



## PRESS RELEASE

### RESULTS FROM MASITINIB STUDY AB12005 IN PANCREATIC CANCER PRESENTED AT THE ASCO ANNUAL MEETING WITH THE FULL ABSTRACT PUBLISHED IN THE JOURNAL OF CLINICAL ONCOLOGY

Paris, 10 June, 2021, 6.30pm CET

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that results from masitinib study AB12005 in pancreatic cancer, have been presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting by the principal coordinating investigator Dr Joël Ezenfis (Head of the Medical Oncology Department the Centre Hospitalier Sud Francilien, France). The ASCO Annual Meeting, one of the world's largest meetings for oncology medical professions, was held from June 4–8 as a virtual format this year.

Study AB12005 was a placebo controlled, randomized (2:1) trial, evaluating oral masitinib (6 mg/kg/d) plus gemcitabine (1000 mg/m<sup>2</sup>) in chemo-naïve unresectable locally advanced pancreatic cancer (LAPC) or metastatic cancer 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).

The prerecorded presentation entitled '*Masitinib plus gemcitabine as first-line treatment of pancreatic cancer with pain: Results from phase 3 study AB12005*' was released on Friday 4<sup>th</sup> June as part of the Gastrointestinal Cancer Poster Discussion Session, and the abstract has been published in the Journal of Clinical Oncology [1] ([https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15\\_suppl.4018](https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.4018)). Highlights from the presentation included:

- Masitinib plus gemcitabine confers a meaningful overall survival benefit of +1.8 months relative to control in LAPC patients with pain, and a significant 54% reduced risk of death (p=0.005).
- Masitinib plus gemcitabine increased median progression free survival by 3.6 months, corresponding to a significant 54% reduced risk of disease progression (p=0.004) in LAPC patients with pain.
- No survival benefit was seen for the overall study population, which included metastatic patients.

Joël Ezenfis said: "*These results are confirmatory for a positive benefit/risk in patients with unresectable locally advanced pancreatic ductal adenocarcinoma with pain criteria, a population that was previously identified from phase 3 study AB07012 [2]. For study AB12005, an 18-month overall survival rate of 34% for the masitinib treatment-arm versus 10% for the placebo arm was observed. Of equal importance, toxicities for the masitinib and gemcitabine combination were manageable with similar rates of severe and serious adverse events relative to control*".

#### **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  $\geq$  1 mg/kg/day), and iii) chemotherapy naïve for the advanced/metastatic disease. 92 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  $\geq$  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.

### **Reference**

- [1] Joel Ezenfis, et al. Masitinib plus gemcitabine as first-line treatment of pancreatic cancer with pain: Results from phase 3 study AB12005. DOI: 10.1200/JCO.2021.39.15\_suppl.4018 Journal of Clinical Oncology 39, no. 15\_suppl (May 20, 2021) 4018-4018.  
[2] Deplanque 2015, Ann Oncol. doi: 10.1093/annonc/mdv133. <http://annonc.oxfordjournals.org/content/26/6/1194>.

### **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](http://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 published by AB Science. 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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