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Clarification concerning the manufacturing of masitinib

The control of impurities is adequate and in line with ICH guidelines

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), confirms that there are no concerns related to the manufacturing of masitinib, and in particular, that the control of impurities is adequate and in line with ICH guidelines.

The CHMP stated, upon completion of the assessment of the application for conditional marketing authorization of masitinib in second line treatment of GIST and in pancreatic cancer, that " *[…] there were concerns about the quality control of the medicine during manufacture, which led to uncertainties about the impurities that patients would be exposed to*".

This statement has been perceived as an indication that there were problems in the manufacturing of masitinib leading to the inadequate presence of impurities, and that such problems could be an obstacle to the clinical development program or the registration of masitinib.

AB Science would like to reassert that the manufacturing process of masitinib is robust and well under control, meaning that batches produced consistently meet the specifications, and in particular meet the specifications set in recent guideline on acceptable limit on mutagenic impurities.

The issue was left outstanding by CHMP during the re-examination procedure for the following reasons:

- The initial method of detection proposed for potentially mutagenic impurities could only warrant a level below 1000 ppm (particle per million), which was considered as insufficient
- A finer method allowing for detection at the 1 ppm level was developed to address CHMP requirement but could not be available before the end of the initial assessment.
- The relevant sections of the marketing authorization dossier could not be updated during the re-examination procedure because the legislation does not allow new data to be submitted during a re-examination procedure (Article 62(1) paragraph 5 of Regulation (EC) No 726/2004).

The actual content of mutagenic impurities in masitinib is in fact well below the limit considered as acceptable by the CHMP for oncology indications, and is in line with the limits recommended as per guidance for non-oncology indications. Indeed, the actual content of potentially mutagenic impurities in masitinib is in the range of 5 ppm to 20 ppm, whereas an upper limit of 830 ppm was considered as acceptable by the CHMP for oncology indications, and a limit between 17 ppm and 33 ppm is recommended for non-oncology indications in a recent guidance from 2013 (ICH M7 draft guidance EMA/CHMP/ICH/83812/ 2013).

Therefore, it can be confirmed that the actual content of mutagenic impurities is not a concern for the Health authorities for the continuation of the clinical program of masitinib both in oncology and non oncology indications as well for future marketing authorization applications.

AB Science confirms that the masitinib program of clinical development in oncology and non oncology continues and that the next indication for which decisive end of phase 3 data is expected is mastocytosis.

About ICH M7 draft guidance EMA/CHMP/ICH/83812/ 2013

The guidance ICH M7 draft guidance EMA/CHMP/ICH/83812/ 2013 on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk" states that "in clinical development, using less than lifetime (LTL) concept, a daily intake of mutagenic impurities of 120µg/day are acceptable for treatment duration of less than 1 month, daily intake of mutagenic impurities of 20µg/day are acceptable for treatment duration of up to 12 months, and daily intake of mutagenic impurities of 10µg/day are acceptable for treatment duration of up to 10 years."

In case of masitinib used at the maximum dose of 6 mg/kg/day in non-oncology indications , this translates to a limit of 33 ppm for studies of a treatment duration of up to one year, and 17 ppm for studies with a treatment duration of more than one year. All studies with masitinib in non-oncology have a duration of less than one year, except multiple sclerosis study with a duration of two years.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel 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. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumor regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system 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 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. 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, and is pursuing thirteen phase 3 studies in human medicine in first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, 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's website: www.ab-science.com

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