



Paris, August 5 2019, 7.30am

Update on masitinib clinical program

AB Science SA (NYSE Euronext - FR0010557264 - AB) provides an update on its masitinib clinical program.

The key points of the masitinib clinical program are:

- Rationalization of the study portfolio to target key indications based on value creation selection criteria
- Further development of masitinib in seven indications, each having a global potential market size of several billion euros
- Six results of phase 3 studies expected for these indications in the next 15 months (two in Q3 2019, one in Q4 2019, three in 2020)

As part of its restructuring performed over the last 2 years, AB Science has decided to streamline its clinical masitinib portfolio in order to increase shareholder value creation.

AB Science decided to select targeted indications based on the following criteria:

- Market size
- Expected time to market
- Patent duration by indication
- Clinical need and competitive landscape
- Probability of successful clinical authorization
- Final results of phase 3 studies or interim analysis

Based on these criteria, which are key to maximize the shareholder value creation, AB Science decided to focus its masitinib clinical program on 7 indications:

- Amyotrophic lateral sclerosis:
 - o Positive phase 3 results published in the *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration* journal
 - o Launch of a confirmatory phase 3 study before end of 2019 with expected results in 2021
 - o Possible EMA filing for conditional marketing authorization in 2020
- Indolent systemic mastocytosis:
 - o Positive phase 3 results published in *The Lancet*
 - o Launch of a confirmatory phase 3 study before end of 2019 with expected results in 2021
- Severe asthma uncontrolled with oral corticosteroids and severe asthma uncontrolled with high dose of inhaled corticosteroids and with elevated eosinophil levels:
 - o Two phase 3 results expected in Q3 2019 and first half of 2020
 - o IDMC recommendation to continue the severe asthma uncontrolled with oral corticosteroids study without resampling option on 50% of patients treated
- Progressive primary and secondary multiple sclerosis:
 - o Phase 3 results expected in Q3 2019
 - o Positive interim analysis on 50% of patients treated on one of the tested doses, which measures the probability of success above 80%
- Alzheimer's disease:
 - o Phase 3 results expected in Q4 2019
 - o Positive interim analysis on 75% of patients treated on one of the tested doses, which measures the probability of success above 80%
- Pancreatic cancer in first line:

- First phase 3 study generated an efficacy hypothesis in the subpopulation of patients with pain
- Confirmatory phase 3 results expected in 2020
- Positive interim analysis of this confirmatory phase 3 study after 50% of death events, in the pre-specified subgroup of patients with pain and a non-resectable advanced tumor, which measures the probability of success above 80%
- Metastatic prostate cancer eligible to docetaxel:
 - Phase 3 results expected in 2020
 - Positive interim analysis of this phase 3 study after 50% of tumor progression events, in the pre-specified sub-population based on a biomarker flagging the metastasis progression, which measures the probability of success above 80%

The potential market size and the competitive landscape in these seven indications are as follows:

Indication	Number of patients targeted by masitinib		Registered masitinib competitors (US treatment price in US dollars)
	Europe	US	
Alzheimer's Disease	3 000 000	2 000 000	No approved drug as an add-on to cholinesterase inhibitors or memantine
Severe Asthma – ICS	900 000	600 000	<ul style="list-style-type: none"> • Omalizumab (\$11 000) • Mepolizumab (\$35 000) • Dupilumab (\$31 000) • Reslizumab (\$31 000) • Benralizumab (\$31 000)
Severe Asthma – OCS	40 000	30 000	
MS – Primary Progressive	90 000	55 000	<ul style="list-style-type: none"> • Ocrelizumab (\$65 000) • Ocrelizumab (\$65 000) • Mitoxantrone (\$1 400)
MS – Relapse-free Secondary Progressive	260 000	170 000	
Pancreatic Cancer	100 000	60 000	<ul style="list-style-type: none"> • Abraxane (\$240 000) • Erlotinib (\$6 650) • Folfirinox
Prostate Cancer	75 000	50 000	No approved drug as an add-on to docetaxel
Amyotrophic Lateral Sclerosis	30 000	20 000	<ul style="list-style-type: none"> • Edavarone (\$145 000) • Riluzole (\$1 400)
Indolent Systemic Mastocytosis	6 000	4 000	No approved drug

Based on the abovementioned selection criteria, the non-resectable or metastatic stage 3 or stage 4 melanoma program is not part of the 7 strategic priorities of masitinib's clinical program. This is because of the indication's relatively small clinical market size and because of the time needed for marketing authorization, which would require the launch of an additional phase 3 study.

This decision does not call into question the activity of masitinib in this indication in terms of tumor response, as indicated in the press release of August 2, 2019.

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.

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