AB SCIENCE

Emerging pharmaceutical company in targeted therapies

OVERVIEW OF 2015 AND PERSPECTIVES FOR 2016

JANUARY 2016

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OVERVIEW OF 2015

PERSPECTIVES FOR 2016

CLINICAL DEVELOPMENT OF MASITINIB

Masitinib is a tyrosine kinase inhibitor targeting mast cells and macrophages and developed in thirteen phase 3 indications in oncology, in neurology, and in inflammatory diseases.

Indications with phase 3 on-going with masitinib

Oncology Digestive cancers
GIST L1
GIST L2
Pancreatic cancer
Metastatic colorectal cancer in 2nd line
Oncology - Heamatology
Multiple Myeloma in 2nd Line
Peripheral T-cell lymphoma
Oncology - Hormonal cancer and other cancer
MCR Prostate Cancer in 1st line
Melanoma with Kit JM mutation
CNS disease
Amyotrophic lateral sclerosis
Progressive forms of multiple sclerosis
Alzheimer's diseases
Inflammatory diseases
Severe systemic Mastocytosis
Severe asthma uncontrolled by oral corticosteroids

POSITIVE PHASE 3 IN MASTOCYTOSIS

The phase 3 study of masitinib in severe systemic mastocytosis was successful.

- **Claim**
  - Treatment of adult patients with smouldering or indolent systemic mastocytosis with severe handicaps unresponsive to optimal symptomatic treatments
  - Rare disease caused by mutations in the tyrosine kinase KIT and characterized by proliferation and accumulation of mast cells in various tissues, causing a wide variety of clinical manifestations
  - Estimated 10,000 patients in the USA and in the EU in the claim
- **Orphan Drug status at FDA and EMA for masitinib**
- **Phase 3 Design**
  - Masitinib was compared to placebo, on top of optimal symptomatic treatment before baseline and throughout the study
  - 222 patients enrolled: 135 severe systemic mastocytosis for primary efficacy and safety analysis and 87 other (cutaneous mastocytosis and non severe systemic mastocytosis) for descriptive safety analysis only
  - Pre-specified primary efficacy endpoint: Response rate on 4 severe symptoms: Pruritus, Flushes, Hamilton rating scale for depression (HAMD-17), Fatigue Impact Scale (FIS)
  - 24 week treatment period, with possible extension
  - 15 participating countries: Austria, Czech Republic, France, Germany, Greece, India, Italy, Latvia, UK, USA, Poland, Russia, Slovakia, Spain, Switzerland

POSITIVE PHASE 3 IN MASTOCYTOSIS

The phase 3 study in mastocytosis was positive on the pre-specified primary endpoint and other secondary endpoints.

❖ Successful primary analysis

	Masitinib	Placebo	p-value	Odd ratio
4H75%: Cumulative 75% response rate on pruritus or flushes or depression or fatigue	**18.7%**	**7.4%**	**0.0076**	**3.63**

❖ Successful secondary analyses

	Masitinib	Placebo	p-value	Odd ratio
3H75%: Cumulative 75% response rate on pruritus or flushes or depression	24.7%	9.8%	0.0071	3.06
2H75%: Cumulative 75% response rate on pruritus or flushes	27.2%	10.7%	0.038	2.63
Pruritus 75% : Cumulative 75% response rate on the handicaps of pruritus	22.0%	7.3%	0.0322	3.13

❖ Successful analyses on objective markers of mast cell activation

	Masitinib	Placebo	p-value
Tryptase relative change from baseline Mean±SD	-18 ± 21.4	2.2 ± 26.9	0.0001
Relative change from baseline in the Body Surface Area covered by the Urticaria Pigmentosa corrected with Wallace formula	-12.34(26.41)	15.91(59.79)	0.0210
Darrier sign disappearance for patients with “Darrier sign” at baseline	18.92%	2.70%	0.0187

❖ Response sustainable at two years

	Masitinib	Placebo	p-value	Odd ratio
4H75% over W8 – W96 period	17.2%	7.1%	0.0102	3.37
3H75% over W8 – W96 period	22.1%	8.6%	0.0030	3.10

The objective to de-risk the phase 3 program in particular in non-oncology through futility analyses was successfully achieved in 2015.

- Futility tests were performed, primarily in non-oncology indications which present the greatest uncertainty, in order to concentrate investments only on projects presenting a probability of success greater than 50%
  - Futility test were performed with conditional power of 20%
  - This is equivalent to a predictive probability of success of 46% with the pre-planned resampling option at interim analysis
- Based on these tests
  - The following phases 3 were continued:
    - Severe asthma uncontrolled by oral corticosteroids
    - Alzheimer's disease
    - Progressive forms of multiple sclerosis
    - Amyotrophic lateral sclerosis
    - Melanomas expressing juxta-membrane mutation of c-Kit
  - The clinical development in rheumatoid arthritis was stopped

OVERVIEW OF 2015 - PUBLICATIONS RELATED TO MASITINIB

Publications related to masitinib in 2015 confirmed the interest for masitinib in oncology and neurology.

❖ Pancreatic cancer

Ann Oncol. 2015 Jun. A randomized, placebo-controlled phase III trial of masitinib plus gemcitabine in the treatment of advanced pancreatic cancer. Deplanque G et al.

❖T-cell lymphoma

Abstract on on-going phase 3 study was presented at American Society of Hematology (ASH) 2015 Annual Meeting (December 5-8, in Orlando, US)
And will be presented at the Annual T-cell Lymphoma Forum (January 28-30, 2016, in San Francisco, California

❖Colorectal cancer

Abstract on on-going phase 2 study was presented in congress 2015 American Society of Clinical Oncology (ASCO) Annual Meeting (May 29 – June 2 in Chicago, Illinois, US)
And at the European Cancer Congress 2015 in Vienna (25-29 September 2015)

❖Melanoma

Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2015 Dec;159(4):695-7. Rapid and clinically significant response to masitinib in the treatment of mucosal primary esophageal melanoma with somatic KIT exon 11 mutation involving brain metastases: A case report. Prosvicova J et al.

❖Multiple sclerosis

Neurotherapeutics. 2016 Jan 4. Therapeutic Advances and Future Prospects in Progressive Forms of Multiple Sclerosis. Shirani A et al.
Inflamm Allergy Drug Targets. 2015. A systematic review of drugs in late-stage development for the treatment of multiple sclerosis: a focus on oral synthetic drugs. Safavi M et al.

❖Alzheimer's disease

Expert Rev Neurother. 2015 Jun. Masitinib for the treatment of mild to moderate Alzheimer's disease. Folch J et al.

❖Ischemic Stroke

Naunyn Schmiedebergs Arch Pharmacol. 2015 Jan. Neuroprotective effect of masitinib in rats with postischemic stroke. Kocic I et al.

AB Science continued to develop its capabilities to accelerate its clinical development program with more than 1,000 patients recruited in 2015.

- Around 140 employees with AB Science, primarily dedicated to clinical development program
- Studies carried out in more than 30 countries, in Europe, Asia, North America, and Latin America
- Above 1,000 patients enrolled in the clinical program in 2015
- Around 4,000 patients already enrolled into masitinib clinical development program

AB Science has cash until S1 2017, which is the expected period for registration in mastocytosis.

- Anticipated annual cash burn : 20M€
- Cash as of end S1 2015 : 29M€
- Funding after S1 2015 : 11.4M€
  - Equity raised in S2 2015: 7.4M€
    - 6M€ through PACEO
    - 1.4M€ through exercise of BSPCE et stock-options
  - Research Tax Credit to be collected : 4M€
- Equity line in place with SocGen and CACIB (Credit Agricole Investment Banking)

OVERVIEW OF 2015

PERSPECTIVES FOR 2016

UPCOMING NEWSFLOW

13 significant news are expected in 2016 and 2017.

Indications and expected timelines	Q1 2016	Q2 2016	Q3 2016	Q4 2016	S1 2017	S2 2017
Indolent Systemic Mastocytosis	Filing				Registration[1]	
Severe asthma uncontrolled with OCS				Interim Analysis		
Amyothrophic Lateral Sclerosis (ALS)	Interim Analysis			Final Analysis		Registration[2]
Alzheimer's disease					Interim Analysis	
Progressive forms of multiple sclerosis					Interim Analysis	
Metastatic melanoma with JM mutation of c-KIT					Interim Analysis	
Pancreatic cancer					Interim Analysis	
T-cell lymphoma		Futility analysis			Interim Analysis	
GIST in second-line treatment						Interim Analysis

1: Subject to review by competent authorities
2: Subject to positive phase 3 results, possibly earlier if interim analysis is successful

UPCOMING NEWSFLOW

Significant news expected include:

- 2 possible registrations
  - Severe systemic mastocytosis
  - Amyotrophic lateral sclerosis
- 1 final phase 3 result
  - Amyotrophic lateral sclerosis
- 8 results from interim analyses
  - Severe asthma uncontrolled with oral corticosteroids
  - Alzheimer's disease
  - Progressive forms of multiple sclerosis
  - Metastatic melanoma with JM mutation of c-KIT
  - Pancreatic cancer
  - T-cell lymphoma
  - GIST in second-line treatment

Here are the target prices of the analysts covering AB Science after integration of mastocytosis phase 3 study results:

Keay Nakae (USA) Chardan Capital Markets, LLC **knakae@chardancm.com**	Target Price: 30.00€ - Buy
Sébastien Malafosse (France) Oddo Securities - Oddo & Cie **smalafosse@oddo.fr**	Target Price: 40.20€ - Buy
Arnaud Guerin (France) Portzamparc Société de Bourse **guerin@portzamparc.fr**	Target Price: 27,50€ - Buy