PRESS RELEASE

RESULTS FROM MASITINIB STUDY AB12005 IN PANCREATIC CANCER SELECTED FOR PRESENTATION AT THE ASCO ANNUAL MEETING

Paris, May 20, 2021, 6pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announced that results from masitinib study AB12005 in pancreatic cancer, have been selected for presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting.

The 2021 ASCO Annual Meeting, taking place online June 4-8, will bring together one of the largest, most diverse audiences in oncology. This is historically one of the world's largest meetings for the oncology medical professions, with a registered attendance of 45,000 participants for the 2020 Annual Meeting.

Joël Ezenfis, Head of the Medical Oncology Department the Centre Hospitalier Sud Francilien, France, and principal coordinating investigator of the study, will present results from masitinib study AB12005 as part of a Poster Discussion Session. This work was selected by the ASCO Scientific Program Committee from among more than 5,400 submitted abstracts.

Presentation details are as follows:

- Session Title: Poster Discussion Session, Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
- On-Demand Session Release Date and Time: June 04, 2021, 3;00PM (CEST)
- Presentation Title: *Masitinib plus gemcitabine as first-line treatment of pancreatic cancer with pain: Results from phase 3 study AB12005*
- Authors: Joel Ezenfis, Julien Taiëb and Olivier Hermine for the AB12005 Study Group

The full abstract will be published in the 2021 ASCO Annual Meeting Proceedings (a supplement to Journal of Clinical Oncology) and also posted on the ASCO 2021 Annual Meeting website: https://meetinglibrary.asco.org/session/13626

Joël Ezenfis said: *"These results from study AB12005 are welcome news in the fight against pancreatic cancer. Masitinib, an oral tyrosine kinase inhibitor that targets inflammatory cells associated with a pro-tumoral immune response, improved prognosis for unresectable, locally advanced pancreatic ductal adenocarcinoma patients with pain".*

Study AB12005 was a placebo controlled, randomized (2:1) trial, evaluating oral masitinib (6 mg/kg/d) plus gemcitabine (1000 mg/m²) in chemo-naïve unresectable locally advanced pancreatic cancer (LAPC) or metastatic with pain criteria (defined as visual analog scale of pain intensity >20 or patient taking an opioid analgesics dose ≥1 mg/kg/d).

The study was successful if the difference in median OS (primary endpoint) relative to control, reached a 2.5% level of statistical significance for either the predefined LAPC subgroup (n=92) or the overall population (n=379).

Highlights from the presentation include:

- Masitinib plus gemcitabine confers a meaningful overall survival benefit of +1.8 months relative to the control arm, corresponding to a significant 54% reduced risk of death (p=0.005) in LAPC patients with pain.
- No survival benefit was seen for the overall study population, which included metastatic patients.
- Survival response rate were consistent with overall survival results.
- Masitinib plus gemcitabine increased median progression free survival (PFS) by 3.6 months, corresponding to a significant 54% reduced risk of disease progression (p=0.004) in LAPC patients with pain.
- Toxicities were manageable with similar rates of severe and serious adverse events relative to control.
- AB12005 results are confirmatory for positive benefit/risk in unresectable locally advanced pancreatic cancer with pain.
- Findings provide further clinical evidence associating mast cells with pancreatic cancer.

AB12005 Study Design

Study AB12005 was a randomized, placebo-controlled, phase 3 study of masitinib in first-line treatment of unresectable locally advanced or metastatic pancreatic cancer patients with pain at baseline or taking opioids.

The pre-specified primary endpoint was overall survival. The primary analysis was pre-specified both in the overall population and also in patients with unresectable locally advanced tumors, with alpha spending split at a 2.5% level of significance between the overall population (2.5%) and locally advanced subgroup (2.5%). The distinction between unresectable locally advanced or metastatic disease status was a stratification factor, thereby ensuring that treatment-arms were unbiased for this known prognostic factor. Secondary endpoints included progression free survival according to central RECIST criteria and change in pain from baseline.

The study enrolled 383 patients (randomization 2:1 between masitinib and placebo) with i) histologically or cytologically confirmed adenocarcinoma of the pancreas, unresectable locally advanced or metastatic stage, ii) pain related to the disease (Visual Analogue Scale > 20 mm or opioid analgesics at a dose ≥ 1 mg/kg/day), and iii) chemotherapy naïve for the advanced/metastatic disease. 89 patients had unresectable locally advanced with pain criteria.

Efficacy analysis was performed in the modified intent-to-treat (mITT) population, which included all randomized patients who took at least one dose of study treatment (masitinib/placebo) and with pain criteria (VAS > 20 and/or patients treated with opioid analgesics dose ≥ 1 mg/kg/day at baseline). There was a difference of 4 patients between the ITT population and the mITT population, with 1 patient receiving no study treatment and 3 patients without pain criteria.

Rationale for developing masitinib in patients with pancreatic cancer with pain

A first phase 2/3 study (AB07012) enabled the identification of a subgroup based on the level of pain at baseline where survival was statistically increased (+2.6 months, p=0.012, Hazard Ratio=0.62). Pain intensity was assessed via a visual analog scale (VAS) at baseline. This linear scale provides a visual representation of pain as perceived by the patient. Pain intensity was represented by a 100 mm long, continuous line free of any internal reference marks. One extremity indicated an absence of pain (0-value) and the other extremity indicated very severe pain (100-value). The VAS threshold for the 'pain' subgroup was set to VAS ≥20 mm, which is consistent with established precedent from the scientific literature [1-4].

There is evidence from the scientific literature in support of biological plausibility for the observed masitinib treatment-effect in patients with baseline pain (VAS ≥ 20). The presence of pain in pancreatic cancer 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 modulating mast cell related remodeling of the tumor microenvironment.

About pancreatic cancer

The estimated prevalence of people living with pancreatic cancer is 21 per 100,000 [5]. At the time of diagnosis, most patients with pancreatic ductal adenocarcinoma present with locally advanced or metastatic disease and only 10-20% of cases are candidates for curative surgery. Median overall survival is between 6 to 7 months and 1-year survival rates range between 17 to 25% [6;7]. As such, population with unresectable pancreatic cancer in first line is around 100,000 in the EU and 60,000 in the USA.

From the first Phase 3 study AB07012 [8] and literature [9], around 50% of patients with pancreatic cancer had pain intensity (VAS > 20) and 25% to 50% of pancreatic cancer patients are patients with unresectable locally advanced tumors.

Reference

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[4] Christy AL, Brown MA. The multitasking mast cell: positive and negative roles in the progression of autoimmunity. J Immunol. Sep 1 2007;179(5):2673-2679
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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, inflammatory diseases and viral 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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