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AB Science announces publication of a significant response case with masitinib in a patient with c-KIT-mutated metastatic melanoma

First report of brain metastases responding to masitinib

On-going phase 3 with masitinib in c-KIT-mutated metastatic melanoma will have interim analysis in 2017

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announces the publication of an article entitled "Rapid and clinically significant response to masitinib in the treatment of mucosal primary esophageal melanoma with somatic KIT exon 11 mutation involving brain metastases: A case report".

The authors present the first patient with c-Kit exon 11 mutated primary esophageal melanoma, metastasizing into visceral organs and to the brain and treated with oral tyrosine kinase inhibitor masitinib. The patient showed objective and clinical significant therapeutic response to masitinib. After initiation of masitinib, dysphagia and odynophagia disappeared within 1 week. Following 1 month of treatment, computed tomography showed a regression in the number and size of brain metastatic lesions and regression in visceral lesions. This therapeutic response, despite the aggressive disease on treatment initiation, effectively enabled the patient to have 6 months of quality life.

The authors conclude that this report corroborates the plausibility of treating advanced melanoma carrying a mutation of c-Kit with masitinib and that the observed masitinib treatment effect on the brain suggests accumulation of therapeutically relevant concentration of masitinib in the central nervous system.

The authors also remarked that this case report was noteworthy due to the observation that under circumstances of brain-blood barrier (BBB) disruption by intracranial metastases, masitinib was observed to accumulate in the central nervous system (CNS) at sufficient concentrations to exert a direct inhibitory action. This has possible ramifications for masitinib treatment of other intracranial neoplasm such as GIST and brain metastases. Moreover, because masitinib is being developed for neurodegenerative indications such as Alzheimer's disease, the prospect that it may be able to cross a disrupted BBB is of interest because it brings into play certain additional mechanisms of action.

This publication is now freely accessible online from the peer-reviewed journal Biomedical Papers of the Medical Faculty of the University Palacký and can be cited as: Prosvicova J, et al. Rapid and clinically significant response to masitinib in the treatment of mucosal primary esophageal melanoma with somatic KIT exon 11 mutation involving brain metastases: A case report. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2015 Dec; 159(4):695-697 (doi: 10.5507/bp.2015.061). The publication can currently be accessed through the journal's "Epub Early View" page:
http://biomed.papers.upol.cz/getrevsrc.php?identification=public&mag=bio&raid=1266&type=fin&ver=2

This case report provides further evidence of the potency of masitinib in tumors expressing the juxta-membrane mutation of c-Kit. Human cancers involving the juxta-membrane and pursed with masitinib include GIST and c-Kit melanoma.

On-going phase 3 will have interim analysis in 2017

A phase 3 trial (AB08026) is ongoing in patient with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a mutation in the juxta-membrane (JM) domain of c-Kit.

This form of melanoma is very rare and is estimated to account for less than 3% of melanoma patients. However, a tyrosine kinase inhibitor targeting the JM mutation of c-Kit could be highly beneficial for this population and complement current immunotherapy drugs. The study is open to applicable patients at any line of treatment, i.e. before or after treatment with immunotherapies.

Masitinib is a highly potent inhibitor of this c-Kit mutation and blocks its activity at nanomolar concentration. This mutation is also the primary oncogenic event in canine mast cell tumors, for which masitinib is already registered both by FDA and EMA, and also in GIST where masitinib is in phase 3 development.

The study plans to enroll 120 patients and was previously assessed as non-futile by the Independent Data Safety Monitoring Committee (IDMC).

The next step for this study is an interim analysis, expected in 2017 once two-thirds of the planned study population had reached the time-point to assess efficacy.

Scientific rationale is based on the inhibition of c-Kit in juxta membrane position and modulation of the innate immunity

Melanomas are not genetically or histologically homogenous and may follow different paths to oncogenic transformation. Several key molecular pathways have been implicated in melanoma pathogenesis and maintenance, suggesting an alternative way to categorize tumors based on the basis of their driving oncogenic mutations. This in turn introduces the possibility to develop/apply more targeted therapies.

BRAF and NRAS are the most frequently identified mutations and rarely coexist. Others, such as GNAQ and GNA11, are far less common. c-Kit is another oncogenic mutation that drives tumor progression and which is mutually exclusive with other mutations.

Preclinical studies have shown that, *in vitro,* masitinib potently and selectively inhibits the JM mutation of c-Kit receptor. In an *in vivo* model of tumor growth where the tumor cells expressed a murine homologue of JM-mutated c-Kit, tumor growth was observed to stabilize in mice treated with masitinib. The inhibition of tumor growth was dose-dependent and complete disappearance of the tumor could be observed.

This indicates that masitinib has a strong potential to kill JM-mutated c-Kit melanoma cells, thus increasing the prognosis of patients whose melanoma bears a JM-mutated c-Kit.

Targeted population is rare

KIT-mutant melanoma represents approximately 3% of melanomas overall.

Altogether, the prevalence of melanoma with JM-mutated c-Kit is estimated at 7,500 patients in the USA and Europe.

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 first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, T-cell lymphoma, mastocytosis, severe asthma uncontrolled by oral corticosteroid, 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 website: http://www.ab-science.com

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