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Masitinib in Mastocytosis – Summary of Web Conference

In 2015 AB Science will have readout of phase 3 in severe systemic mastocytosis, which is non futile near completion

AB Science will expand the mast cell franchise by initiating phase 3 studies in a common disease called MCAS and in pediatric mastocytosis

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), provides a summary of the key points of the web conference held on 7th November 2014 on masitinib in the treatment of mastocytosis with key opinion leaders from this disease.

The current phase 3 study in mastocytosis has been assessed in September 2014 as non futile by the Independent Data Safety and Monitoring Committee at a time when the study was close to completion. A futility analysis tests the inability of a clinical study to achieve its efficacy objective. The phase 3 read-out in severe systemic mastocytosis is expected anytime in 2015. The target population in adult patients with severe systemic mastocytosis is estimated at 10,000 in the USA and in the EU. In case of positive results, filing at both FDA and EMA would be pursued.

In order to expand the mast cell franchise that started with severe systemic mastocytosis in adults, AB Science has decided to initiate in 2015 two new phase 3 studies in Mast Cell Activation Syndrome (MCAS) and in pediatric mastocytosis.

Mastocytosis in children gives urticaria pigmentosa and is primarily due to mutations of c-Kit that are efficiently inhibited by masitinib. The target population in children with mastocytosis is estimated at 20,000 in the USA and in the EU.

MCAS targets a much broader population than mastocytosis. MCAS is a common disease caused by activation of mast cells and associated with the same symptoms as in mastocytosis, such as chronic fatigue, pain, depression, diarrhea, irritable bowel, pruritus, flush and anaphylaxis, but it affects around 5 to 10% of general population. MCAS could include part of diseases such as multiple sclerosis, Crohn's disease, inflammatory bowel disease, Duchene muscular dystrophy, chronic fatigue syndrome, when such diseases exhibit clear signs of mast cell hyperactivity (such as increased tryptase in blood, increased histamine in urine, dermographism). Because masitinib has been designed to be a potent inhibitor of mast cell activation (through its action against c-Kit, Lyn and Fyn tyrosine kinases), it is a suitable drug candidate in MCAS. As for systemic mastocytosis, MCAS symptoms can be mild, moderate, or severe. The proportion of severe forms where masitinib could be developed is unknown but the prevalence of severe forms of MCAS is estimated by experts to be up to a 100 times larger than in mastocytosis on the basis of their own clinical experience. In MCAS, the mutations of c-Kit or other genes driving the activation of mast cells are unknown but different from the ones driving mastocytosis. The phase 3 clinical study that AB Science will launch in 2015 will be used to identify those mutations.

The safety database of masitinib is adequate to support registration in mastocytosis, especially in the context of an orphan designation. Indeed, in case of filing, the safety database presented would include 250 patient enrolled in mastocytosis studies, and would exceed guideline requirements for drugs intended for long-term treatment in non-life threatening disease, with over 1,500 patients exposed to masitinib,

including over 600 patients (versus 300 required) treated for 6 months and over 300 patients (versus 100 required) treated for 12 months.

Potential objections on Manufacturing or Preclinical data have been resolved through the applications filed at EMA for GIST and pancreatic cancer.

AB Science is ideally positioned to commercialize masitinib in mastocytosis in case of registration. A network of physician specialists is already structured in Europe, with ECNM (like in GIST). Similarly a network of patients is already structured through national patient associations in the main countries, and founders of AB Science are also founders of the French patient association AFIRMM with over 2,500 patients identified. AB Science developed close relationship with patients association and Key Opinion Leaders in the past 10 years. No license has been granted so far and AB Science retains 100% of masitinib rights.

Intellectual Property for masitinib is secured in mastocytosis until 2028, potentially until 2031, and potentially until 2034 for MCAS. Patent protection on composition of matter for masitinib has been filed and delivered and will be extended until 2028 through patent term extension (PTE). A further protection until 2028 has been achieved through a synthesis process patent already granted. In addition, further protection could be obtained until 2031 for the treatment of severe systemic mastocytosis and until 2034 for treatment of MCAS, respectively through patents filed in 2011 after phase 2 results in mastocytosis and in 2014 for MCAS. A 10 year exclusivity period can be granted from the date of registration since masitinib has been granted orphan drug status in mastocytosis by both FDA and EMA. A further 6 months exclusivity can be granted in case on implementation of a pediatric investigation plan, as will be the case for masitinib in mastocytosis.

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 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 human 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 first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and Amyotrophic Lateral 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

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markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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AB Science - Financial Communication & Media Relations

investors@ab-science.com