Paris, May 15 2017, 6pm

Following ANSM decision requesting temporary suspension of masitinib clinical studies in France

Summary of the conference call held on May 12, 2017

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), provides the summary of the questions and answers of both conference calls held on May 12, 2017, following ANSM decision requesting suspension of masitinib clinical studies conducted in France by AB Science, until their compliance is confirmed by an external audit.

ANSM decision is related to an implementation problem and does not question the fundamentals of the masitinib clinical results or the fundamentals of its development.

1 – Questions and answers related to Good Clinical Practice (GCP) compliance of clinical studies and pharmacovigilance system deviations

The ANSM decision follows the findings of the inspection that was carried out as part of the procedure for the marketing authorization of masitinib in mastocytosis, which showed GCP deviations in the conduct of the mastocytosis pivotal study (AB06006) and deviations related to the pharmacovigilance system.
AB Science indicated that:

- The EMA inspection focused on study AB06006 conducted between 2009 and the beginning of 2015 and does not therefore reflect the quality system put into place since mid-2015. Indeed, since mid-2015, the company has implemented a new quality system to ensure compliance with the GCP requirements.
- All the deficiencies identified in the pharmacovigilance system have been corrected following the inspection and the pharmacovigilance system currently in place is now GCP compliant.

AB Science proposed to ANSM an action plan to demonstrate that the deviations have been corrected. This action plan is based on the implementation of independent audits in order to provide the ANSM with confirmation that the quality system is BPC compliant. Additionally to the audits, the investigator brochure will be updated on the basis of the latest safety data (2017 Investigator Brochure) and will integrate the full safety data remonitoring for all studies and will confirm that masitinib safety profile is acceptable (see section 2).

ANSM validated this action plan. AB Science knows how to respond to ANSM's request. There is therefore no uncertainty about the actions to be taken to restart studies in France. AB Science is not in the situation where the benefit balance of masitinib is questioned, but is facing an implementation problem, with steps for its resolution clearly identified. The company is therefore confident about the prospect of being authorized to restart the studies in France within a reasonable period of a few months.

<u>What is the duration of the planned independent audits?</u>

As decided by AB Science, external audits of the different systems ensuring data quality will be initiated in May and will last for a few months. The ANSM accepted the principle of restarting the clinical studies on the basis on findings from these independent audits. Two different audits are planned:

- an audit of quality systems, starting with the pharmacovigilance system
- an audit of the clinical sites, starting with the mastocytosis and ALS clinical sites for which registration dossier is ongoing in both indications

Why AB Science did not perform these audit before?

Since mid-2015, AB Science implemented a new quality system to comply with the GCP requirements, with a priority focus on collection and remonitoring of all safety data and key efficacy data. AB Science also corrected the deficiencies in the pharmacovigilance system, which is now GCP compliant according to AB Science.

An independent audit plan will now be launched as soon as possible.

AB Science recognizes that these external audits should have been carried out previously, in order to ensure the GCP compliance of the quality system and clinical data reliability.

What do you mean by data «remonitoring»?

The data «remonitoring» consists in reconciling the data of the patient's medical record - the source data - and the data entered in the case report form by the hospital staff. The objective is therefore to check the completeness and the accuracy of the efficacy and safety data collected in the clinical studies.

Does ANSM decision seem exaggerated or fully justified? Is this a political decision?

AB Science does not want to comment on reasons for the ANSM decision. AB Science is actively collaborating with ANSM and focus on the implementation of the proposed action plan.

The following points can be emphasized:
- ANSM is known to be a conservative agency.
- AB Science's strategy of developing masitinib in a large number of indications and without licensing agreement implies increased vigilance and expectations from health authorities. AB Science indicates that approximately 30 inspections were carried out on the masitinib product alone in 10 years.

AB Science does not consider this decision to be political. The reasons are related to quality procedure deviations from AB Science, the product benefit is not questioned.

Why was the ANSM decision only made now?

The ANSM decision follows the findings of an inspection that was carried out recently as part of the procedure for the marketing authorization of masitinib in mastocytosis.

How did AB Science come to such a deadlock? How can AB Science rebuild its credibility?

For AB Science this is not a deadlock, but a temporary decision that will be lifted following positive results of the audit plan.
AB Science implemented an action plan validated with ANSM to cancel the suspension:
- The immediate launch of two independent audits of quality systems and clinical sites in order to demonstrate that the quality system is GCP compliant and that collected data are reliable.
- The release of 2017 investigator brochure, which will integrate the data remonitoring of all safety data for all studies and will confirm that masitinib safety profile is acceptable (see section 2).

The quality system upgrade to GCP requirements has already been done. This upgrade must now be demonstrated by an external audit.

In addition, the two phase 3 studies in mastocytosis and ALS are positive. In ALS, the results will be presented this week at the ENCALS annual meeting in Ljubiana, Slovenia. The next step will be the EMA's decision related to masitinib registration in ALS, expected by the end of 2017. AB Science indicates that a competing product was recently approved by the FDA, following a study with a fewer patients and a lower functional score improvement compared with masitinib, allowing AB Science to hope for a favorable CHMP vote in ALS, on the basis of a GCP compliant quality system. In addition, 50,000 patients signed a petition in the United States requesting the registration of masitinib in ALS as soon as possible.

What are the expected delays on the ongoing programs?

AB Science would like to highlight that this decision applies in France only. AB Science's studies continue in more than 25 countries, which are not affected by the decision. In France, studies are not prohibited, only suspended. Moreover, this suspension has a low impact on the conduct of AB Science studies, since:

- France accounts for less than 5% of patient recruitment in the ongoing studies
- Patients who could be discontinued account for less than 1% of the number of patients to be recruited in phase 3 studies

The impact is therefore limited, especially because AB Science believes a resumption of recruitment on the basis of the conclusions of the external audit can be achieved within a reasonable period of a few months.

Will other national agencies revise their position and follow the ANSM's decision?

To date, AB Science did not receive any notification from another agency requesting the suspension of studies. In addition, AB Science informed all European health agencies about:

- The findings observed in the EMA inspection in mastocytosis
- The correction of these deviations, with the implementation of a new GCP compliant quality system
- The launch of an independent audit of both systems and clinical sites to demonstrate that the system is GCP compliant
- The release in the coming months of the 2017 investigator brochure including the full remonitoring of efficacy and safety data for the studies

To date, AB Science does not know what the position of the other agencies will be following the EMA inspection. It should be noted that in the past, ANSM decisions have not always been followed by other agencies, which remain independent.

In the case other European agencies would suspend the clinical studies, it should be noted that the clinical studies of masitinib are conducted in Western Europe, North America, Latin America, Eastern Europe, Asia, North Africa, South Africa and the Middle East. The development of masitinib is therefore not dependent on a particular geographical area and even less on a country.

2- Questions and answers related to reliability of safety and efficacy data

Data collected in clinical studies are not invalidated or lost.

- Following the implementation of the new quality system in mid-2015, the data collected after this date are reliable. This has been confirmed by the 11 site inspections carried out by national health authorities outside France, with no unreported serious or severe adverse event. The Canadian Health Authority concluded that the ALS study is conducted under GCP compliance.
- The data prior to mid-2015 have been remonitored. This remonitoring of all studies concerned key efficacy data and adverse events. This full remonitoring was performed between mid-2015 and November 2016 for all studies except mastocytosis and following EMA inspection between January

2017 and March 2017 for mastocytosis study. The sustained efforts made since 2015 to reassess all pre-2015 safety data allows us to state with a high level of confidence that all adverse drug reactions have been collected and assessed and that the safety profile of masitinib is not modified following this remonitoring.

The 2017 investigator brochure, which will include data remonitoring, will be sent to the health authorities in the coming months.

We already know that the collected and remonitored data do not change the masitinib safety profile.

In addition, independent audits of data quality for key efficacy endpoints and adverse effects in mastocytosis and ALS are conducted to ensure their reliability and to secure registration in both indications.

In summary, no efficacy and safety data have been lost. No study is irreversibly damaged. The safety profile of masitinib is not modified after this full remonitoring.

Have side effects been hidden or underestimated?

The efficacy and safety data remonitoring showed that masitinib safety profile has not been modified since the adverse events which had not been correctly reported were for their overwhelming majority mild or moderate adverse events. In the mastocytosis study, only four severe adverse events had not been reported: one peripheral edema in the masitinib arm and three severe adverse events in the placebo arm.

The 2017 investigator brochure, which will include data remonitoring, will be sent to the ANSM and health authorities in the coming months.

In its letter, ANSM notified that there were several deviations on inclusion and exclusion criteria. Is this problem fixed? Additionally, ANSM highlighted many protocol deviations that could have impacted the outcome on the primary endpoint, what do you think they refer to?

In its letter, the ANSM refers to several inspections, some of which date back to 2006. The findings related to inclusion and exclusion criteria do not concern mastocytosis and ALS studies and have been resolved.

Protocol deviations that could have impacted the outcome on the primary endpoint are related to clinical batches records, including treatment number correspondence lists that have been received by AB Science's Pharmaceutical Operations department in preparation for an inspection, without AB Science being informed of the presence of these lists, and discovered during EMA inspection. These lists only concern a very small number of the patients included in the mastocytosis study and have no impact on other studies, including the ALS study. Regarding the mastocytosis study, the inspection showed that no modification of the protocol had occurred after the receipt of these lists and showed no use of these lists before unblinding.

What studies will have to be redone to comply with the requirements of the ANSM?

Clinical studies are not to be redone. AB Science must provide evidence to the ANSM that the quality system is now GCP compliant. This is why AB Science proposed to conduct an independent audit of systems and clinical sites to demonstrate this. The ANSM accepted the principle of restarting clinical studies on the basis of the conduct of this independent audit. In addition, AB Science indicates that the efficacy and safety data remonitoring was carried out for all studies between mid-2015 and March 2017. The upcoming audit will confirm the reliability of these data.

3- Questions and answers related to masitinib safety data

AB Science's position diverges from ANSM's position on this question. AB Science also notes that in its letter, ANSM conditions the restart of studies to GCP compliance confirmation, and not to a masitinib safety profile reassessment.

Masitinib adverse events published by The Lancet do not correspond with ANSM's position. Why?

AB Science does not agree with ANSM's position regarding masitinib safety profile and reiterates that the masitinib safety profile has been assessed as acceptable in all ongoing indications by the Independent Data Monitoring Committees (IDMC) of the studies, which have access to unblinded data, as well as by health agencies of more than 25 countries where masitinib is currently developed, and finally by the ethics committees which have authorized the studies.

Regarding masitinib risks analysis, AB Science confirms the following:

- Risk of severe skin toxicity has been reduced since the implementation of the new risk management plan in 2012. Moreover, the suspected Stevens Johnson syndrome cases have been reviewed by two independent experts and no case of Stevens Johnson syndrome have occurred on the 3500 recruited patients, proving the control of this risk.
- The risk of severe neutropenia was minimized by the risk management plan in 2012, around 1% and remained stable. Also, all the neutropenia are reversible as soon as the treatment is discontinued.
- Clinical risk analysis does not indicate an identified risk of death or renal toxicity or cardiac toxicity. A follow-up on 250 patients of the left ventricular ejection fraction showed no risk increase. Similarly, a QT/QTc study did not show an increase in this risk.
- Finally, the carcinogenic risk observed in non-clinical studies in animals was evaluated in detail by the EMA during the procedure for the marketing authorization of masitinib in mastocytosis and this assessment shows that the risk of tumors is specific to evaluated animal species and not transposable to humans. Moreover, the genotoxic risk is below the acceptable limits set in EMA guidelines for a lifetime treatment in a non-life-threatening indication.

4- Questions and answers related to ANSM decision impact on masitinib development in amyotrophic lateral sclerosis

What is the impact of ANSM's decision on registration dossiers for mastocytosis and amyotrophic lateral sclerosis (ALS)?

The CHMP vote will take place this week. Nevertheless, AB Science reiterates that efficacy and safety data remonitoring for the mastocytosis study was carried out after the EMA inspection. Therefore, the marketing authorization procedure is likely to be negatively impacted in this indication. In any case, in accordance with current practice and similarly to previous dossiers, AB Science does not communicate on the marketing authorization process for masitinib and on discussions related to this process with the health authorities before the CHMP.

Concerning the registration dossier in the ALS, there is no impact according to AB Science. The EMA inspection for this study as part of the procedure for the marketing authorization will take place in the fourth quarter of 2017, after the efficacy and safety data remonitoring, which has already been carried out and after the external audit of systems and clinical sites that will take place in the coming months and which will demonstrate the reliability of the data. Therefore, the ALS registration dossier will be more robust in terms GCP compliance.

Could the masitinib safety profile in ALS be a problem?

The masitinib safety profile in systemic indolent mastocytosis is acceptable. Masitinib's safety profile can only be more acceptable in ALS, which is a life-threatening disease. In addition, due to a lower masitinib dose in the ALS study, the masitinib safety profile should be better in the ALS study and highly acceptable for EMA.

Masitinib safety data in ALS will be presented at ENCALS this week (European Network for the Cure of ALS).

Since ALS is a life-threatening disease like GIST or pancreatic cancer, how GCP compliance had been evaluated by CHMP in these two dossiers?

There was no GCP finding in the masitinib registration dossier in pancreatic cancer, although the masitinib marketing authorization filing in pancreatic cancer occurred before the new quality system implementation in mid-2015.

GCP deviations were observed in the GIST registration dossier. A data remonitoring was therefore carried out by AB Science and finally EMA did not object on GCP compliance in GIST.

5- Other questions and answers

For how long the stock market trading will be suspended?

Stock market trading recovery is planned on Tuesday 16 May at the opening. AB Science decided to suspend the stock market trading for two days (Friday May 12, 2017 and Monday May 15, 2017) in order to provide the necessary explanations to all shareholders, following the ANSM decision.

Can you extend the stock market trading suspension until CHMP decision, the clarification of the situation with ANSM, or at least the availability of the external audit conclusions?

This is not desirable to suspend the stock market trading for several weeks or months. The stock market trading recovery is scheduled for Tuesday, May 16. AB Science believes that the necessary clarifications will have been provided to shareholders in the meantime.

Why was this information given before the markets closed?

The ANSM made public its decision on its website on Thursday May 11, 2017 at 5pm, without having previously informed AB Science. AB Science was surprised by this decision of the agency and therefore issued a press release on Friday May 12, 2017 at 3 am to explain its position.

In view of the current situation, is it possible to have details about the recent sale of shares by Alain Moussy?

The sale of Alain Moussy's shares took place on March 31, 2017. This sale followed the announcement of positive results in amyotrophic lateral sclerosis, which allowed Alain Moussy to find a buyer for the sale of a block of shares, off-market. Moreover, this sale of shares was carried out with the sole purpose of repaying a maturing bank debt. This debt had been contracted in order to finance the acquisition of AB Science shares as part of stock option plans.

The ANSM letter informing of a possible decision to suspend clinical trials was received by AB Science on April 19, 2017. Alain Moussy was therefore not aware of the ANSM intentions at the time of the sale of the shares.

With these new delays, will you have new needs of cash in the coming months?

The company recently raised 34 million euros through private placements, before knowing ANSM intentions to suspend clinical studies in France. As of March 31, 2017, AB Science had a cash position of 58.5 million euros, sufficient to continue the development of masitinib. AB Science does not need additional cash in the short term.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases, and in certain diseases of the central nervous system. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and microglia and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these diseases.

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 in cancers, inflammatory diseases, and central nervous system diseases, both in humans and animal health.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA. The company is currently pursuing thirteen phase 3 studies in human medicine in metastatic prostate cancer, metastatic pancreatic cancer, relapsing metastatic colorectal cancer, relapsing metastatic ovarian cancer, GIST, metastatic melanoma expressing JM mutation of c-Kit, relapsing T-cell lymphoma, severe asthma, amyotrophic lateral sclerosis, Alzheimer's disease and progressive forms of multiple sclerosis. 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

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