AB SCIENCE

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2010 sales turnover: 917 K€ vs 316 K€ in 2009

# Very good performance of masitinib in veterinary medicine during its first full year of commercialization.

Continued advances in development pipeline: Significant progresses in human medicine and FDA registration granted in veterinary medicine

**AB Science SA** (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced its sales for the fourth quarter of 2010 and presents key highlights for this period and recent events.

this Commenting on announcement, Alain Moussy, CEO of AB Science declared: « In 2010, AB Science continued the commercialization of masitinib in veterinary medicine in Europe, with steadily growing sales close to one million euro for this first full year. We were granted authorization by the FDA to commercialize our anti cancer drug for dogs in the USA, which is the largest market in the world for this type of product. Commercialization was initiated early 2011. In addition, we continued to develop our pipeline of projects, in line with the objectives set during the IPO. With five human phase 3 on-going, and new major phase 2 studies initiated, AB Science has a strong pipeline. This pipeline combined with growing sales makes us feel confident for 2011 ».

## I. Highlights of the fourth quarter 2010 and recent events

During the past quarter, and since the end of 2010 fiscal year, AB Science made significant progresses in its development pipeline.

In Human Medicine

- AB Science announced the launch of two new phase 3 clinical trials with the Masitinib followed by the recruitment of the first patients :
  - o In the treatment of metastatic melanoma expressing c-Kit JM mutation
  - In the treatment of persistent severe asthma

The Masitinib is currently evaluated in 5 phase 3 studies : three in oncology (pancreatic cancer, gastro-intestinal stromal tumor (GIST), and metastatic melanoma bearing JM mutation of c-Kit) and in two inflammatory diseases (mastocytosis, an orphan disease, and persistent severe asthma).

Of interest, the juxta-membrane mutation of the c-Kit is expressed in canine mast cell tumors where masitinib is already registered. This mutation is also present in gastro-intestinal stromal tumor where masitinib is currently in a phase 3 study in first line of treatment, and in a phase 2 study in second line of treatment in resistance to imatinib. In these cancers, Masitinib is used as a single agent without combination with chemotherapy. These indications are the basis of the development program of the masitinib and present the highest chances of success due to an action mechanism well understood.

- AB Science announced the launch of three new phase 2 studies with the Masitinib in oncology :
  - o In the treatment of metastatic melanoma (not expressing the JM mutation of c-Kit),
  - In the treatment of stomach cancer,
  - In the treatment of peripheral T-cell lymphoma.

Masitinib is currently evaluated in nine phase 2 studies in oncology :

- One phase 2 evaluating masitinib as a single agent versus sunitinib in second line treatment of GIST, after failure to imatinib,
- Seven phase 2 evaluating masitinib combined with standard chemotherapies in the treatment of metastatic solid tumors (non small cell lung, prostate, colorectal, breast, breast triple negative, melanoma, stomach)
- One phase 2 in a hematological cancer, T-cell lymphoma, initiated in humans thanks to very promising results obtained with masitinib in the treatment of dogs with the same disease.
- AB Science also announced the presentation at ASCO of the 4-year follow-up data from a phase 2 clinical study of masitinib in the first line treatment of GIST. These data are encouraging for masitinib in first line treatment of GIST, in particular with the median progression free survival of 41 months. If this trend was confirmed in the phase 3, 200 patients could be enough to demonstrate superiority of masitinib over imatinib.

## Status of program of clinical studies of masitinib

Clinical Studies	Status at IPO	Current status
Oncology-Solid Tumors - Masitinib in monotherapy (JM mutation of c-Kit)		
1 - Gist first line (phase 3)	Recruitment on-going	Recruitment on-going
2 - Metastatic melanoma bearing JM mutation of c-Kit (phase 3)	Not initiated	Recruitment on-going
3 - GIST second line (phase 2)	Recruitment on-going	Recruitment on-going
Oncology-Solid Tumors - Masitinib in combination with chemotherapy		
4 - Pancreatic cancer (phase 3)	Recruitment on-going	Recruitment completed
5 - Lung cancer (phase 2)	Authorised	Recruitment on-going
6 - Prostate cancer (phase 2)	Authorised	Recruitment on-going
7 - Colorectal cancer (phase 2)	Authorised	Recruitment on-going
8 - Breast cancer triple negative (phase 2)	Authorised	Recruitment on-going
9 - Metastatic breast cancer (phase 2)	Authorised	Recruitment on-going
10 - Metastatic melanoma (phase 2)	Not initiated	First patient enrolled
11 - Stomach cancer (phase 2)	Not initiated	Authorised
Oncology - Hematology		
12 - Multiple Myeloma (phase 3)	Authorised	Authorised
13 - T-cell lymphoma (phase 2)	Not initiated	Authorised
Inflammatory pathologies		
14- Mastocytosis (phase 3)	Recruitment on-going	Recruitment on-going
15 - Severe Asthma (phase 3)	Not initiated	Recruitment on-going
16 - Rhumatoid arthritis (phase 3)	Not initiated	Authorised
Central Nervous system pathologies		
17 - Progressive Multiple sclerosis (phase 3)	Not initiated	Authorised
18 - Alzheimer disease (phase 3)	Not initiated	Design validated

### In Veterinary Medicine

- AB Science received from the FDA (Food and Drug Administration) to authorization to commercialize masitinib in the USA for treatment of canine mast cell tumor. Effective commercialization in the USA started early February 2011.
- AB Science published in the American Journal of Veterinary Research phase 3 results showing increased long-term survival in canine mast cell tumor under masitinib treatment, which is the objective in oncology. As such, these results should contribute to position masitinib as the reference treatment in this disease.
- AB Science published in The Veterinary Journal results from a preclinical study showing that masitinib can act as a potentiator of chemotherapies.

This study provides further evidence that masitinib can exert an anticancer action that extends beyond the inhibition of its main tyrosine kinase targets by acting in synergy with standard chemotherapies. It this reinforces the strategy of evaluation masitinib in combination with standard chemotherapies in the treatment of different human cancers.

### Other events

AB Science obtained early 2011 a credit line of €1.7 million, running until February 2016. This credit line was received from the bank Neuflize OBC (group ABN Amro) and BNP Paribas, has a 5 year term, starting from the date of contract signature, with a 2 year differed payment period. It is counter guaranteed by Oseo at 60%.

This credit line is aimed at financing projects supporting the growth of the company. Given the fact that the marginal cost per patient is  $10k\in$  in the phase 3 studies evaluating masitinib, this non dilutive funding is significant for the company as the amount received approximately accounts for the cost of the phase 3 study in metastatic melanoma bearing JM mutation of c-Kit phase (200 patients).

### II. Financial Statement for the Fourth quarter

The income of AB Science was 253 k€ in the fourth quarter of 2010, versus 176 k€ in the fourth quarter of 2009, rising by 43.8%

Overall, AB Science reported an income of 917 k€ for the twelve months of fiscal year 2010 ending on December 31<sup>st</sup> 2010, versus 316 k€ in 2009. This income arose from the commercial exploitation of masitinib in veterinary medicine. This increase in sales occurred in a peculiar competitive environment, our direct competitor having supplied free stocks of its drug to veterinarians.

#### III. Financial Status on December 30th 2010

AB Science cash<sup>i</sup> position was 19.9 M€ on December 31st 2010, versus 5.3 M€ on December 31st 2009. The net cash outflow<sup>ii</sup> was 8.3 M€ for the 2010 period, compared to 6.9 M€ for the 2009 period.

#### 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 new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases and central nervous system diseases), in both human and veterinary medicines. Thanks to its extensive research and development capabilities, AB Science has its own portfolio of molecules. Masitinib, a lead compound, has already been registered in veterinary medicine in Europe and in the USA, and is

pursuing nine phase 3 studies in human medicine, including five studies on-going in pancreatic cancer, GIST, in metastatic melanoma expressing JM mutation of c-Kit, in mastocytosis, and severe persistent asthma.

Further information is available on AB Science's website: <u>www.ab-science.com</u>

AB Science - Communication financière & Relations Presse

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<sup>&</sup>lt;sup>i</sup> Cash: cash and cash equivalents and deposit certificates. Excludes public grants notified but not yet received.

<sup>&</sup>lt;sup>ii</sup> Net cash outflow : Total disbursement for the period, les cash inflows of the period from operating income, public grants, tax credit (research, VAT ) and bank loans. Dilutive cash inflows, resulting from capital increases, are excluded from the net cash outflow.