (Euronext - FR0010557264 - AB) is providing a summary of the live webcast held on March 4, 2024, giving an update on AB Science development.

The webcast presentation is available on the company's website, in the section « Press Releases »: <https://www.ab-science.com/news-and-media/press-releases/>

The presentation covered four topics:

- Status of conditional approval application of masitinib in ALS with EMA and Health Canada
- Status of the masitinib platform clinical development program
- Status of masitinib licensing partnership
- Status of the microtubulin platform clinical development program
- Status of masitinib and AB8939 intellectual property

Status of conditional approval application of masitinib in ALS with EMA and Health Canada

- Regarding EMA, the application was filed in August 2022. An Oral Explanation was planned in January 2024, however, CHMP proposed that AB Science submit a written response to the List of Outstanding Issues at D195 of the procedure, instead of addressing these issues through the Oral Explanation, which is unusual. A decision is now expected by the end of Q2 2024.
- Regarding Health Canada, a Notice of Deficiency-Withdrawal (NOD/w) has been issued and AB Science intends to submit a Request for Reconsideration. This reconsideration process involves new assessors and offers the possibility to have an opinion from a panel of experts. A decision is now expected by the end of Q3/Q4 2024.

Of note, the press release dated 26 February 2024 incorrectly stated that Health Canada issued a Notice of Non Compliance – Withdrawal (NON/w) when the decision issued was in fact a Notice of Deficiency – Withdrawal (NOD-W).

The issuance of NOD-W or NON-W indicate different regulatory decisions. A NOD-W is issued if, during the scientific review of the response to a Notice of Deficiency (NOD), it is found that the submission/application remains deficient. On the other hand, a Notice of Non-Compliance Withdrawal is issued when, during the scientific review of the response to a Notice of Non-Compliance (NON), it is determined that the submission remains non-compliant.

Three key major clinical objections and intended counterarguments for reconsiderations have been presented. They are the following:

- Amendments
 - Multiple amendments have been made that create uncertainty on the reliability of study data. Several concerns were resolved, namely, changing study status from phase 2 to phase 3, the fact that multiple amendments may be an inevitability, that amendments were not data-driven, that the study had broad inclusion criteria and there may be a need to limit heterogeneity, and that post-onset decline of 1.1 point per month may be relevant.

- However, Health Canada was concerned that amendments were late and not sufficiently justified. AB Science intends to justify that the distinction between Normal and Fast progressors was made when the data were entirely blinded and in a sufficiently prospective manner since 88% of the data still needed to be acquired at that time, and that the amendment was justified to minimize expected high missing data due to discontinuations from Fast progressors (confirmed to be >50% at week 48).
- Missing data
 - The concern regarding non-linearity of the ALSFRS-R data set distribution used for primary analysis (ANCOVA test) was resolved.
 - However, Health Canada was concerned that the treatment of missing data using LOCF methodology could potentially create a bias in favor of treatment.
 - AB Science intends to justify that sensitivity analysis of the primary analysis based on non LOCF recognized methods are successful and convergent (multiple imputational model, jump to reference, copy incremental model), and that the CAFS endpoint, incorrectly assumed by the Agency to be based on LOCF methodology, whereas it is not, approached the conventionally statistically significant outcome of 5% ($p=0.0776$), even though the study was not powered for this secondary endpoint.
- Application of EMA guideline on subgroups
 - Health Canada was concerned that the new proposed claim in patients with ALS prior to any complete loss of function is considered post hoc and that overall survival benefit in this claim could have been biased by confounding factors.
 - AB Science intends to justify that in the EMA guidance (EMA/CHMP/539146/2013) on the investigation of subgroups in confirmatory clinical trials, it is written that the guideline is applicable to a subgroup that has not been pre-specified.
 - In this claim, the treatment effect is exceptionally strong based on CAFS ($p=0.029$) and survival (+22 months $p=0.0192$). Furthermore, OS is the gold standard endpoint in ALS and is unbiased regardless of post study treatments because no drug has demonstrated OS benefit (except riluzole, which was available to all patients) and because all patients had the same possibility to benefit from tracheostomy or permanent or non-permanent ventilation.

Based on the supporting arguments and counterarguments outlined above, AB Science intends to submit a Request for Reconsideration. Other points of concern identified by the agency will also be responded to.

Status of the masitinib platform clinical development program

Masitinib offers a late stage and diversified platform of 8 indications, primarily centered around neuro-degenerative diseases (namely, amyotrophic lateral sclerosis, progressive form of multiple sclerosis, mild and moderate Alzheimer's disease) and mast cell diseases (indolent systemic mastocytosis, mast cell activation syndrome), but also sickle cell disease, metastatic castrate refractory prostate cancer eligible to docetaxel, and COVID-19.

- In amyotrophic lateral sclerosis (ALS), no drug has generated a consensus based on definitive evidence of efficacy. Enrolment in the phase 3 confirmatory masitinib study (AB19001), is slower than that of the previous (AB10015) study, due to design features of the phase 3 (run-in period of 3 months, patient eligibility restricted to moderate ALS severity, exclusion of newly registered drugs and a blinded extension period).
- In multiple sclerosis (MS), there is no approved drugs for non-active secondary progressive MS and only one for primary progressive MS. Masitinib stands-out as the only non BTK inhibitor in phase 3 clinical development. The confirmatory phase 3 masitinib study (AB20009) is authorized by the FDA and key European countries and initiation is expected in 2024.
- In Alzheimer's disease (AD), masitinib is positioned in mild and moderate forms of Alzheimer's disease, where no novel treatment has been approved. New treatments have been approved in early

Alzheimer. The confirmatory phase 3 masitinib study (AB21004) is authorized by FDA and key European countries with initiation expected in 2024.

- In indolent systemic mastocytosis (ISM), masitinib has a different positioning from other KIT-816 inhibitors and its benefits are optimal on different symptoms such as neurological symptoms, depression but also pruritus and flush. The confirmatory phase 3 masitinib study (AB15003) is ongoing and additionally, a phase 2 study (AB20006) is also ongoing in MCAS, another mast cell disease not involving the KIT-816 mutation.
- In sickle cell disease (SCD), there is an increasing interest with several new drugs being in clinical development; however, unlike masitinib, none target mast cells, which are involved in Vaso Occlusive Crisis. A phase 1/2 study, financed by the RHU program for a budget of 10M€, is planned, with an objective to identify biomarkers of a mast cell signature and to assess the efficacy of masitinib in the treatment of acute and chronic complications. AB Science will be free to continue the development of masitinib in SCD based on phase 2 data with biomarkers.
- In metastatic castrate refractory prostate cancer (mCRPC) eligible to docetaxel, there is no drug registered in combination with docetaxel and there is an unmet medical need after failure to hormonotherapy and eligible to docetaxel. A first phase 3 study of masitinib in combination with docetaxel was positive. Submission of a confirmatory phase 3 study is planned in 2024, following scientific advice received from EMA and FDA, who both recommended to demonstrate benefit on radiographic progression free survival with no need to prove efficacy on overall survival.
- In COVID-19, read-out of two phase 2 studies is expected in 2024, the first evaluating masitinib anti-inflammatory activity in hospitalized patients in need of oxygen with moderate and severe COVID-19, and the second one evaluating masitinib anti-viral activity in ambulatory or hospitalized patients with symptomatic mild and moderate COVID-19 and with comorbidities.

Status of masitinib licensing partnership

Discussions for masitinib licensing with a pharmaceutical company are ongoing and the process is expected to be completed by the end of 2024.

The scope of the license is mainly neurodegenerative indications, including ALS.

The discussions are with companies that do not condition the signature of a binding offer to a positive opinion from EMA and Health Canada in ALS.

AB Science is currently aiming to develop a liquid formulation for masitinib in ALS. A liquid formulation would be beneficial for ALS patients because they have difficulties in swallowing. A liquid formulation is beneficial for the masitinib development plan as differential pricing will be facilitated between ALS (liquid formulation) and other indications (tablets). The development of any new formulation will require bioequivalence studies and is expected to take two years.

Status of the microtubulin platform clinical development program

The microtubule destabilizer agents (MDAs) platform is focused in haemato-oncology with two drugs, AB8939 and AB12319.

AB8939 has the potential to improve acute myeloid leukemia (AML) treatment based on three differentiating features of its mechanism of action.

- AB8939 is not metabolized by an enzyme called myeloperoxidase, produced by the disease itself, unlike other MDAs.
- AB8939 avoids multidrug resistance because it does not bind and is not transported by Pgp/BRCP, so it is not washed out from the cells, unlike other MDAs.
- AB8939 has a strong synergistic effect with reference treatment azacitidine, called Vidaza.

The phase 1 study of AB8939 has completed its first step (determination of maximum tolerated dose following 3 consecutive days of AB8939 treatment), and key agencies have authorized this study to proceed with the next step (determination of maximum tolerated dose following 14 consecutive days of AB8939 treatment).

The phase 1 is expected to be completed in 2024 and a phase 2 will be initiated in 2025 with an intention to design the study to support accelerated approval.

Status of masitinib and AB8939 intellectual property

Masitinib intellectual property rights are protected until 2036 in mastocytosis, until 2037 in ALS, and potentially until 2041 in MS and ALZ and 2042 in prostate cancer.

AB8939 intellectual property rights in AML are secured until 2036 through a 'composition of matter' patent and potentially until 2044 in AML with chromosome abnormality (MECOM) through a 'second medical use' patent.

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.

Forward-looking Statements - AB Science

This press release contains forward-looking statements. These statements are not historical facts. These statements include projections and estimates as well as the assumptions on which they are based, statements based on projects, objectives, intentions and expectations regarding financial results, events, operations, future services, product development and their potential or future performance.

These forward-looking statements can often be identified by the words "expect", "anticipate", "believe", "intend", "estimate" or "plan" as well as other similar terms. While AB Science believes these forward-looking statements are reasonable, investors are cautioned that these forward-looking statements are subject to numerous risks and uncertainties that are difficult to predict and generally beyond the control of AB Science and which may imply that results and actual events significantly differ from those expressed, induced or anticipated in the forward-looking information and statements. These risks and uncertainties include the uncertainties related to product development of the Company which may not be successful or to the marketing authorizations granted by competent authorities or, more generally, any factors that may affect marketing capacity of the products developed by AB Science, as well as those developed or identified in the public documents published by AB Science. AB Science disclaims any obligation or undertaking to update the forward-looking information and statements, subject to the applicable regulations, in particular articles 223-1 et seq. of the AMF General Regulations.

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