

**PRESS RELEASE**

**InFlectis BioScience Announces Successful Completion of Phase 1 Clinical Trial of Oral IFB-088**

***Results show IFB-088 is safe and well tolerated in healthy volunteers  
Data supports initiation of Phase 2 trial in Charcot-Marie-Tooth disease***

**For Immediate Released  
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**Nantes, France** – 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 the results of its Phase 1 study of IFB-088, an oral small molecule targeting the stress-induced PPP1R15A/PP1c phosphatase complex, in 72 healthy volunteers. Results of this randomized, double-blind, placebo-controlled, single- and multiple-dose escalation study (SAD/MAD) demonstrated that administration of IFB-088 was safe and well tolerated. No serious adverse events, dose-limiting toxicities, or clinically significant abnormalities were observed. The pharmacokinetic parameters were consistent with data derived from extensive studies in animal models.

Anne Visbecq, Chief Medical Officer of InFlectis BioScience SAS, said: *"We are very pleased with the outcomes of the IFB-088 Phase 1 trial, which confirm the good tolerance profile of IFB-088 even in high dose groups. No safety concern has been identified and pharmacokinetics were as expected."*

*"Results from this study provide the first clinical data for IFB-088 and creates a path forward for its evaluation as a potential first-in-class oral therapeutic treatment of CMT disease,"* commented Philippe Guédât, Ph.D., President and Chief Executive Officer, InFlectis BioScience. *"We look forward to working towards a U.S. and EMA IND filing in the coming months."*

**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 improves protein homeostasis following a stress (e.g., misfolded protein accumulation, oxidative stress, etc.) activating the Unfolded Protein Response or the Integrated Stress Response observed in several neurodegenerative disorders, including CMT. IFB-088 is targeting the stress-induced PPP1R15A/PP1c phosphatase complex involved in dephosphorylation of translation initiation factor eIF2 $\alpha$ . Thus, IFB-088 regulates the protein translation rate in stressed cells to a level manageable by 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 THE IFB-088 PHASE 1 P188 CLINICAL TRIAL**

The Phase 1 P188 clinical trial, conducted in France, was a randomized, double-blind, placebo-controlled, single (SAD) and multiple ascending dose (MAD) study of IFB-088, designed to evaluate the safety, tolerability and pharmacokinetics of IFB-088 in healthy subjects. The study enrolled 72 adult male volunteers into 6 SAD cohorts of 8 subjects, with IFB-088 given orally as single doses ranging from 2.5 mg to 60 mg daily, and 3 MAD cohorts of 8 subjects, with IFB-088 given orally at doses ranging from 15 to 50 mg/day for 14 consecutive days.

## **ABOUT INFLECTIS BIOSCIENCE ([www.infectisbioscience.com](http://www.infectisbioscience.com))**

InFlectis BioScience is a France-based clinical stage company committed to the development of innovative therapeutics harnessing the Integrated Stress Response for the treatment of a broad range of diseases. Dysregulation of Integrated Stress Response (ISR) signaling has important pathologic consequences linked to neurodegenerative diseases, inflammation and cancers. Harnessing the ISR by the pharmacological modulation of eIF2 $\alpha$  dephosphorylation to restore cellular homeostasis, is a new frontier pioneered by InFlectis BioScience since 2013. Through its unique and selective mode of action on the ISR, InFlectis BioScience is developing a breakthrough pharmacological approach that, for the very first time, has the potential to treat a wide range of diseases caused by various genetic mutations. Thus, the benefit of modulating eIF2 $\alpha$  dephosphorylation with small chemical compounds, like IFB-088, was demonstrated in validated animal models of Charcot-Marie-Tooth (CMT), Amyotrophic Lateral Sclerosis (ALS) and Multiple Sclerosis (MS). The primary focus of InFlectis BioScience is the development of novel therapeutics that improve the life of patients with CMT, the most common inherited neurological disorder. InFlectis is also contemplating other promising therapeutic indications among neuro-degenerative diseases, inflammation and cancers. Based in Nantes in Western France, InFlectis BioScience is part of the science park of the economic area of Nantes Atlantique.

## **INFLECTIS BIOSCIENCE SAS**

### **Philippe Guédât**

President and CEO

[philippeguédât@infectisbioscience.com](mailto:philippeguédât@infectisbioscience.com)

### **Pierre Miniou**

Chief Operating Officer

[pierreminiou@infectisbioscience.com](mailto:pierreminiou@infectisbioscience.com)