



**PRESS RELEASE**

## **AB SCIENCE PRESENTS ITS FINANCIAL RESULTS FOR THE FIRST HALF OF 2024 AND THE KEY EVENTS OF THE PERIOD**

### ▪ **Clinical development**

- Masitinib platform:
  - Ongoing re-examination by EMA and Health Canada of the marketing authorisation application for masitinib in amyotrophic lateral sclerosis (ALS)
  - Update on the development of masitinib in progressive forms of multiple sclerosis following the ECTRIMS 2024 conference
  - Positive results from the phase 2 study of masitinib in Covid-19
  - Strengthening the intellectual property of masitinib in mastocytosis
- Microtubule platform:
  - Update on the AB8939 microtubule program and in particular on the ability of AB8939 to generate a response on MECOM rearrangement

### ▪ **Financial and corporate situation**

- Operating deficit of 3.6 million euros as of June 30, 2024, down 59.5% compared to the first half of 2023
- Cash position of 9.1 million euros as of June 30, 2023, to which is added 5 million euros from the capital increase by private placement announced in September 2024
- Completion of the settlement and delivery of the 5 million euros capital increase

*Paris, October 10, 2024, 8.30am CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announces its half-year financial results as of June 30, 2024 and provides an update on its activities.

### **KEY EVENTS RELATED TO CLINICAL DEVELOPMENT DURING THE FIRST HALF OF 2024 AND SINCE JUNE 30, 2024**

#### **EMA negative opinion on the marketing authorisation application for masitinib in amyotrophic lateral sclerosis and ongoing re-examination of the dossier by EMA**

AB Science announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted, in line with the trend vote, a negative opinion on the application for conditional marketing authorization of masitinib in the treatment of amyotrophic lateral sclerosis (ALS).

AB Science requested a re-examination on the basis of:

- First and foremost, the urgent need for patients to have early access to a promising treatment.
- The opportunity of having the dossier re-examined by new rapporteurs and by a *Scientific Advisory Board*.

AB Science highlights the difficulty of a conditional marketing authorization in ALS and cannot guarantee a positive outcome following this re-examination.

The reasons which nevertheless led AB Science to request a re-examination of the file are as follows:

- Acceptable masitinib safety: First, the CHMP confirmed that the safety of masitinib is deemed acceptable, which is a key consideration in the context of a conditional marketing authorization where confirmatory evidence of efficacy is required.
- Objection concerning deviations from Good Clinical Practice: As per EMA guidance (EMA/868942/2011), impact analyses of all protocol deviations that could not be corrected were performed and showed no impact, resolving Good Clinical Practice issues as per guideline.
- Objection concerning the exclusion of fast progressors: The amendment transitioning from phase 2 to phase 3 excluding fast progressors from the primary analysis population was necessary and well justified, in order to have a more homogenous population with greater chance of reaching week 48 time point and minimizing missing data. Furthermore, the amendment was implemented early enough and while the study was blinded, removing any methodological issues.
- Objection concerning the treatment of missing data in the primary analysis: Multiple sensitivity analysis of the primary analysis; using non LOCF (Last Observation Carried Forward) methods for imputation of missing data, are positive and consistent, including two analyses previously recommended by the CHMP, demonstrating the robustness of the primary analysis, thus resolving the objection concerning the treatment of missing data.
- Objection on the subgroup data: There was an important imbalance in a subset of patients experiencing complete loss of function (i.e., ALSFRS-R score of zero) in one or more of the item scores (20% in the masitinib arm versus 8% in the placebo arm), because ALSFRS-R score was minimized but not stratified by category of severity. The subgroup defined as patients prior to any complete loss of function (i.e. excluding the overmentioned biased subset) accounted for 86% of the population and showed extremely compelling results, including a significant 12 months survival benefit. The subgroup analysis is the strict application of EMA guidance (EMA/CHMP/539146/2013), which is applicable to post hoc analysis and to registration with single pivotal study, thus resolving the objection regarding subgroup data.

The re-examination of the dossier by EMA is ongoing.

**Notice of Deficiency-Withdrawal (NOD/w) regarding the New Drug Submission (NDS) for masitinib in the treatment of amyotrophic lateral sclerosis (ALS) in Canada and ongoing re-examination of the dossier by Health Canada**

AB Science announced in February 2024 that Health Canada issued a Notice of Deficiency-Withdrawal (NOD/w) regarding the New Drug Submission (NDS) for masitinib in the treatment of ALS and indicated its intention to submit a reconsideration request.

In April 2024, AB Science announced that Health Canada had granted eligibility for reconsideration request. The reconsideration process will re-examine, with new assessors, the decision based on information that was included in the original submission.

The re-examination is ongoing by Health Canada.

**Update on the AB8939 microtubule program and in particular on the ability of AB8939 to generate a response on MECOM rearrangement**

AB Science provided an update on the microtubule program AB8939 and in particular the ability of AB8939 to generate response on MECOM rearrangement.

AB8939 is a novel microtubule destabilizer currently evaluated in phase 1 clinical trial (study AB18001, NCT05211570) in patients with refractory and relapsed acute myeloid leukemia (AML).

The phase 1 clinical trial of AB8939 completed its first step, consisting in determining the maximum tolerated dose following 3 consecutive days of AB8939 treatment, and was authorized to proceed with the next step, consisting in determining the maximum tolerated dose following 14 consecutive days of AB8939 treatment.

The phase 1 clinical trial continues to determine MTD and the study is now at the last cycle of the 14 days evaluation. The next step will be to determine the MTD in the combination of AB8939 with Vidaza® (azacitidine).

AB Science previously reported a case of complete bone marrow response in an AML patient in failure to prior treatment with azacitidine and presenting with a MECOM gene rearrangement, which consists of chromosomal aberrations of EVI1 oncogene, leading to one of the worst prognostics in AML and is associated with lack of response and resistance to conventional chemotherapy.

New data confirm that there is a signal of activity against MECOM, with AB8939 generating a complete response in combination with Vidaza, as evidenced by a synergistic effect in a patient-derived xenograft (PDX) mouse model bearing the MECOM rearrangement. PDX are cell lines coming from patients that are grafted to immune deficient mice to mimic as closely as possible the human disease.

- AB8939 was able to generate 50% response when used as a single agent on MECOM cell lines ex vivo in a non-clinical setting.
- In the phase 1 trial, 4 patients bore the MECOM rearrangement and 50% responded to AB8939 when used as a single agent.
- In phase 1, so far, AB8939 does not appear to be toxic to bone marrow, avoiding severe neutropenia and suggesting the possibility to use the drug for long-term treatment.

These data taken together confirm the opportunity to develop AB8939 in phase 2 clinical trial in MECOM as a single agent or in combination with Vidaza.

The advantage is that a small study could be sufficient to comply with FDA guideline on accelerated approval.

### **Update on the development of masitinib in progressive forms of multiple sclerosis following the ECTRIMS 2024 conference**

AB Science provided an update on the development of masitinib in progressive forms of multiple sclerosis (MS), following the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 2024 conference.

The development of masitinib in progressive forms of multiple sclerosis is based on the MAXIMS study (AB20009), a randomized, double-blind, phase 3 study of masitinib 4.5 mg/kg/day in patients with primary progressive multiple sclerosis (PPMS) and non-active secondary progressive multiple sclerosis (nSPMS).

The recent results of tolebrutinib in non-active secondary progressive MS presented at the ECTRIMS 2024 conference, reinforce the scientific hypothesis that targeting microglia in nSPMS is a valid approach. Tolebrutinib belongs to a class of drugs that target microglia through an enzymatic target called BTK (Bruton Tyrosine Kinase).

Masitinib also targets microglia but through a different enzymatic target called M-CSFR1 (Macrophage Colony Stimulating Factor Receptor-1) and generated positive results in phase 2B (AB07002), which are consistent with tolebrutinib data.

- EDSS progression confirmed at 3 months was reduced by 37% with masitinib in study AB07002 and by 23% with tolebrutinib in the Hercules study (although the reduction in study AB07002 did not reach the conventional 5% p-value since the study was not powered to detect a significant effect in this secondary endpoint, having 300 patients in the masitinib 4.5 or placebo arms as compared with 1100 patients in the Hercules trial).
- EDSS progression confirmed at 6 months was reduced by 32% with masitinib and by 31% with tolebrutinib.

Importantly,

- Masitinib significantly improved manual dexterity measured by 9-hole Peg test, in study AB07002 (-4,28 ; p=0,0388).
- Masitinib has shown the ability to decrease serum neurofilament light chain (NfL) concentration in an animal model of MS, and by extension therefore, possibly neuronal damage.

- Masitinib not only targets microglia but also mast cells, which play a crucial role in progressive MS and in the experimental autoimmune encephalomyelitis (EAE) model of MS, as shown by numerous publications.

Masitinib benefits from a large safety database with long-term exposure across various indications. In non-oncology indications, around 2,200 patients have received at least one dose of masitinib, more than 1,300 patients have received masitinib for more than six months and close to 1,000 patients have received masitinib for more than one year.

BTK safety profiles shows increase in liver injury, hypertension and infections which seem to be a class effect, leaving room for alternative drugs.

As a conclusion, masitinib represents a potential credible alternative to BTK inhibitors in the development of new drugs both in primary and non-active secondary progressive MS.

### **Positive results from the phase 2 study of masitinib in Covid-19**

AB Science announced the results of a Phase 2 study evaluating masitinib in COVID-19. This Phase 2 study (AB20001) was designed to evaluate the safety and efficacy of masitinib plus isoquercetin in hospitalized patients with moderate COVID-19 (WHO 7-point ordinal scale level 4) or severe COVID-19 (level 5). The study initially planned to recruit 200 patients (over 18 years of age with no upper age limit). The primary objective was to improve the clinical status of patients after 15 days of treatment, as measured by the WHO 7-point ordinal scale. Following a DSMB recommendation, decision was taken to continue the study only in level 4 patients (i.e. hospitalized patients with oxygen supply <6 L/min with SpO<sub>2</sub> maintained ≥92%).

The study could not recruit the planned 200 patients. The decision was therefore taken to stop inclusion after 95 patients were randomized. The objective was to detect a trending treatment effect with 95 patients that would translate into a significant effect when simulating the same effect with the planned enrolment of 200 patients. If this objective was reached, then the conclusion would be that it is worth continuing to evaluate masitinib as an agent in the treatment of covid in patients hospitalized with moderate need of oxygen.

The study showed an odds ratio of 2.4 in favor of the treatment arm after 15 days of treatment, superior to the odds ratio of 2.2 initially hypothesized, with p=0.038 simulated with 200 patients and p=0.072 detected with 95 patients recruited. Sensitivity analyses at day 12, 13 and 14 with 95 patients recruited displayed a p-value of respectively p=0.016, 0.019, 0.018 and odds ratio 3.2, 3.2 and 3.4. This was due to improvement of certain placebo patients at day 15 but not before. The safety was in line with the known safety profile of masitinib.

### **Strengthening the intellectual property of masitinib in mastocytosis**

AB Science announced that the European Patent Office has issued a Notice of Allowance for a patent relating to methods of treating severe systemic mastocytosis (i.e. a medical use patent) with masitinib. This new European patent provides intellectual property protection for masitinib in this indication until October 2036.

The same medical use patent strategy has been successfully applied in amyotrophic lateral sclerosis, with a worldwide patent granted until 2037, and is being applied in other indications such as multiple sclerosis, Alzheimer's disease for protection until 2041, and in prostate cancer for protection until 2042.

## **CONSOLIDATED FINANCIAL ELEMENTS FOR THE FIRST HALF OF 2024**

The operating result as of June 30, 2024 corresponds to a loss of €3,582k, compared to a loss of €8,850k as of June 30, 2023, representing a reduction in the operating deficit of €5,268k (59.5%).

- Operating income consists exclusively of revenue related to the exploitation of a veterinary medicine. Revenue is up compared to June 30, 2023 and amounts to 560 thousand euros as of June 30, 2024 compared to 448 thousand euros as of June 30, 2023. This increase in operating income over the period compared to the previous period is due to the resumption of sales from May 2023, after a disruption in the supply of Masivet between August 2022 and April 2023 following a change in the synthesis process of the active ingredient of Masivet which required a request for variation of the marketing file of Masivet to the European Medicines Agency (EMA). The EMA issued a favorable decision in April 2023, from which date the exploitation of Masivet was able to resume.

- Research and development expenses decreased by 65.5% between the first half of 2024 and the first half of 2023, amounting to 2,564 thousand euros for the first half of 2024 compared to 7,213 thousand euros for the first half of 2023. This decrease reflects the implementation of the partnership research strategy for the continued clinical development of masitinib.
  - Marketing costs fell by 12.8% from 218 thousand euros as of June 30, 2023 to 190 thousand euros as of June 30, 2024.
  - Administrative expenses decreased by 21.4% between the first half of 2024 and the first half of 2023.
  - The financial result corresponds to a loss of 887 thousand euros for the first half of 2024, compared to a loss of 1,569 thousand euros for the first half of 2023. As of June 30, 2024, other financial income, which amounted to 274 thousand euros, mainly corresponds to the following operations:
    - o to late payment interest collected with the research tax credit 2020 – 2021 – 2022 (83 thousand euros)
    - o to the change in the fair value of the BSAs linked to the EIB loan (140 thousand euros)
    - o to the variation in the fair value of ADPE (49 thousand euros).
- Other financial charges (55 thousand euros) are mainly related
- o to the reprocessing of rents in IFRS 16. (9 thousand euros)
  - o to the change in the fair value of the BSAs linked to the EIB loan (45 thousand euros)
- These effects have no impact on cash flow.

The net loss as of June 30, 2024 amounted to 4,469 thousand euros, compared to a loss of 10,411 thousand euros as of June 30, 2023, a decrease of 57.1% for the reasons mentioned above.

The following table summarizes the half-yearly consolidated accounts for the first half of 2024 established in accordance with standards IFRS, and comparative information with the first half of 2023:

<i>In thousands of euros, except for share data</i>	30/06/2024	30/06/2023
<b>Net turnover</b>	<b>560</b>	<b>448</b>
Cost of sales and marketing expenses	(93)	(219)
Marketing expenses	(190)	(218)
Administrative expenses	(1,295)	(1,648)
Research and development expenses	(2,564)	(7,213)
<b>Operating income</b>	<b>(3,582)</b>	<b>(8,850)</b>
Financial income	322	1,042
Financial expenses	(1,210)	(2,610)
<b>Financial income</b>	<b>(887)</b>	<b>(1,569)</b>
<b>Net income</b>	<b>(4,469)</b>	<b>(10,411)</b>
<b>Other comprehensive income for the period net of tax</b>	<b>85</b>	<b>51</b>
<b>Total comprehensive income for the period</b>	<b>(4,384)</b>	<b>(10,360)</b>
Basic earnings per share - in euros	(0.09)	(0.22)
Diluted earnings per share - in euros	(0.06)	(0.22)

<i>In thousands of euros</i>	30/06/2024	31/12/2023
Cash and cash equivalents	9 128	6,006
<b>Total assets</b>	<b>22,982</b>	<b>25,499</b>
Equity	(24,599)	(21,010)
Non-current liabilities	(30,032)	(27,825)
Trade payables	(10,584)	(11,075)
Current liabilities	(17,548)	(18,683)

## **OTHER CORPORATE INFORMATION FOR THE FIRST HALF OF 2024 AND SINCE JUNE 30, 2024**

### **Capital increase by private placement for an amount of 5 million euros**

AB Science has announced a capital increase of 5.0 million euros through the issue of 5,368,725 new ordinary shares, each of which is attached to share subscription warrants. This capital increase was subscribed by qualified European investors.

The Capital Increase consisted of a private placement pursuant to Articles L. 225-136 of the French Commercial Code and L. 411-2 1° of the French Monetary and Financial Code and has been carried out with a waiver of preferential subscription rights, pursuant to the delegation of authority granted to the Board of Directors under the 19th resolution of the Combined General Shareholders' Meeting of June 26, 2024. The Capital Increase has taken the form of the issuance of 5,368,725 new ordinary shares (the "New Shares") to each of which are attached a share subscription warrant (the "Warrants").

Two tranches of New Shares have been issued:

- for the first tranche of 4,294,980 New Shares, two Warrants give right to the subscription of one ordinary share;
- for the second tranche of 1,073,745 New Shares, three Warrants give right to the subscription of one ordinary share.

The Capital Increase is made through a cash contribution of 5.0 million euros.

All of the 5,368,725 New Shares and all of the 2,505,405 new shares that would be issued upon exercise of the warrants, i.e. a total of 7,874,130 shares in the Company, represent 13.3% of the Company's current share capital.

The issue price of the New Shares has been set at 0.93132 euro (0.01 euro par value and 0,92132 euro of issue premium) and the exercise price of the Warrants at 1.16415 euro, representing a total fundraising of 5.0 million euros (taking into account the exercise of the warrants, the maximum amount of the Capital Increase could be increased to a total amount of 7.9 million euros). The issue price of the New Shares has been calculated based on the volume-weighted average price of AB Science shares over the last three trading days (on Euronext Paris) preceding the price calculation, with a 10% discount.

The Warrants may be exercised from November 26, 2026 to December 31, 2028, will be immediately detached from the New Shares upon their issuance and will not be listed.

AB Science completed the settlement and delivery of this capital increase.

The proceeds of the Capital Increase will provide AB Science with the additional resources necessary to finance its activities over the next twelve months.

### **Subscription by Alpha Blue Ocean of a tranche of one million shares within the framework of the Term Capital Increase Program (PACTTM)**

The PACT<sup>TM</sup> program entered into with Alpha Blue Ocean (ABO) was renewed on April 28, 2023 for a period of 24 months. The Board of Directors of AB Science decided to draw down one million shares under this program, on the basis of the 17th resolution of the combined general meeting of shareholders of June 30, 2023 (reserved cash capital increase with waiver of preferential subscription rights). They were subscribed by Alpha Blue Ocean at the end of March 2024 at a price of 2.5701 euros (i.e. the volume-weighted average price of AB Science's shares on Euronext Paris during the three trading sessions preceding the drawdown request). AB Science received the entire proceeds from the issue of the shares subscribed by Alpha Blue Ocean, and 80% of these proceeds were placed in an escrow account. Alpha Blue Ocean is now responsible for selling, in an orderly manner, the subscribed AB Science shares. During the first half of 2024, 377,393 shares were placed. 95% of the sale proceeds (reduced by a structuring fee equal to 3% of the issue price) is paid monthly to AB Science, directly by Alpha Blue Ocean or by drawing on the escrow account referred to above, after deduction of the 20% deposit of the issue proceeds retained by AB Science. In total, over the first half of 2024, these disposals resulted in payments by ABO, net of commission, of 682,181 euros (including the 20% of the issue proceeds initially retained by AB Science).

The IFRS accounting treatment of the PACT<sup>TM</sup> program is detailed in note 13 of the appendix to the half-yearly accounts (impact on equity and debts, cash receipts, amount of the escrow account as of June 30).

### **Coverage initiation by DNA Finance and In Extenso Finance**

AB Science announced that two financial analysis firms, DNA Finance and In Extenso Finance, have initiated the coverage of the Company.

DNA Finance estimates that AB Science stands out as a compelling investment opportunity in the biotech sector.

In Extenso has initiated a strong buy opinion on the share.

These new coverages aim to strengthen the AB Science visibility among French and international institutional investors and to broaden its investor base. They are in addition to the coverage by Chardan, an investment bank based in the United States and specialized in biotechnologies and health technologies.

**Partial payments of 2020, 2021 and 2022 research tax credit by the tax administration in 2024, for a total amount of 7,913 thousand euros**

**Confirmation by the Paris Court of Appeal of the acquittal of the CEO of AB Science, Alain Moussy, and reduction of the amount of the financial penalty imposed on AB Science**

AB Science and the Chairman of the French market regulator (Autorité des Marchés Financiers - AMF) had filed an appeal to the Paris Court of Appeal against the decision of the AMF Sanctions commission, dated March 24, 2022, which acquitted Alain Moussy, CEO of AB Science, for an alleged insider trading and sanctioned AB Science for a failure to comply with some of its communication obligations (as part of the assessment of conditions for a deferral of privileged information publication), as indicated in the AB Science press release of March 29, 2022.

The Paris Court of Appeal confirmed the fully acquittal of Alain Moussy and reduced by 200,000 euros the amount of the financial penalty pronounced against AB Science. This amount of 200,000 euros will have to be reimbursed by the French Treasury, as AB Science has paid the full financial penalty initially pronounced by the AMF Sanctions commission on March 24, 2022.

**Cancellation of category C preference shares in March 2024**

The balance of 262,704 category C preference shares (the "ADPC") was repurchased for a symbolic euro by AB Science with a view to their cancellation, in application of the financial restructuring agreement signed on April 21, 2023.

**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](http://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.

For additional information, please contact:

**AB Science**

Financial Communication & Media Relations

[investors@ab-science.com](mailto:investors@ab-science.com)