InFlectis BioScience

Press release

InFlectis BioScience IFB-088 enters phase-1 clinical trial

Nantes, France – May 22th, 2018. InFlectis BioScience SAS, a drug discovery company committed to the development of innovative therapeutics harnessing the Integrated Stress Response for the treatment of a broad range of diseases, today announced that the French National Agency for Medicines and Health Products Safety (ANSM) approved the Company's Clinical Trial Application (CTA) to begin a Phase 1 study of IFB-088 (study P-188). First results from the study are expected in the first half of 2019. This study will provide the safety data necessary for Phase 2 studies in Charcot-Marie-Tooth (CMT) patients that are expected to begin end of 2019.

A Clinical Trial Application (CTA) was submitted to ANSM in March 2018 for a phase 1 clinical trial to investigate the safety, tolerability and pharmacokinetics of IFB-088 when administered in single and multiple doses in healthy volunteers. It was approved on May 18th, 2018. This Phase 1 trial of IFB-088 follows a standard single ascending dose and multiple ascending dose design with the enrolment of 72 healthy volunteers.

Following the successful completion of the Phase 1 study, InFlectis BioScience will transition the IFB-088 program into a Phase 2 clinical trial to test the drug treatment's efficacy in treating patients with Charcot-Marie-Tooth disease. Based on preclinical evidences and proofs of concept in CMT1A and CMT1B animal models, the European Commission and the Food and Drug Administration (FDA) have both already granted orphan drug designation (ODD) to IFB-088 in CMT.

Philippe Guédat, Président and CEO of InFlectis BioScience *SAS said: "We are very pleased to have received the authorization to initiate a human clinical trial with IFB-088. Entering the clinic represents a significant step for IFB-088 and one step closer to reaching CMT patients who are suffering from this rare and debilitating neuropathy. In addition to CMT, the drug might also be assessed in the future in other degenerative pathologies for which InFlectis has already obtained preclinical efficacy in animal models".*

Notes for editors:

ABOUT IFB-088 (also known as Sephin1)

IFB-088 is a first-in-class orally available small molecule drug candidate with a validated mechanism of action and a promising pharmacokinetic profile for targeting the central and peripheral nervous system. IFB-088 is a selective inhibitor of PPP1R15A (GADD34), a stress-induced PP1 phosphatase regulatory subunit involved in the unfolded protein response. PPP1R15A inhibition by IFB-088 regulates the protein translation rate in stressed cells to a level manageable by the available cellular proteins that assist in protein folding (so-called "chaperones"), thereby restoring proteostasis. IFB-088 is strikingly specific for stressed cells, avoiding persistent inhibition of protein synthesis in normal, non-stressed cells.

ABOUT A CLINICAL TRIAL APPLICATION (CTA)

The French National Agency for Medicines and Health Products Safety (ANSM), the pharmaceutical regulatory body in France, requires that a Clinical Trial Application (CTA) is filed and approved before the start of a clinical trial in France. This process is equivalent to the IND-filing process with the U.S. Food and Drug Administration (FDA).

All studies involving a medical or therapeutic intervention on healthy volunteers or patients must be approved by a supervising ethics committee before permission is granted by ANSM to run the trial. In France and in the EU, they are called Ethics committees. In the US, this body is called the Institutional Review Board (IRB).

Data from trials conducted in France may be used as the basis for filing an IND with the FDA or CTA with the European Medicines Agency for additional or later-stage trials.

ABOUT INFLECTIS BIOSCIENCE (www.inflectisbioscience.com)

InFlectis BioScience is a clinical stage company committed to the development of innovative therapeutics harnessing the Integrated Stress Response (ISR) for the treatment of a broad range of diseases. The company plans to demonstrate the clinical effectiveness of its drug candidate IFB-088 for the treatment of Charcot-Marie-Tooth diseases type 1A (CMT-1A) and 1B (CMT-1B). The company is also developing IFB-088 for the treatment of rare eye diseases. Meanwhile, InFlectis BioScience develops new chemical series for the treatment of non-orphan diseases. Based in Nantes in Western France, InFlectis BioScience is part of the science park of the economic area of Nantes Atlantique.

INFLECTIS BIOSCIENCE SAS

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