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AB Science outlook for 2019 - Summary of webcast part 2

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), is providing a summary of the web conference held on June 5, 2019 on its clinical programs outside of amyotrophic lateral sclerosis and mastocytosis.

Severe asthma

- Rationale

The development of masitinib in asthma is based on the targeting of mast cells [1 ;2 ;3;4].

- Clinical development program

The clinical development program in asthma is comprised of one proof of concept study [5], one pivotal study in severe asthma uncontrolled by oral corticosteroids (OCS), and one pivotal study in severe asthma uncontrolled by inhaled corticosteroids (ICS).

The first phase 2/3 (study AB07015) is evaluating masitinib at the dose of 6.0 mg/kg/day in patients treated with severe asthma uncontrolled with high dose of OCS. IDMC reviewed safety data every six months and always recommended the continuation of the study based on review of safety data. Based on interim analysis, IDMC recommended the continuation of study AB07015 with no requirement to increase the study sample size. This recommendation from the IDMC means that the probability of success of the study is above 80%, assuming that the patients enrolled after the interim analysis behave similarly to those analyzed at the interim analysis. The next step for this study is the final read-out, which is expected in Q3 2019.

The second phase 3 (study AB14001) is evaluating masitinib 6.0 mg/kg/day in patients treated with severe asthma uncontrolled with high dose of ICS and with high level of eosinophils. The next step for this study is the final read-out, which is expected in Q4 2019.

- Competitive landscape

Masitinib positioning differs from registered treatments (tyrosine kinase inhibitor, targeting of mast cells, orally administered drug, potential claim in severe asthma uncontrolled by OCS regardless of eosinophil levels).

Progressive forms of Multiple Sclerosis

- Rationale

Data show that mast cells can actively participate in the pathogenesis of multiple sclerosis, as the presence of mast cells (MCs) and increased concentration of MCs constituent have been reported in MS plaques [6].

- Clinical development program

The clinical development program in progressive forms of MS is comprised of one proof of concept study [7], and one pivotal study.

The phase 2/3 (study AB07002) is evaluating two doses of masitinib (4.5 mg/kg/day and 6.0 mg/kg/day) in patient with primary and secondary progressive MS. IDMC reviewed safety data every six months and always recommended the continuation of the study based on review of safety data. Based on interim analysis, IDMC

recommended the continuation of study AB07002 with no requirement to increase the study sample size. This recommendation from the IDMC means that the probability of success of the study is above 80%, assuming that the patients enrolled after the interim analysis behave similarly to those analyzed at the interim analysis. The next step for this study is the final read-out, which is expected in Q3 2019.

- Competitive landscape

Masitinib differentiates from registered drugs, as these drugs are not administered orally (intravenous form). There is still a need in MS for new drugs, in particular based on different mechanism of action.

Alzheimer's disease

- Rationale

The rationale for evaluating masitinib in Alzheimer's Disease is based on masitinib's targeting of mast cells and microglia via inhibition of the c-Kit, Lyn, and CSF1R kinases, and inhibition of Fyn.

- Clinical development program

The clinical development program in Alzheimer's Disease is comprised of one proof of concept study [8], and one pivotal study.

The phase 2/3 (study AB09004) is evaluating two doses of masitinib (4.5 mg/kg/day and 6.0 mg/kg/day) in patient with mild or moderate forms of Alzheimer's Disease. IDMC reviewed safety data every six months and always recommended the continuation of the study based on review of safety data. The next step for this study is an interim analysis planned in June 2019, based on 75% of patient enrolled and reaching the 6 months endpoint. Final read-out of the study is planned in Q4 2019.

- Competitive landscape

There is no approved drug given as an add-on to cholinesterase inhibitors or memantine in mild to moderate forms of Alzheimer's disease. These drugs do not compete with masitinib, which is given as an add-on to these treatments.

Metastatic Castrate Resistant Prostate Cancer (mCRPC)

- Clinical development program

The clinical development program in mCRPC is comprised of one proof of concept study, and one pivotal study.

The phase 3 (study AB12003) is evaluating masitinib at 6.0 mg/kg/day in combination with docetaxel in first line treatment of mCRPC. The primary analysis is planned in the overall study population and in a pre-specified subgroup based on biomarker (undisclosed to protect intellectual property). This targeted subgroup is estimated to account for about two-thirds of the eligible population. IDMC reviewed safety data every six months and always recommended the continuation of the study based on review of safety data. Based on the interim analysis, the IDMC recommended the continuation of the study in the pre-specified sub-population with a small resampling. This recommendation from the IDMC means that the probability of success of the study is 80% in the selected sub-population, assuming that the patients enrolled after the interim analysis behave similarly to those analyzed at the interim analysis. The next step for this study is the final read-out, which is expected in 2020.

- Competitive landscape

The only approved drug in metastatic castration resistant Prostate cancer eligible to chemotherapy is Docetaxel. Masitinib does not compete with Docetaxel as it is given in combination with this drug.

Pancreatic cancer

- Clinical development program

The clinical development program in metastatic or locally advanced pancreatic cancer is comprised of one proof of concept study [9], one phase 2/3 pivotal study [10] and one confirmatory pivotal study.

The phase 2/3 study (AB07012) enabled the identification of a subgroup based on the level of pain (marker of mast cell activation) at baseline where survival was statistically increased.

The confirmatory phase 3 (study AB12005) is evaluating masitinib 6.0 mg/kg/day in combination with gemcitabine in first line treatment of locally advanced or metastatic pancreatic cancer. IDMC reviewed safety data every six months and always recommended the continuation of the study based on review of safety data. The next step for this study is an interim analysis planned in June 2019. Final read-out of the study is planned in 2020.

- Competitive landscape

Masitinib differentiates from registered drugs (orally administered drug, less restrictive eligibility criteria).

Masitinib intellectual Property Status

Masitinib IP rights are secured up to 2031 in progressive forms of MS, until 2032 in severe asthma, and 2033 in pancreatic cancer.

Protection	Item	Duration of protection	Status
Patent on composition of matter and PTE	Patent on composition of matter has been filed and delivered. It will be further extended until 2028 through patent term extension (PTE)	Until 2028	Delivered
Synthesis process patent	A further protection until 2028 has been achieved through synthesis 'process' patent	Until 2028	Delivered
Orphan drug status	Masitinib has been granted orphan drug designation by both EMA and FDA for pancreatic cancer	Exclusivity of 7 years for FDA and 10 years for EMA	Delivered
Phase 3 'Method of use' patents	Asthma (severe)	Until 2032	Delivered
	Multiple sclerosis (MS)	Until 2031	Delivered
	Pancreatic cancer patients with pain	Until 2033	Delivered

AB8939

- AB8939 profile and positioning

AB8939 is a microtubule destabilizer, that is 100 times more potent than doxorubicine (the reference drug in acute myeloid leukemia). AB8939 differs from other drugs targeting microtubule as it is a synthetic drug not derived from nature and as it is not transported by Pgp protein, thereby overcoming multidrug resistance. Unlike vinca alkaloids (vincristine or vinblastine), AB8939 is not deactivated by myeloperoxidase enzyme.

AB8939 is first developed in acute myeloid leukemia since cancer cells proliferate rapidly in this disease. AB8939 has the potential to be developed in other cancers in a second step.

- Clinical development

AB Science is planning to launch a phase 1/2 study with AB8939 to investigate its tolerability and efficacy in patients with Acute Myeloid Leukemia.

References

- [1] Theoharides TC et al. The critical role of mast cells in allergy and inflammation. *Ann N Y Acad Sci.* 2006 1088:78-99.
- [2] Okayama Y et al. Role of mast cells in airway remodeling. *Curr Opin Immunol.* 2007 19(6) :687-93
- [3] Kim YS et al. *Eur J Immunol.* 2007 37(4):1107-15
- [4] Lee-fowler et al, 2012: The tyrosine kinase inhibitor masitinib blunts airway inflammation and improves associated lung mechanics in a feline model of chronic allergic asthma
- [5] Humbert et al, 2009: Masitinib, a c-kit/PDGF receptor tyrosine kinase inhibitor, improves disease control in severe corticosteroid-dependent asthmatics
- [6] Krüger et al : Mast cells and multiple sclerosis : a quantitative analysis. *Neuropathology and Applied Neurobiology.* 2001; 27:275-280
- [7] Vermersch et al. *BMC Neurology* 2012, 12:36: Masitinib treatment in patients with progressive multiple sclerosis: a randomized pilot study
- [8] Piette et al. *Alzheimer's Research & Therapy* 2011, 3:16: Masitinib as an adjunct therapy for mild-to-moderate Alzheimer's disease: a randomised, placebo-controlled phase 2 trial
- [9] Mitry et al. *Cancer Chemother Pharmacol* DOI 10.1007/s00280-010-1299-8: Safety and activity of masitinib in combination with gemcitabine in patients with advanced pancreatic cancer
- [10] Delplanque et al. *Annals of Oncology* 00: 1–7, 2015 doi:10.1093/annonc/mdv133: A randomized, placebo-controlled phase III trial of masitinib plus gemcitabine in the treatment of advanced pancreatic cancer

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.

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, and inflammatory 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 filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. 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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