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Update on phase 1/2 program with masitinib in solid tumors

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), presents an update of its masitinib phase 1/2 program in solid tumors.

AB Science has developed an extensive phase 1/2 program in solid tumors with masitinib to ascertain which indications should be pursued in phase 3. This program is close to completion with the status of each study summarized below:

Status of masitinib phase 1/2 studies in solid tumors

Indication	Status	Patients	Passed pre-planned Primary statistical test	Decision to move to phase 3
Digestive cancers				
Pancreatic cancer (phase 3)	Completed	• 348 (overall) • Subgroups o 137 o 40	• No in overall population • Survival advantage in subgroup o Pain subgroup o ACOX-1 subgroup	Yes
GIST in 2nd line	Completed	44	Yes	Yes
Metastatic gastric cancer in 2nd line	Completed	45	Yes	Yes
Metastatic colorectal cancer in 2nd line	Completed	54	Yes	Yes
Metastatic liver cancer	On-going	34	-	-
Hormonal cancers				
mCR Prostate Cancer in 2nd line	Completed	60	Yes	Yes
Metastatic triple neg. breast cancer	Completed	45	Yes	Decision pending completion of phase 2 in breast cancer
Metastatic breast cancer	On-going	54	-	-
Others				
Peripheral T-cell lymphoma	Completed	45	Phase 2 not read and transformed into phase 3	Yes
Glioblastoma multiform	Completed	36	No	No
Metastatic NSCL cancer	Completed	30	No	No
Metastatic melanoma	Completed	42	No	No
Metastatic head and neck cancer	On-going	32	-	-

Each of these phase 2 study designs incorporated a pre-defined statistical test to detect a superiority trend in overall survival between masitinib in combination with standard-of-care chemotherapy when compared against its relevant historical meta-analysis benchmark. The outcome of this test determines whether or not a confirmatory phase III study should be initiated. This statistical test was considered positive based on the upper bound for the confidence interval of Hazard Ratio being lower than 1, which corresponds to a relative survival benefit for patients in the masitinib treatment-arm.

Out of the phase 2 studies initiated:

- Four studies passed their predefined statistical test instigating launch of randomized controlled phase 3 studies in each indication. Those indications include the digestive cancers of GIST, gastric cancer and colorectal cancer, as well as prostate cancer.
- One study passed its predefined statistical test in triple negative breast cancer. A decision to move to phase 3 is pending results from an on-going phase 2 study in breast metastatic cancer.
- One study in T cell refractory lymphoma was accelerated to a phase 3 randomized controlled trial validated by health authorities in the world.
- Three studies did not meet their pre-specified statistical test and a decision has been made not to launch phase 3. Those studies were non small cell lung (NSCL) cancer, metastatic melanoma not bearing the juxtamenbrane mutation of c-Kit, and glioblastoma.
- Three studies are still on-going, in breast cancer, liver cancer, and head & neck cancer.

From this phase 1/2 clinical program the following comments can be made:

Masitinib seems to be particularly effective in digestive cancers where phase 2 data looks encouraging with respect to relevant benchmark data. Consequently, phase 3 studies are on-going or in the process of being launched in GIST, pancreatic cancer, colorectal cancer, and gastric cancer (esophagogastric adenocarcinoma).

As a reminder, in the aforementioned phase 1/2 studies the improved median overall survival observed for patients from the masitinib treatment-arm when compared against relevant benchmark data were, respectively:

- GIST 2nd line - 29.8 vs. 17.4 months [1]
- Pancreatic cancer
  - subpopulation with ACOX-1 biomarker - 11.7 vs. 5.6 months [2]
  - subpopulation with pain - 8.0 vs. 5.4 months [2]
- Metastatic colorectal cancer 2nd line - 17.6 vs. 10.0 months [3]
- Metastatic gastric cancer 2nd line - 11.0 vs. 7.5 months [4]

These results are compatible with the known mechanism of action for masitinib. Pre-clinical data and cumulative clinical experience show that masitinib may be capable of generating an important survival benefit in various cancers by targeting mast cells and macrophages. Masitinib acts as a modulator of the tumor microenvironment. The expected consequence of these actions is to extend survival by controlling the aggressiveness, transformation, and dissemination of the tumors. Publications have shown that there is a higher prevalence of both mast cells[A] and tumor associated macrophages[B] in digestive cancers when compared with other cancers. Furthermore, both cells have been identified as a negative prognosis factor on survival. Thus, masitinib may retard the aggressive course of tumor progression in certain patients with these digestive system cancers.

A second group of cancers that appear susceptible to masitinib treatment are hormonal cancers such as prostate cancer and breast cancer. It is still however too early to say this with certainty, because results from the metastatic breast cancer study are still unknown.

Abstracts reporting phase 1/2 results for colorectal cancer[3], gastric cancer[4], and triple negative breast cancer[5] have been presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting.

Finally, T cell lymphoma is an exception. Masitinib's mechanism of action in this indication also involves targeting of PDGFR. The decision to launch this program came from observed veterinary cases of complete response in dogs with T-cell lymphoma treated with masitinib. This treatment effect was confirmed in a study of 11 dogs showing an Objective Response Rate of 72%, including 3 dogs with complete response and 5 dogs with partial response, over a sustained period[6].

AB Science will continue to report results of the end of the phase 1/2 program along with any decision on whether or not to launch confirmatory phase 3 studies.

[1] Adenis 2014, Ann Oncol. doi:10.1093/annonc/mdu237. http://annonc.oxfordjournals.org/content/25/9/1762
[2] Deplanque 2015, Ann Oncol. doi: 10.1093/annonc/mdv133. http://annonc.oxfordjournals.org/content/26/6/1194
[3] Taieb 2015, ASCO Annual Meeting Abstract: #3526.
[4] Zaanan 2015, ASCO Annual Meeting Abstract: #4027.
[5] Campone 2015, ASCO Annual Meeting Abstract: #1070.
[6] See AB Science press release: www.ab-science.com/file_bdd/content/1432745180_PressReleasePhase3TCellEn.pdf

[A] Literature on implication of mast cells in solid tumors:
- Sharon A. Oldforda, Jean S. Marshalla 2014, Mast cells as targets for immunotherapy of solid tumors
- Xiaosun Liu et al. 2014, Intratumor IL-17-Positive Mast Cells Are the Major Source of the IL-17 That Is Predictive of Survival in Gastric Cancer Patients
- Ribatti 2010, Int J Exp Pathol. 91(4):350-6
- Ammendola 2013, Gastroenterol. Res. Pract. ID 703163
- Liu 2014, PLoS ONE. 9(9):e106834
- Wu 2013, Int J Surg Pathol 21(2):111-20
- Malfettone 2013 J Cell Mol Med. 17(8):1025-37
- Gounaris 2007, Proc Natl Acad Sci USA 104:19977–19982
- Blatner 2010, PNAS 6;107(14):6430-5

[B] Literature on implication of tumor associated macrophages in solid tumors:
- Laurent P 1965, Acta Pathol Microbiol Scand. 1965;64:41-49, The two histological main types of gastric carcinoma: diffuse and so-called intestinal-type carcinoma
- Tong Ding et al. 2008, High tumor-infiltrating macrophage density predicts poor prognosis in patients with primary hepatocellular carcinoma after resection
- Xiao-Dong Zhu et al. 2008, High expression of macrophage colony-stimulating factor in peritumoral liver tissue is associated with poor survival after curative resection of hepatocellular carcinoma
- Pippa Newell et al. 2012, Circulating and intratumoral macrophages in patients with hepatocellular carcinoma: correlation with therapeutic approach

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 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. The company is currently pursuing 12 indications in phase 3 studies in human medicine, in GIST (in first-line and in second-line), in metastatic melanoma expressing JM mutation of c-Kit, in multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and Amyotrophic Lateral Sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: www.ab-science.com.

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