Paris, June 4th 2012, 8:00 CET

AB Science announces publication of three ASCO presentations detailing the results of masitinib in the treatment of advanced GIST

AB Science SA (NYSE Euronext-FR0010557264-AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announces today that data from the development program of masitinib in gastrointestinal stromal tumors (GIST) have been presented as part of three presentations delivered at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting, 1-5 June in Chicago, Illinois. These presentations were as follows:

I. **Oral presentation "Masitinib mesylate in imatinib-resistant advanced GIST: A randomized phase II trial" (**Abstract #10007, Sarcoma Oral Abstract Session) was delivered by Professor Adenis on June 4th.
Full abstract available online at: http://abstract.asco.org/AbstView_114_96397.html.

II. **Poster presentation "Masitinib in imatinib-naive advanced gastrointestinal stromal tumor (GIST): Five-year follow-up of the French Sarcoma Group phase II trial"** (Abstract #10089, Sarcoma General Poster Session), was delivered by Dr Le Cesne on June 3rd.
Full abstract available online at: http://abstract.asco.org/AbstView_114_96371.html.

III. **Poster presentation "Masitinib in comparison to imatinib as first line therapy of patients with advanced gastrointestinal stromal tumor (GIST): A randomized phase III trial"** (Abstract # TPS10102, Sarcoma General Poster Session, Trials in progress), was delivered by Professor Adenis on June 3rd.
Full abstract available online at: http://abstract.asco.org/AbstView_114_96314.html.

Full publication of these ASCO presentation slides will be available from ASCO's Virtual Meeting website (www.asco.org/vm).

I. Masitinib in second-line treatment of advanced GIST

The oral presentation "Masitinib mesylate in imatinib-resistant advanced GIST: A randomized phase II trial", delivered by Professor Antoine Adenis (Centre Oscar Lambret, Lille, France), reported encouraging data from a phase II study of masitinib in Gleevec®-resistant gastrointestinal stromal tumors (GIST).

- **Masitinib compares favorably to sunitinib in terms of toxicity.**
- **Masitinib appeared to show good therapeutic benefit in terms of overall survival.**
- **According to these preliminary results, a phase III study (masitinib vs. sunitinib) has been initiated in Europe and the US.**

Masitinib significantly improved overall survival in patients with Gleevec®-resistant GIST as compared to Sutent® (sunitinib) from Pfizer, which is currently the standard of care for second-line treatment of GIST. In this study, 44 patients with inoperable, locally advanced or metastatic GIST and showing disease progression while treated with Gleevec® (imatinib) (400 to 800 mg/day) received either masitinib (23 patients) at 12 mg/kg/day or sunitinib (21 patients) until progression. After a median follow-up of 17 months, the updated median overall survival was not reached for masitinib versus 16 months for sunitinib (Hazard Ratio: 0.27 [0.09; 0.78]). This is an improvement from the previous data disclosed after a median follow-up of 14 month, at which time the Hazard Ratio was: 0.32 [0.11; 0.91]. After 18 months, 82% [59%; 93%] of patients treated with masitinib were still alive, versus 33% [8%; 62%] for patients treated with sunitinib. Masitinib was well tolerated, with 17% of patients reporting non-hematological grade 3 related adverse events, as compared with 62% of patients in the sunitinib treatment-arm. No patients receiving

masitinib reported any related serious adverse events compared with 19% of patients in the sunitinib treatment-arm.

A phase III study has been initiated in this indication on the basis of these results, with recruitment of the first patient announced on 15th May 2012. This is a phase III, multicenter, randomized, open-label, controlled, two-parallel group study evaluating the efficacy and safety of masitinib as compared with sunitinib (Sutent®) in GIST patients after progression under imatinib (Gleevec®). This study will recruit around 200 patients from 50 sites around the world, randomized with a 1:1 ratio between masitinib and sunitinib. The primary end-point is overall survival.

II. Masitinib as first-line treatment of advanced GIST

Two other presentations were also delivered, one reporting on the 5-year follow-up data from a phase II clinical study of masitinib in the first-line treatment of locally advanced or metastatic GIST, and a related presentation describing the ongoing phase III study for this indication.

The poster communication "Masitinib in imatinib-naive advanced gastrointestinal stromal tumor (GIST): Five-year follow-up of the French Sarcoma Group phase II trial", delivered by Dr Axel Le Cesne (Institut Gustave Roussy, Villejuif, France), reported on the latest data from a multicenter, open label, phase II study, evaluating efficacy and safety of masitinib as a first-line treatment of advanced GIST.

- **5-year follow-up data substantiates that masitinib has an effective and sustainable activity in imatinib-naïve GIST patients.**
- **Median overall survival in masitinib compares favorably to that of imatinib especially in patients with KIT exon 11 mutation subpopulation.**
- **Adverse events occurred mainly during the first year, with good long term tolerance experienced thereafter.**

With a median follow-up of 72 months, the updated overall survival data for the KIT exon 11 mutation subpopulation (N=10) had not yet been reached (NR [64 months; NA]), whilst the median progression free survival was 45 months [20; NA]. These data compare favorably to historical imatinib data of 60 months and 27 months, respectively. Results for the overall study population (N=30) were equally encouraging, with updated median overall survival and progression free survival at 65 months [53; NA] and 41 months [18; 51], respectively. These data compare favorably to historical imatinib data of 55 months and 18 months, respectively.

III. About the phase III study in Gleevec®-naïve GIST (first-line) - trial in progress

The poster communication "Masitinib in comparison to imatinib as first line therapy of patients with advanced gastrointestinal stromal tumor (GIST): A randomized phase III trial", delivered by Professor Antoine Adenis (Centre Oscar Lambret, Lille, France), reported on the progress and characteristics of this phase III study.

- **Considering the promising long term efficacy observed in survival and safety from phase II, there is a compelling motive to perform a head-to-head comparison of masitinib against imatinib in first-line setting.**
- **On May 11th 2012, an Independent Data Monitoring Committee gave its positive opinion to continue this study.**

This prospective, multicenter, randomized, open-label, active-controlled, 2-parallel group, phase III study compares efficacy and safety of masitinib (7.5 mg/kg/day) to the active control of imatinib (400 or 600 mg/day) in first-line treatment of patients with advanced GIST. This study will recruit around 200 patients from sites around the world, randomized with a 1:1 ratio between masitinib and imatinib. The primary endpoint is progression free survival, defined as the delay between the date of randomization to the date

of documented progression or any cause of death during the study. Overall survival will be the main secondary endpoint.

About GIST

Gastrointestinal stromal tumor (GIST) is a sarcoma, which is a type of cancer that develops in the cells of the body's connective or supportive tissues. GIST arises within the gastrointestinal tract. It is estimated that approximately 5,000 to 6,000 new patients are diagnosed with GIST each year in the United States. In 2010, the global GIST therapeutics market was valued at $920m and is forecast to grow at a rate of 2% over the next 7 years.

Masitinib received orphan drug designation in the treatment of GIST from both FDA and EMA.

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

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