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AB Science announces issuance of a new European patent for protecting the use of masitinib in pancreatic cancer patients with pain until 2033

Recruitment target before possible resampling of mastinib confirmatory study in pancreatic cancer has been reached

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced that the patent offices of Europe (EP13 773 731.8), Singapore (11201502626P) and South Africa (ZA2015/03054) have each issued a Notice of Allowance for a patent relating to methods of treating pancreatic cancer in a human patient with its lead compound masitinib. To complement patent protection in Europe, counterpart patent applications have also been filed in several major international markets including the United States.

Intellectual Property protection for masitinib is secured in pancreatic cancer until 2033. This newly issued patent further enhances the Company's key patent family for masitinib and extends protection for masitinib in this indication by 5 additional years.

More specifically, the new patent is directed to the use of masitinib in combination with gemcitabine for treatment of pancreatic cancer in a patient population selected for treatment based upon the predictor factor of disease related pain intensity. This patient population is fully consistent with the current clinical development program of masitinib in pancreatic cancer and ongoing international phase 3 randomized clinical trial (AB12005).

Masitinib has also been granted orphan drug status in pancreatic cancer by both FDA and EMA.

Alain Moussy, CEO and co-founder of AB Science said, "The issuance of this patent is especially timely because the recruitment target of 330 patients in the ongoing confirmatory phase 3 study has just been reached. An interim analysis will be available by the end of this year with a possible resampling option in the overall population with pain or in the subgroup of patients with pain and locally advanced tumour."

The new patent was based on data generated from the AB07012 phase 3 study of masitinib in treatment of advanced pancreatic adenocarcinoma. Results have previously been published in the peer-reviewed journal Annals of Oncology under the title of, 'A randomized, placebo-controlled phase III trial of masitinib plus gemcitabine in the treatment of advanced pancreatic cancer'. This article is freely available at http://annonc.oxfordjournals.org/lookup/doi/10.1093/annonc/mdv133. Key findings from that study are described below:

- It was revealed that the marker of baseline pain intensity, assessed via a visual analog scale (VAS) at baseline, has prognostic value, with patients from this subgroup experiencing aggressive disease progression while receiving Gemzar[®] (gemcitabine, from Eli Lilly and Company).
- This subgroup represents a critical unmet medical need as evidenced from a shorter median OS of approximately 5.5 months.
- In the pain subgroup, administration of masitinib in combination with Gemzar[®] produced a statistically significant overall survival advantage of +2.6 months (Hazard Ratio=0.62[0.43;0.89]) when compared with placebo administered in combination with Gemzar[®].
- Safety of the combination remained acceptable with no overall detrimental effect on quality of life.
- There is evidence from the scientific literature in support of biological plausibility for the observe masitinib treatment-effect in patients with baseline pain (VAS ≥ 20). The presence of pain in

pancreatic ductal adenocarcinoma is thought to flag an increased mast cell activity within the tumor microenvironment which promotes disease progression.

 Masitinib's highly selective inhibition of mast cell activation is expected to be of therapeutic benefit by impacting on mast cell related remodeling of the tumor microenvironment.

"A confirmatory phase 3 randomized clinical trial is currently ongoing in this indication with an objective to replicate in a prospective manner the first study's results which are consistent with the known masitinib mechanism of action and its target, mast cells", said Professor Olivier Hermine, President of the Scientific Committee of AB Science. "If successful this would support the use of masitinib plus gemcitabine as a new treatment option for this subgroup of pancreatic cancer patients with pain and poor prognosis".

About advanced pancreatic adenocarcinoma

Incidence of pancreatic cancer has markedly increased over the last few decades. Pancreatic cancer is now the twelfth most common cancer in the world, with 338,000 new cases diagnosed in 2012¹. The estimated 5-year prevalence of people in the world living with pancreatic cancer is 4.1 per 100,000. This cancer is almost always fatal, and is the seventh most common cause of death from cancer. Patients diagnosed with pancreatic cancer often have a poorer prognosis compared with other cancers in part because early detection is difficult. At the time of diagnosis, most patients with pancreatic adenocarcinoma present with locally advanced or metastatic disease and only 10-20% of cases are candidates for curative surgery. For patients with unresectable, locally advanced or metastatic pancreatic adenocarcinoma, median overall survival is between 6 to 7 months and 1-year survival rates range between 17 to 25% a.

1 <u>http://globocan.iarc.fr/Pages/fact_sheets_population.aspx</u>.

2 Heinemann V, et al. BMC Cancer. 2008;8:82.

3 Von Hoff DD, et al. N Engl J Med. Oct 31 2013;369(18):1691-1703.

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 and is developed in twelve phase 3 indications 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, mastocytosis, 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

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 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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