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AB Science Announces Positive Top-Line Results from Phase 3 Trial of Masitinib in Adults with Severe Systemic Mastocytosis

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today announced that that a phase 3 study evaluating masitinib in the treatment of adult patient with severe systemic mastocytosis has met its primary objective well as all its secondary objectives

Top-line results will be detailed in the coming days.

About the phase 3 study in severe systemic mastocytosis

The phase 3 study was designed to evaluate masitinib efficacy and safety in severe systemic mastocytosis patients, with or without D816V mutation of c-Kit. The primary objective of the phase 3 study was to detect a statistically significant difference between masitinib (plus concomitant symptomatic treatments) and placebo (plus concomitant symptomatic treatments) in cumulative response on four severe symptoms, referred to also as handicaps.

Patients enrolled in the phase 3 study had between one and four of the following severe mastocytosis-related symptoms at baseline:

- Pruritus score ≥ 9
- Number of flushes per week ≥ 8
- Depression measured by the Hamilton rating scale (HAMD-17) score ≥ 19
- Asthenia measured by the Fatigue Impact Scale total score ≥75

The study enrolled 135 patients with severe systemic mastocytosis.

Primary objective:

Primary analysis (referred to as "4H75% response") was based on the comparison between masitinib and placebo in the number of actual responses between week 8 and week 24 divided by the total number of possible responses over the same treatment period. At each patient evaluation between weeks 8 and 24, each of the above four severe symptoms was evaluated. An improvement ≥ 75% with respect to baseline in one symptom represented one positive treatment response.

Secondary objectives:

Secondary analyses were based on the following endpoints:

- Cumulative 75%-response rate for pruritus (1H75% response)
- Cumulative 75% response rate on the handicaps of pruritus or flushes (2H75% response)
- Cumulative 75% response rate on the handicaps of pruritus or flushes or depression (3H75% response)
- Mean change in tryptase level relative to baseline at week 24, in patients with baseline level ≥20 µg/L.

The symptoms of pruritus and flush are well-recognized to be associated with mast cell activation in mastocytosis.

Depression is a symptom that has an important impact on quality of life of patients suffering from mastocytosis, and is therefore of high clinical relevance.
Tryptase is a biological product released by mast cells and an established marker of mast cell burden and activity.

Targeted population with masitinib in mastocytosis

Mastocytosis is an orphan disease characterized by an abnormal proliferation or activation of mast cells either in the skin or in bone marrow or other organs. Mastocytosis comes in two main forms: indolent and aggressive. Indolent forms of mastocytosis can be either cutaneous or systemic. The prevalence of indolent systemic mastocytosis, including smoldering systemic mastocytosis, is estimated to be 1/26,000 in Europe[1]. The symptoms and handicaps are severe in about one third of the patients; hence, an estimated target population for masitinib of approximately 1/78,000 of the general population.

Since the prevalence of indolent forms of systemic mastocytosis is reputed to be comparable across countries, the target population for masitinib could reach 10,000 adult patients in the USA and in Europe.

1: Prevalence of rare diseases: Bibliographic data, Orphanet Report Series, Rare Diseases collection, July 2015, Number 1: Listed in alphabetical order of disease or group of diseases.
http://www.orpha.net/orphacom/cahiers/docs/GB/Prevalence_of_rare_diseases_by_alphabetical_list.pdf

Orphan Drug Status

Masitinib has been granted orphan drug status in mastocytosis by both FDA and EMA.
There is currently no drug approved for the treatment of indolent mastocytosis.
Masitinib is the first drug to be evaluated in phase 3 in the indolent form of mastocytosis, systemic or not, severe or not.

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 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 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, T-cell lymphoma, mastocytosis, severe asthma uncontrolled by oral corticosteroid, 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: http://www.ab-science.com

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markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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