

Emerging pharmaceutical company in targeted therapies

Assemblée Générale AB Science du 29 juin 2018

ORGANISATION

AB Science has completely reorganized its clinical development department, with the appointment of 7 new highly experienced professionals.

New positions

- Jean-Pierre Lehner (MD) : Scientific Senior Vice-President
 - MD, 30 years of industry experience, with more than 20 years of experience at Sanofi
 - Former Chief Medical Officer and Senior Vice President of Sanofi until 2012, in charge of global regulatory affairs, pharmacovigilance, and medical affairs.
 - Participated to the registration of 30 drugs throughout his career.
- Medical Director
 - MD, 30 years of industry experience.
 - Previously head of regulatory and medical affairs for emerging markets at Sanofi.
- Director of Quality Assurance
 - 21 years of industry experience, 7 years as CEO of a company specialized in Quality Management, 14 years of experience as of Head of Quality and COO.
- Head of clinical development
 - MD, 20 years experience at Boehringer-Ingelheim.
 - Previously Regional Director of Clinical Operation for Asia Pacific and Japan at Boehringer-Ingelheim.

Replacement

- Director of Pharmacovigilance and Clinical Safety
 - MD, 20 years of industry experience, 13 years of as Managing Director and Head of Medical Affairs of mid-size CRO;
 - 7 years with Serono as Head of Worldwide Corporate Clinical Safety
- Head of Biometry

16 years of experience in quantitative research & data analysis, including 7 years with GSK and Pfizer.

- Director of Data Management and IT systems
 - 15 years experience in Data Management and IT systems. Previously head of R&D IT systems at Menarini.



ORGANISATION

AB Science is proud that Olivier Hermine, co-founder and chairman of the scientific committee of AB Science, was appointed to the French Académie des Sciences.



Olivier Hermine

- Professor in hematology in the Paris-Descartes University
- Head of the hematological department at the Necker-Enfant maladies hospital
- Leader of the CALYM team "Molecular Mechanisms of Hematologic Disorders and Therapeutic Implications" at the Imagine institute Inserm U 116 CNRS ERL 8654.
- Coordinator of the Reference center of mastocytosis (CeRemast).
- His research interests include lymphoproliferation linked to hepatitis C virus, mantle cell lymphomas and regulation of erythropoiesis.

HIGHLIGHTS



ANSM Hold

- AB Science has upgraded its organization, management seniority, processes and tools related to clinical development.
- AB Science is in close contact with ANSM to resume the clinical studies in France.

Masitinib in ALS

- Masitinib is recognized by the scientific community as a promising drug in amyotrophic lateral sclerosis (ALS)
- AB Science is currently validating through a scientific advise with EMA the design of a confirmatory phase 3 in ALS, which is expected to start in 2018
- AB Science intends to discuss with EMA the possibility to resubmit a conditional marketing authorization for masitinib in ALS based on the final results from the phase 2/3 study AB10015.

NEWSFLOW ANTICIPATED FOR 2018 AND 2019

AB Science generated two phase 3 with positive results and expects significant milestones in the coming months. Certain analyses were postponed in order to ensure they were carried out within the new quality system. Initiation of confirmatory studies is postponed until lifting of the ANSM clinical hold, to ensure GCP compliance from the start for these studies.



Indications	Statut	Next Steps
Inflammatory diseases		
Indolent Systemic Mastocytosis	 Positive phase 3 	 Q4 2018² : Initiation of phase 3 confirmatory study
Severe asthma uncontrolled with OCS	 Enrolment completed 	 Q4 2018¹ : Final analysis
Neurology		
Amyothrophic Lateral Sclerosis (ALS)	 Positive phase 3 	 Q4 2018² : Initiation of phase 3 confirmatory study
Alzheimer's disease	 Study non-futile 	 Q4 2018¹ : Interim analysis Q2 2019¹ : Final analysis
Progressive forms of multiple sclerosis	 Enrolment completed Interim analysis : No need to increase the number of patients to be enrolled 	 Q2 2019¹ : Final analysis
Oncologie		
Metastatic refractory prostate cancer (mRCPC)	 Interim analysis completed Continuation in a subpopulation with 468 patient, calculated to have a probability of success above 80% in the selected sub-population 	 2019¹ : Final analysis
Pancreatic cancer	 Enrolment on-going 	 Q4 2018¹ : Interim analysis 2019¹ : Final analysis
Refractory colorectal cancer	 Enrolment on-going 	 Q3 2018¹ : Trend analysis 2019¹ : Final analysis
Refractory Ovarian cancer	 Enrolment on-going 	 Q4 2018¹ : Trend analysis 2019¹ : Final analysis

1: Subject to pace of patient enrolment in the studies 2: With lifting of ANSM clinical hold