



## PRESS RELEASE

### **AB SCIENCE PRESENTS ITS FINANCIAL INFORMATION AS OF DECEMBER 31, 2021 AND THE KEY EVENTS OF THE PERIOD**

#### ▪ **Clinical development**

- Authorization by Health Canada to file a New Drug Submission for masitinib in the treatment of amyotrophic lateral sclerosis under the NOC/c policy
- Publication of new long-term data showing that masitinib extended survival in amyotrophic lateral sclerosis by 25 months, provided that treatment starts early in disease course
- Continuation of the development program in Covid-19 and recommendation without restriction of the Data and Safety Monitoring Board to continue study AB20001 for hospitalized moderate patients
- Launch of a confirmatory Phase 3 study with masitinib in progressive forms of multiple sclerosis
- Positive results of the Phase 3 study with masitinib in prostate cancer
- Validation by Health Authorities of a new risk management plan for masitinib
- Launch of a Phase 2 study with masitinib in patients with severe mast cell activation syndrome (MCAS)
- Launch of a new proprietary compound (AB8939) in clinical phase with the launch of a Phase 1/2 study in acute myeloid leukaemia

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

- Operating loss of €13.8 million, a 6.4% reduction in expenses as compared to 2020
- Cash position of €8.7 million as of 31 December 2021, plus the €7.5 million financing signed in February 2022 and the €7.1 million of 2020 and 2021 tax credit
- €6.0 million financing in the form of a state-guaranteed loan (PGE)
- EIB loan of €15 million undrawn in 2021 and continuing in 2022
- Agreement with historical shareholders and implementation of a joint strategy to increase the value of masitinib including financing for 12 to potentially 36 months and search for a licensing agreement
- Decision of the Enforcement Committee of the French market regulator (AMF) to consider that there was no privileged information at the time of the capital increases and at the time of the sale of shares by its CEO in March 2017
- AB Science's decision to appeal the decision of the AMF Enforcement Committee for deferring privileged information in April 2017
- Changes in the Board of Directors

Paris, 29 April 2022, 6.30pm CET

**AB Science SA** (Euronext - FR0010557264 - AB) today reports its revenues for the year 2021 and provides an update on its activities.

## **CLINICAL DEVELOPMENT KEY EVENTS DURING THE YEAR 2021 AND SINCE DECEMBER 31, 2021**

### **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.

### **Publication of new long-term data showing that masitinib extended survival in amyotrophic lateral sclerosis by 25 months, provided that treatment starts early in disease course**

The survival analysis followed all patients originally randomized in study AB10015 for an average duration of 75 months from the date of diagnosis. In ALS patients with mild or moderate disease severity at baseline, it was seen that treatment with 4.5 mg/kg/day masitinib as an add-on to standard riluzole prolonged survival by 25 months relative to those treated with riluzole alone, with a 44% reduced risk of death. Patients with mild or moderate disease severity correspond closely to the patient cohort enrolled in confirmatory phase 3 study, AB19001.

This new survival data has been published in the peer-reviewed journal *Therapeutic Advances in Neurological Disorders*.

### **Continuation of the development program in Covid-19 and recommendation without restriction of the Data and Safety Monitoring Board to continue study AB20001 for hospitalized moderate patients**

AB Science has initiated the continuation of a development program in the treatment of Covid-19, with on the one hand a non-clinical part, with the signing of an exclusive license agreement with the University of Chicago to carry out research on the prevention and treatment of humans infected with nidoviruses, coronaviruses and picornaviruses, and on the other hand the initiation of a second phase 2 study in the treatment of Covid-19.

The Phase 2 study (AB21002) evaluates the antiviral efficacy of masitinib at 3 different dosages, administered as an add-on to best supportive care, with respect to placebo plus best supportive care. The study is planned to recruit 78 patients (over 18 years of age with no upper age limit). The primary efficacy objective will be to demonstrate that masitinib can reduce the viral load of SARS-CoV-2 (the virus responsible for COVID-19) faster than a placebo control group, which will receive best supportive care. The population of study AB21002 therefore targets ambulatory (non-hospitalized) patients with mild disease or hospitalized patients without requirement for non-invasive ventilation (a score of 4 and 5 on the WHO clinical progression scale for COVID-19).

A second randomized (1:1), open-label, phase 2 study (AB20001) is ongoing and evaluates 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 is planned to recruit 200 patients (over 18 years of age with no upper age limit). The Data and Safety Monitoring Board (DSMB) recommended without restriction to continue the study in hospitalized patients with moderate oxygen requirements. In line with this recommendation, AB Science has made the decision to continue the study in moderate patients only. The study is therefore now planned to include 200 patients with score of 4 on the WHO clinical progression scale.

### **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. Results from that study were presented during the 8th Joint Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) – European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Meeting (MSVirtual2020). The 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 results of Phase 3 clinical study with masitinib in Prostate Cancer**

Masitinib Phase 3 study (AB12003) in metastatic castrate-resistant prostate cancer (mCRPC) eligible to chemotherapy met its predefined primary endpoint. The study results were presented at the American Urological Association (AUA) 2021 Annual Meeting, held on September 10-13, 2021.

### **Validation by Health Authorities of a new risk management plan for masitinib**

In July 21, AB Science announced the resumption of patient enrollment in its ongoing studies. This resumption follows the decision in June 2021 to voluntarily suspend the inclusion of new patients in clinical studies with masitinib after the detection of a potential risk of ischemic heart disease with masitinib. AB Science implemented a risk management plan to reinforce patient safety, which allowed the resumption of patient enrollment.

### **Launch of a Phase 2 study with masitinib in patients with severe mast cell activation syndrome (MCAS)**

AB Science announced that its Phase 2 study with masitinib in patients with mast cell activation syndrome (MCAS) has been approved by the U.S. Food and Drug Administration (FDA).

The study will enroll 60 patients from numerous study centers. The treatment objective in severe MCAS is to reduce symptoms (pruritus, flush, depression) and improve impaired quality-of-life.

MCAS is a disease caused by inappropriate activation of mast cells, which can lead to mast cell mediator release symptoms with a severity ranging from mild to life-threatening.

Because masitinib has been designed to be a potent inhibitor of mast cell activation (through its action against wild-type c-Kit, Lyn and Fyn tyrosine kinases), it is uniquely well-suited for the treatment of severe MCAS, unlike other c-Kit tyrosine kinase inhibitors that typically target specific c-Kit mutations that are associated with systemic mastocytosis.

The study was also approved by the French agency in January 2022.

### **Launch of a Phase 1/2 study with AB8939 in acute myeloid leukemia**

AB Science announced that its clinical trial with AB8939 in adult patients with relapsed/refractory acute myeloid leukemia (AML) has been approved by Health Canada.

AB8939 is a new generation synthetic microtubule destabilizer with the ability to overcome multidrug resistance and the potential for broad applicability as a potent anticancer drug.

The therapeutic potential of AB8939 has been demonstrated by preclinical results. *In vivo* data in a mouse model showed that AB8939, administered alone or in combination with Ara-C, increased survival compared to Ara-C alone.

AB8939 was entirely discovered by the laboratories of AB Science, which retains full ownership of intellectual rights, and is an example of AB Science's focus on innovative drug development focused on improving patients' lives.

### **CONSOLIDATED FINANCIAL INFORMATION FOR THE YEAR 2021**

The operating loss as of 31 December 2021 corresponds to a loss of €13,808K, compared to a loss of €14,749K as of 31 December 2020, i.e. a decrease in the operating loss of €941K (6.4%).

- Operating income, exclusively made up of sales related to the operation of a veterinary medicine, was stable compared to 31 December 2020 and amounted to €1,607K.
- Operating expenses amounted to €15,415K as of 31 December 2021 compared to €16,332K as of 31 December 2020, a decrease of 5.6%.
- Marketing expenses amounted to €493K as of 31 December 2021 compared to €781K as of 31 December 2020, a decrease of 36.9%.
- Administrative expenses increased by 35.48%, from €2,641K as of 31 December 2020 to €3,578K as of 31 December 2021. This increase is mainly due to the recognition of a provision relating to a penalty from the French Market Regulator of €1 million.
- Research and development expenses decreased by 12.5% compared to 31 December 2020 (€12,841K as of 31 December 2020 versus €11,233K as of 31 December 2021). This variation is explained by the end of a number of studies where masitinib is being developed, which has led to a decrease in clinical costs (clinical partners, hospitals, laboratories, etc.).

The financial result as of 31 December 2021 is a loss of €618K compared to a loss of €289K a year earlier. The loss of €618K is mainly due to the recognition of the discounting of conditional advances (representing a loss of €1,262K) and the change in fair value of financial liabilities (gain of €703K). These effects generate non-recurring and non-cash results.

The net loss as of 31 December 2021 was €14,463K compared to €15,045K as of 31 December 2020.

The following table summarizes the consolidated financial statements for the year 2021 prepared in accordance with IFRS, and comparative information with the year 2020:

<i>In thousands of euros, except for share data</i>	<b>31/12/2021</b>	<b>31/12/2020</b>
<b>Net turnover</b>	<b>1,607</b>	<b>1,583</b>
Cost of sales and marketing expenses	(111)	(69)
Marketing expenses	(493)	(781)
Administrative expenses	(3,578)	(2,641)
Research and development expenses	(11,233)	(12,841)
<b>Operating income</b>	<b>(13,808)</b>	<b>(14,749)</b>
Financial income	887	698
Financier expenses	(1,506)	(986)
<b>Financial income</b>	<b>(618)</b>	<b>(289)</b>
<b>Net income</b>	<b>(14,463)</b>	<b>(15,045)</b>
<b>Other comprehensive income for the period net of tax</b>	<b>274</b>	<b>(332)</b>
<b>Total comprehensive income for the period</b>	<b>(14,189)</b>	<b>(15,378)</b>
Basic earnings per share - in euros	(0.30)	(0.34)
Diluted earnings per share - in euros	(0.30)	(0.34)

<i>In thousands of euros</i>	<b>31/12/2021</b>	<b>31/12/2020</b>
Cash and cash equivalents	8,721	20,660
<b>Total Assets</b>	<b>21,271</b>	<b>29,688</b>
Equity	(23,198)	(19,549)
Non-current liabilities	26,986	26,650
Trade payables	11,368	13,286
Current liabilities	17,482	22,587

## **OTHER CORPORATE INFORMATION FOR YEAR 2021 AND SINCE DECEMBER 31, 2021**

### **State-guaranteed loan (PGE)**

AB Science has obtained in March and April 2021 the agreement of Société Générale, Bpifrance and Banque Populaire for a total of 6 million euros in financing in the form of a state-guaranteed loan (PGE - *prêt garanti par l'État*), in the context of the COVID-19 pandemic.

Each bank provided a loan of 2 million euros. This loan is 90% guaranteed by the French State, with an initial maturity of 12 months and an extension option of up to five years, exercisable by AB Science.

### **Agreement with historical shareholders and implementation of a joint strategy to increase the value of masitinib including financing for 12 to potentially 36 months and search for a licensing agreement**

AB Science announced that it has signed an agreement with historical shareholders to implement a joint strategy to increase the value of masitinib. Under this agreement, these historical shareholders, representing today 8.7% of the company's share capital, undertake to act in concert with the founding shareholders of AB Science in order to:

- study strategies to optimize the value of masitinib, in particular in the context of a potential strategic alliance with one or several pharmaceutical company(ies) for the clinical development and commercialization of masitinib in one or more major indication(s), and/or in one or more major region(s); and
- study the opportunity of listing AB Science on a foreign market, in particular the NASDAQ (through an American Depository Receipts program).

The agreement will be implemented subject to the condition of obtaining a final exemption decision from the French Autorité des Marchés Financiers, free and clear of any appeal, confirming that there is no need for a public offer.

This agreement also includes the signature of a firm financing option for an amount of €25 million over the next 12 months, at the initiative of AB Science. These financings will have to be carried out within the framework of the "private placement" or "capital increase reserved for categories of persons" resolutions that are currently in place. With this agreement, AB Science's financial visibility is extended

beyond 24 months. This funding commitment may be increased by an additional 50 million euros, at the rate of 25 million euros per year from the first anniversary date, subject to a clause of absence of significantly unfavorable event.

Finally, this agreement includes a lock-up by certain minority shareholders on 1.8 million shares for a period of three years (or until the implementation of the value enhancement strategy if this occurs before the end of the three-year period).

### **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 2021**

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. In accordance with Article R. 621-44 of the Monetary and Financial Code, this appeal must be lodged within two months of notification of the AMF Enforcement Committee's decision, i.e. by 31 May 2022.

### **Changes in the Board of Directors**

AB Science has announced the reorganization of its Board of Directors with the co-optation of four new independent directors, Cécile de Guillebon, replacing Nathalie Riez, Catherine Johnston-Roussillon, replacing Emmanuel Mourey, Guillemette Latscha, replacing Béatrice Bihr, and Renaud Sassi, replacing Jean-Pierre Kinet.

### **Shareholders' agreements expiring in 2021**

Some agreements expire in 2021. All these agreements are described in chapter 8.5 of the annual financial report as of December 31, 2021.

### **Other events**

- Other securities transactions

During the year 2021, 138, 000 stocks options and 1,921,845 share subscription warrants were granted.

- Other information
  - ✓ Covid-19 pandemic

In 2021, the COVID-19 pandemic had a very limited impact on AB Science's clinical development program, as this crisis occurred at a time when most of AB Science's clinical studies were completed and confirmatory studies had not yet started.

The integrity of the study data is not affected by the pandemic. No treatment interruptions or deaths due to COVID-19 have been observed.

At the employee level, the activity of all employees was maintained in 2021.

- ✓ 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.

- ✓ PEA-PME eligibility

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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