

AB2 Bio appoints Michael Soldan CEO

Experienced industry executive to prepare market entry of lead product, Tadekinig alfa to treat HLH and other rare, orphan diseases

Lausanne (Switzerland), March 3, 2020 — AB2 Bio Ltd, a Swiss advanced clinical-stage biotech company, specialized in developing innovative therapies for the treatment of severe systemic autoinflammatory diseases including rare diseases with high unmet medical needs, announces the appointment of the experienced pharmaceutical executive Michael Soldan, PhD as its Chief Executive Officer.

Dr Soldan joins from global healthcare company Fresenius Kabi, where he was CEO of the Global Biosimilars Business located in Switzerland, responsible for the successful creation, development, launch and commercialization of biosimilars in the U.S., Europe and other parts of the world. He has an extensive background in general management, drug commercialization, business development and regulatory affairs as well as experience of integrating businesses.

Prior to Fresenius Kabi, Dr Soldan was with Merck Group, where he spent two years heading the biosimilars business. He has also held a number of senior regulatory and clinical positions with companies including Boehringer Ingelheim, Biotest, Grünenthal and Aventis Behring. He holds a degree in Pharmacy and a PhD in Pharmacology from Philipps University Marburg, Germany.

“I am very pleased to welcome Michael Soldan to AB2 Bio, where he will bring the benefit of his impressive and wide-ranging career in the pharmaceuticals industry. Dr Soldan’s extensive experience in manufacturing and regulatory affairs is of direct relevance to prepare the next phase of development of AB2 Bio as we continue the pivotal Phase 3 trial of Tadekinig alfa in patients with monogenic, interleukin-18 driven autoinflammatory conditions and progress it towards market,” says Prof. Andrea Pfeifer, AB2 Bio’s Chairwoman.

About the Pivotal Phase 3 Trial

AB2 Bio is conducting a [pivotal Phase 3 clinical trial](#) of Tadekinig alfa in primary, interleukin-18 driven Hemophagocytic Lymphohistiocytosis (HLH) patients with NLRC4 mutation or XIAP deficiency. The primary completion of the trial is expected in 2020.

About HLH

People with HLH usually develop symptoms within the first months or years of life. Symptoms may include fever, enlarged liver or spleen, cytopenia (decreased number of blood cells), and neurological abnormalities. All forms of HLH, including cases treated adequately, may have a high mortality rate. The long-term outlook (prognosis) of familial forms without treatment is poor, with a median survival of less than 2 months to 6 months after diagnosis. These disorders can be either inherited (familial or primary) or secondary to other conditions (rheumatic diseases, cancer or infections) such as Macrophage Activation Syndrome (MAS), a severe complication of rheumatic diseases. NLRC4 mutations and XIAP deficiency are part of primary HLH. Single point mutations in the NLRC4 gene have been identified which give rise to severe, life-threatening systemic inflammation associated with extremely high levels of IL-18, the therapeutic target of Tadekinig alfa.

About Tadekinig alfa

Tadekinig alfa is a recombinant interleukin-18 binding protein (r-hIL-18BP), that binds with high affinity to IL-18, a major inflammatory mediator, and is administered subcutaneously. The IL-18/IL-18BP balance is disrupted in patients with inflammatory diseases, resulting in high levels of free and active IL-18, which leads to pathological inflammation. Administration of Tadekinig alfa restores the IL-18/IL-18BP balance, by removing free IL-18 and thereby reducing inflammation.

Tadekinig alfa is also Phase 3-ready for two additional indications: Macrophage Activation Syndrome (MAS) and Still's Disease. It has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) for the treatment of HLH and Still's disease, including Adult-onset Still's Disease and systemic Juvenile Idiopathic Arthritis, and by the European Medicines Agency (EMA) for the treatment of HLH. In addition, the FDA has granted Breakthrough Therapy Designation for the treatment of monogenic, IL-18 associated autoinflammatory conditions with ongoing systemic inflammation, and Rare Pediatric Disease Designation for the treatment of primary HLH.

About AB2 Bio

AB2 Bio Ltd (www.ab2bio.com) is a private advanced clinical-stage biotech company located in the Innovation Park at the Ecole polytechnique fédérale de Lausanne (EPFL), Switzerland. AB2 Bio is focused on developing best in class innovative therapies, which will not only treat the symptoms but also target the underlying causes of inflammation-based diseases with large unmet medical needs.

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