



**PRESS RELEASE**

## **AB SCIENCE PRESENTS ITS FINANCIAL INFORMATION FOR THE FIRST HALF OF 2022 AND THE KEY EVENTS OF THE PERIOD**

### ▪ **Clinical development**

- Authorization by Health Canada in February 2022 to file a New Drug Submission for masitinib in the treatment of amyotrophic lateral sclerosis (ALS) under the Notice of Compliance with Conditions (NOC/c) policy and formal start of the review in May 2022. Health Canada has a target of 200 calendar days maximum to review the application
- Filing for conditional Marketing Authorization to the European Medicines Agency (EMA) for masitinib in the treatment of amyotrophic lateral sclerosis (ALS) and formal start of the review in August 2022
- Launch of a confirmatory Phase 3 study with masitinib in progressive forms of multiple sclerosis
- Positive recommendation of the Data and Safety Monitoring Board to continue both Phase 2 studies in Covid-19

### ▪ **Financial information and other corporate information**

- Operating loss of €9.6 million as of 30 June 2022, an increase of 58% compared to the first half of 2021
- Cash position of €7.6 million as of 30 June 2022, plus the €7.1 million of 2020 and 2021 research tax credit and a financing agreement with the European Investment Bank of which 12.0 million euros are available at that date

*Paris, September 30, 2022, 6.30pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today reports its revenues for the first half of 2022 and provides an update on its activities.

## **CLINICAL DEVELOPMENT KEY EVENTS FOR THE FIRST HALF OF 2022 AND SINCE JUNE 30, 2022**

### **Authorization by Health Canada to file a New Drug Submission for masitinib in the treatment of amyotrophic lateral sclerosis (ALS) under the Notice of Compliance with Conditions (NOC/c) policy**

AB Science announced that Health Canada has granted authorization to file a New Drug Submission for masitinib in the treatment of amyotrophic lateral sclerosis (ALS) under the Notice of Compliance with Conditions (NOC/c) policy.

If granted, an NOC/c is authorization to market a drug with conditions. Such conditions will be discussed with Health Canada during the procedure.

An assessment named Advance Consideration, performed by a Health Canada *Adjudicating Committee*, is necessary before being granted authorization to file under NOC/c policy.

This assessment was made based on a pre-submission package sent by AB Science including, efficacy data of study AB10015, long-term survival data (75 months average follow-up from diagnosis) of study AB10015, and safety data.

An estimated 3,000 Canadians are currently living with ALS. Each year approximately 1,000 Canadians die from ALS. A similar number of Canadians are diagnosed with ALS each year.

Under the NOC/c policy, Health Canada has a target of 200 calendar days maximum to review the application.

### **Filing for conditional Marketing Authorization to the European Medicines Agency (EMA) for masitinib in the treatment of amyotrophic lateral sclerosis (ALS)**

AB Science filed an application for conditional Marketing Authorization to the European Medicines Agency (EMA) for Alsitek (masitinib) in the treatment of amyotrophic lateral sclerosis (ALS). The application is based on results from the phase 2/3 AB10015 study and its long-term survival follow-up. Study AB10015 was a randomized, double-blind, placebo-controlled trial over a 48-week treatment period, conducted with 394 ALS patients and evaluating Alsitek in combination with riluzole versus riluzole alone.

This decision to file followed a pre-submission meeting held with the Committee for Medicinal Products for Human Use (CHMP) Rapporteur during which new data generated with Alsitek in ALS were presented, in particular, a clinical benefit in terms of a 25-month increase in median overall survival for patients with moderate ALS, which is a cohort that closely resembles newly diagnosed patients. During the pre-submission meeting, AB Science also presented how issues listed in the previous CHMP assessment for Alsitek on ALS (EMA/406203/2018) were resolved, in particular:

- The mode of action of Alsitek in ALS, which has been well-demonstrated and published in peer-reviewed publications.
- A remonitoring of all efficacy and safety data and a complete reassessment of the Alsitek safety database.
- Additional analyses for the primary efficacy endpoint, imputing all missing data for early discontinuation, and a conservative analysis imputing missing data with a penalty for patients who discontinued Alsitek for lack of efficacy or toxicity. These analyses were positive, and all showed a treatment effect in favor of Alsitek and convergent with the primary analysis.
- Long-term follow-up survival data showing a significant benefit in favor of Alsitek in moderate ALS patients (between group difference in median OS of +25 months, hazard ratio 0.56 (95%CI [0.32;0.96])).

This application has now been validated by EMA and review by the CHMP has begun. The CHMP has a target of 210 active evaluation days to review the application.

### **Launch of a confirmatory Phase 3 study with masitinib in progressive forms of multiple sclerosis**

AB Science announced that it has been authorized by the French Medicine Agency, ANSM, to initiate a Phase III study (AB20009) evaluating masitinib in patients with Primary Progressive Multiple Sclerosis (PPMS) or non-active Secondary Progressive Multiple Sclerosis (nSPMS). The study will enroll 800 patients from numerous study centers with Expanded Disability Status Scale (EDSS) score between 3.0 to 6.0 and absence of T1 Gadolinium-enhancing brain lesions as measured by magnetic resonance imaging (MRI).

The primary objective of the study will be to evaluate the effect of masitinib on time to confirmed disability progression, with progression defined as 1-point worsening when EDSS baseline score  $\leq 5.5$ , or 0.5 if baseline score  $> 5.5$  from randomization to week 96.

This confirmatory study follows successful completion of a first Phase 2B/3 study (AB07002) in primary progressive (PPMS) and non-active secondary progressive (nSPMS) multiple sclerosis. This study met its primary analysis endpoint, demonstrating a statistically significant reduction in cumulative change on EDSS with masitinib 4.5 mg/kg/day ( $p=0.0256$ ).

## **Positive recommendation of the Data and Safety Monitoring Board to continue both Phase 2 studies in Covid-19**

AB Science announced the continuation of the Phase 2 study evaluating masitinib in combination with isoquercetin in COVID-19, following the recommendation of the Data and Safety Monitoring Board (DSMB). This randomized (1:1), open-label, phase 2 study (AB20001) is designed to evaluate the safety and efficacy of masitinib plus isoquercetin in hospitalised patients with moderate COVID-19 (WHO 7-point ordinal scale level 4) or severe COVID-19 (level 5). The study is planned to recruit 200 patients (over 18 years of age with no upper age limit). The primary objective is to improve the clinical status of patients after 15 days of treatment, as measured by the WHO 7-point ordinal scale.

The interim analysis was conducted with one third of the patients evaluated, as planned. The purpose of the interim analysis was to assess the safety and efficacy of the treatment. The DSMB recommends continuing the study without restrictions in moderate patients (level 4, i.e. hospitalized patients with oxygen supply <6 L/min with SpO2 maintained  $\geq 92\%$ ). In line with this recommendation, AB Science has made the decision to continue the study only in moderate patients. The study is therefore now planned to include 200 patients at level 4 of the ordinal scale.

AB Science also announced the continuation of the second Phase 2 study evaluating the antiviral activity of masitinib in patients who have a confirmed diagnosis of COVID-19, following the recommendation of the Data and Safety Monitoring Board (DSMB). This randomized (1:1), double-blind, phase 2 study (AB21002) in 78 patients, is designed to evaluate the anti-viral efficacy of masitinib in non-hospitalized patients who are at risk of developing severe COVID-19 and in hospitalized patients with need of oxygen (via face mask or nasal cannula).

The analysis was to assess the safety of the treatment and was based on the first 50% of the patient targeted recruitment. The DSMB indicated that there was no safety concern and recommended continuation of the study without restrictions.

## **CONSOLIDATED FINANCIAL INFORMATION FOR THE FIRST HALF OF 2022**

The operating loss as of June 30, 2022 was 9,562 K€, compared to a loss of 6,040 K€ as of June 30, 2021, i.e. an increase in the operating loss of 3,522 K€ (58.3%).

- Operating income, exclusively made up of sales related to the operation of a veterinary medicine, amounted to 629 K€ as of June 30, 2022 compared to 818 K€ one year earlier
- Operating expenses amounted to 10,192 K€ as of June 30, 2022, compared to 6,858 K€ as of June 30, 2021, an increase of 48.6%.
- Marketing expenses increased by 7.2% from 236 K€ as of June 30, 2021 to 253 K€ as of June 30, 2022.
- Administrative expenses increased by 26.9%, from 1,326 K€ as of June 30, 2021 to 1,682 K€ as of June 30, 2022.
- Research and development expenses increased by 2,800 K€, i.e. 52.8 %, from 5,299 K€ as of June 30, 2021 to 8,099 K€ as of June 30, 2022. This variation is mainly explained by:
  - o the decrease in the research tax credit (600 K€), due to the end of the doubling of subcontracting expenses to public research laboratories in the calculation of the research tax credit base from 2022,
  - o the recognition at 30 June 2021 of income related to the cancellation of old accounts payable (860 K€), and
  - o the recognition on 30 June 2022 of the valuation of warrants (414 K€)

The financial income as of June 30, 2022 is a gain of 2,424 K€ compared to a loss of 1,386 K€ one year earlier. The gain of 2,424 K€ as of 30 June 2022 is mainly related to the recognition of the change in fair value between 31 December 2021 and 30 June 2022 of the preference shares resulting from the

conversion of the bonds in December 2016 (class C) and of the preference shares issued in September 2020 (class D), i.e. a financial gain of 2,244 K€ with no impact on cash over the period.

The net loss as of June 30, 2022 amounts to 7,141 K€ compared to a loss of 4,655 K€ as of June 30, 2021.

The following table summarizes the consolidated financial statements for the first half of 2022 prepared in accordance with IFRS, and comparative information with the first half of 2021:

<i>In thousands of euros, except for share data</i>	30/06/2022	30/06/2021
<b>Net turnover</b>	<b>629</b>	<b>818</b>
Cost of sales and marketing expenses	(158)	3
Marketing expenses	(253)	(236)
Administrative expenses	(1,682)	(1,326)
Research and development expenses	(8,099)	(5,299)
<b>Operating income</b>	<b>(9,562)</b>	<b>(6,040)</b>
Financial income	3,847	1,469
Financier expenses	(1,423)	(83)
<b>Financial income</b>	<b>2,424</b>	<b>1,386</b>
<b>Net income</b>	<b>(7,141)</b>	<b>(4,655)</b>
<b>Other comprehensive income for the period net of tax</b>	<b>174</b>	<b>184</b>
<b>Total comprehensive income for the period</b>	<b>(6,967)</b>	<b>(4,470)</b>
Basic earnings per share - in euros	(0.15)	(0.10)
Diluted earnings per share - in euros	(0.15)	(0.10)

<i>In thousands of euros</i>	30/06/2022	31/12/2021
Cash and cash equivalents	7,643	8,721
<b>Total Assets</b>	<b>21,585</b>	<b>21,271</b>
Equity	(29,530)	(23,198)
Non-current liabilities	31,949	26,986
Trade payables	12,733	11,368
Current liabilities	19,166	17,482

## **OTHER CORPORATE INFORMATION FOR THE FIRST HALF OF 2022 AND SINCE JUNE 30, 2022**

### **Financing of USD 8.5 million through the issuance of bonds with attached warrants**

AB Science reached an agreement with a historical investor on a financing of USD 8.5 million through the issuance of bonds convertible into new ordinary shares with attached warrants (OCABSA).

50,000 OCABSA will be issued, representing a nominal value of USD 8.5 million. It will reinforce the cash position of AB Science for the development of its clinical research program.

50,000 convertible bonds will be issued at their par value of USD 170,0 each (the "PV"), representing a total par value of USD 8.5 million.

### **Decision of the Enforcement Committee of the French market regulator (AMF) following the investigation relating to the financial information and the market for AB Science shares, opened in September 2017**

On March 24, 2022, the AMF Enforcement Committee ruled that there was no privileged information, neither at the time of the two capital increases carried out by AB Science on March 24 and 27, 2017, nor at the time Alain Moussy sold a part of his shares on March 31, 2017. The AMF Enforcement Committee therefore completely exonerated Alain Moussy, prosecuted for insider trading, and found that AB Science had not failed to comply with its disclosure obligations at the time of these capital increases in March 2017.

The AMF Enforcement Committee nevertheless considered that AB Science should have communicated as early as April 7, 2017 the high probability of a negative opinion from the European Medicine Agency (EMA) on the marketing authorization application for masitinib for the treatment of mastocytosis and ordered AB Science to pay the sum of one million euros.

In application of its internal procedures, AB Science had nevertheless put in place a deferral of privileged information from this date of April 7, 2017, considering that the delay in communication was in the interest of the Company and in line with industry practices of not communicating before the final vote of the CHMP, or else withdrawing the registration dossier, which AB Science had no intention to do.

Given this difference in assessment concerning a technical point relating to one of the criteria for the deferred communication of privileged information, as well as the amount of penalty, AB Science has decided to appeal to the Paris Court of Appeal. The President of AMF also appealed against the Enforcement Committee's decision.

### **Other events**

- Considerations arising from the Russia-Ukraine war

Russia launched invasion of Ukraine in February 2022, which, alongside humanitarian concerns, may also have an impact on the health research ecosystem in the form of delays in the conduct of clinical trials. At the date of publication of the December 31, 2021 annual report, there were no significant delays or impacts on the studies monitored in Russia and Ukraine.

- Other securities transactions

During the first half of 2022, 56,990 share subscription warrants and 5,000 stock-options were granted.

- Other information

AB Science confirms its eligibility for PEA-PME (a share savings plan aimed at providing finance to SMEs) in accordance with decree no. 2014-283 of 4 March 2014 taken for the application of article 70 of law no. 2013-1278 of 29 December 2013 of finance for 2014 fixing the eligibility of companies for PEA-PME, i.e. less than 5,000 employees on the one hand, an annual turnover of less than 1,500 million euros or a total balance sheet of less than 2,000 million euros, on the other hand.

### **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.

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