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AB8939 Receives Orphan Drug Designation for Acute Myeloid Leukemia from FDA

AB Science SA (NYSE Euronext - FR0010557264 - AB) announces today that the U.S. Food and Drug Administration (FDA) has granted the company Orphan Drug designation for compound AB8939 in the treatment of acute myeloid leukemia (AML).

The FDA's Office of Orphan Drug Products Development reviews applications for Orphan Drug status to support development of medicines for underserved patient populations, or rare disorders that affect fewer than 200,000 people in the United States. Orphan Drug status entitles the company to a 7-year period of marketing exclusivity in the United States for AB8939, if it is approved by the FDA for the treatment of acute myeloid leukemia. Orphan Drug status enables the company to apply for research grant funding for Phase 1 and Phase 2 clinical trials and tax credits for certain research expenses. It also provides a waiver from FDA's prescription drug user fee, and a potentially faster regulatory process if granted a priority review and/or a breakthrough therapy designation.

The Orphan Drug Designation is for the treatment of acute myeloid leukemia with '1-{4-[2-(5-ethoxymethyl-2-methyl-phenylamino)-oxazol-5-yl]-phenyl}-imidazolidin-2-one', the chemical name for AB8939.

Granting of an orphan designation for AB8939 was based on preclinical evidence demonstrating the potential to improve the treatment of AML. AB8939 may therefore offer an important therapeutic benefit in AML and in particular to those refractory/relapsed AML patients with the poorest prognosis.

AML is a serious, life-threating condition and the most common cause of leukemia-related mortality, with a majority of patients facing a highly unsatisfactory prognosis. As such, AML represents an unmet medical need, with limited therapeutic options for patients who are refractory or too frail to benefit from potentially curative but highly toxic treatment, or for those patients that have relapsed following a first complete response. The prevalence of AML in western countries is around 1 per 5,000 persons [1], corresponding to around 100,000 cases in Europe and 60,000 in the USA. Among the AML patients, it is estimated that approximately 50% of the patients will not have stem cell transplantation and will relapse. Therefore, the estimated targeted population of AB8938 in AML is around 80,000 people in Europe and in the US.

References

[1] National Cancer Institute (https://seer.cancer.gov/statfacts/html/amyl.html)

About AB8939

AB8939 is a novel microtubule destabilizing agent that is differentiated from other drugs of this class primarily by its inability to be transported by P-glycoprotein, thereby having potential to overcome Pgp-dependent multidrug resistance in cancer patients.

About Orphan Drug Designation

The FDA Office of Orphan Products Development (OOPD) mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. In fulfilling that task, OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products.

The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval for investigational use. Sponsors must establish safety and efficacy of a compound in the treatment of a disease through adequate and well-controlled studies. However, the FDA review process may be speedier for Orphan Drugs than those which do not receive Orphan Drug designation.

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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