PRESS RELEASE

AB SCIENCE COMMUNICATES RESULTS FROM PHASE 3 STUDY EVALUATING MASITINIB IN PROSTATE CANCER

Paris, May 26, 2021, 7.15pm CET

AB Science SA (Euronext – FR0010557264 – AB) communicated the results from phase 3 study evaluating masitinib in prostate cancer during the webcast that was held on May 25, 2021.

The presentation is available on the company's website and is available here.

Highlights of this presentation are:

Masitinib is positioned in combination with docetaxel as first-line treatment of metastatic Castrate Refractory Prostate Cancer (mCRPC) eligible to chemotherapy. Metastatic prostate cancer is still an unmet medical need. The median survival of patients with metastatic prostate cancer is around 2 years and the 5-years survival rate is 30% [1] and there is no drug registered in combination with docetaxel.

Masitinib is a tyrosine kinase inhibitor designed to selectively target mast cells (MCs) and macrophages. Innate immune cells, in particular MCs and macrophages, are critical components of the tumor microenvironment, promoting angiogenesis and tumor growth, and also contributing to tumorigenesis by suppression of the immune response:

- The amount of MCs infiltration into human prostate cancer correlates with prognosis, with lower number of MCs in biopsy specimen leading to better prognosis .
- There is a positive correlation between MCs infiltrated and tumor microvessel density, indicating a stimulating role of MCs in tumourigenesis.
- MCs are essential for the outgrowth of early-stage tumors, but not essential at a later stage.
- MCs increase prostate cancer chemotherapy resistance via modulation of p38/p53/p21 signaling.
- Prostate cancer bone metastases strongly expressed c-kit.
- M2 macrophages promote prostate cancer progression and M1 macrophages may also be associated with poor prognosis.

Masitinib has no direct "tumor killer" general activity, but has shown efficacy on tumor proliferation *in vivo*, mediated through the tumor micro-environment
Based on this mechanism of action, masitinib would be expected to be more effective in the earlier stage of the metastatic disease rather than a later stage.

The development program in prostate cancer is comprised of AB07004 phase 1/2 proof of concept study (n=34 pts), which supported the combination of masitinib with docetaxel in mCRPC, and AB12003 phase 3 study also in mCRPC patients.

Study AB12003 was an international (16 countries), multicenter (67 sites), randomized, double blind, placebo-controlled, 2-parallel group, phase 3 study in mCRPC patients eligible to chemotherapy.

- The study aimed to compare the efficacy and safety of masitinib (6.0 mg/kg/day) in combination with docetaxel versus placebo in combination with docetaxel. Docetaxel was combined with prednisone, up to ten cycles.
- The primary endpoint was a composite PFS measured with PCWG2 definition, which is based on the earliest event between radiographic progression, PSA progression, Pain progression, or death.

- The study pre-specified the overall population and a targeted subgroup defined as patients with Alkaline Phosphatase (ALP) below 250 IU/mL at baseline. ALP below 250 IU/mL is a biologic biomarker that was pre-defined to identify patients with lower extent of (bone) metastases and most likely to respond to masitinib.
- The study tested the success of the primary endpoint PFS in these two populations as primary analysis with control of alpha risk test for final analysis set at 3.9% in the targeted subgroup and 3.99% in the overall population with a fall back scheme and taken into consideration interim analysis with a peto function.
- The primary analysis was based on mITT population, which included 450 patients in the targeted subgroup and 712 patients in the overall population. The mITT population exluded 2 patients from ITT population who did not receive the study drug.

Baseline characteristics were globally balanced. Study AB12003 results were the following:

- The study met its primary analysis in the pre-specified targeted subgroup (patients with ALP ≤ 250 IU/mL), demonstrating a statistically significant increase in PFS (p=0.0272).
- Sensitivity analysis of the primary endpoint, including analysis in the ITT population, were all consistent with a benefit measured by Cox model ranging from 21% to 24%.
- The percentage of patients alive with no progression was in favor of masitinib at all timepoints in the targeted subgroup and statistically significantly higher. At 12 months, 18 months and 24 months, the percentage of non-progressors was respectively 32.0%, 27.6% and 23.1% in the masitinib arm as compared with 19.6%, 14.6%, and 12.0% in the control arm (p= 0.0035, p=0.0011, p=0.0028).
- The lower the ALP level, the greater the masitinib treatment effect, in line with greater treatment effect expected in early metastatic phase. PFS benefit was 21% (HR=0.79, p=0.0272) in patients with ALP ≤ 250 IU/mL, versus 27% (HR=0.73, p=0.0126) in patients with ALP ≤ 200 IU/mL, 37% (HR=0.63, p=0.0008) in patients with ALP ≤ 150 IU/mL, and 47% (HR=0.53, p=0.0022) in patients with ALP ≤ 100 IU/mL.
- There was no benefit on overall survival (OS) in the targeted subgroup, at the time of the cut-off. OS may have been impacted by new hormono-therapy and cabazitaxel that are registered after docetaxel and there was no recording of treatments taken after progression with docetaxel in this study.
- There was no PFS benefit in the overall population. In the overall population, there was, however, a statistically significant increase in TTP (+4 months, p=0.0493), showing that masitinib is active in mCRPC.
- The safety of masitinib was consistent with its known tolerability profile.

A new patent was filed based on results from study AB12003, which would permit AB Science to retain exclusive rights on the use of masitinib in Prostate cancer until 2042.

Stéphane Oudard (MD, PhD), Professor of Oncology and Chief of the Oncology Clinical and Translational Research Unit at the Georges Pompidou Hospital in Paris, France said: "*This is the first positive study in a long-time in the treatment of mCRPC in combination with docetaxel. The results show that masitinib is active in mCRPC when administered at the early stage of the metastatic process.*"

Theo M. de Reijke (MD, PhD, FEBU), Associate Professor at the Amsterdam University Medical Centers, Amsterdam, The Netherlands said: *"There is a need for new and effective therapies in the treatment of mCRPC, in particular for patients with low metastatic involvement. ALP is a valid biomarker for metastatic involvement that could be used to identify the best responders to masitinib treatment, since masitinib showed increasing treatment effect with decreasing level of ALP (i.e. lower metastatic involvement).*"

Reference

[1]: American Cancer Society, April 2021

KOL Biographies

The following key opinion leaders participated in the webcast:

Stéphane Oudard, MD, PhD
Stéphane Oudard is a Professor of Oncology and Chief of the Oncology Clinical and Translational Research Unit at the Georges Pompidou Hospital in Paris (2011), France. He is professor in Oncology at the University of Paris, Paris, France.

Professor Oudard received his medical degree from Hôtel-Dieu Hospital, University of Paris, France (1993). On completion of his residency in medical oncology in Paris, Professor Oudard obtained his Masters of Science at Lariboisière-Saint Louis University Hospital, Paris, France (1994) and his Doctorate at Institut Curie, Paris, France (1996). He completed a 2-year fellowship in cancer research at Georgetown University, Washington, DC, USA, before returning to Paris.

He is currently a member of the French Cancer Society, European Society for Medical Oncology (ESMO, scientific committee), and American Society of Clinical Oncology (ASCO). He integrated the research INSERM Unit UMR-970 Paris Cardiovascular Research Center (directed by Pr Eric TARTOUR) a research team focusing on immunomonitoring and immunotherapy of solid tumours. He is the deputy director of CARPEM, a site of integrated cancer research site. As a clinical researcher, Professor Oudard has served as a Coordinator, Investigator, or Co-Investigator on several phase I−III French, European, and international clinical trials. He has been largely involved in the development of docetaxel, cabazitaxel, sorafenib, sunitinib, axitinib and everolimus in uro-oncology tumors. He is a member of the French GETUG group.

His research interests include prostate and kidney cancers, translational research, angiogenesis, immunology, inhibition of glycolysis, and drug resistance. He is the principal investigator of the phase III trials on CABASTY in prostate cancer, on NEMIO in bladder cancer and co-leader of the BIONIKK trial on personalized medicine in mRCC.

Professor Oudard has authored 3 educational books, more than 348 scientific articles and 25 literature reviews published in various international journals.

Theo M. de Reijke, MD, PhD, FEBU
Dr. Theo M. de Reijke is Associate Professor at the Amsterdam University Medical Centers, Amsterdam, The Netherlands.

Theo M. de Reijke performed his medical training at the Free University in Amsterdam and has been working from 1987 until 2018 as urologist at the Amsterdam UMC, location Academic Medical Center in Amsterdam. Since his retirement, he is still appointed at the Amsterdam UMC for two days supervising PhD students and coordinating of an oncology bachelor program at the medical faculty of the University of Amsterdam. In 2004 he successfully defended his thesis on immunotherapy for bladder cancer.

Uro-oncology is his main field of interest, especially non-muscle invasive bladder cancer and upper tract tumours (new imaging modalities) and prostate cancer (focal therapy, new markers and imaging). He has been an active member of the European Organization for Research and Treatment of Cancer – Genito Urinary group (EORTC-GU) for many years. After serving as chairman of the prostate cancer subgroup, he was elected as secretary and later as chairman of the EORTC-GU group until June 2009. In the Netherlands, he has been the chairman of the prostate cancer guideline committee until 2019 and he is member of the bladder cancer guideline committee.

He is member of different international Urological societies (e.g. NvU, EAU, AUA, Endourology Society), reviewer for several international journals and member of scientific boards for different journals. In 2011, he was elected as reviewer of the month for European Urology. He was chairman of the Dutch urological training program for residents and chairman of the European Board of Urology examination committee.

He represents the European Urological Association at the EMA.

He was elected as visiting professor for the medical school of Warsaw and he is honorary member of the Polish and Rumanian Urological Associations and was nominated as honorary member of the Dutch Urological Association.

He is (co) author of over 250 publications in peer reviewed journals and he made contributions to many book chapters. He organised several scientific national and international meetings and is/was coordinator of (inter)national uro-oncology trials.

Olivier Hermine, MD, PhD
Olivier Hermine, MD, PhD is Professor of Hematology at the University of Paris, Chief of adults Hematology staff at Hospital Necker (Paris), member of the French Académie des Sciences and author of over 700 international publications. Olivier Hermine is also co-founder of AB Science and Head of its scientific committee.

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

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