Press release

InFlectis BioScience announces favorable results for IFB-088 Phase 1 Single Ascending Dose clinical trial

- **IFB-088 observed to have a favorable safety, tolerability and pharmacokinetic profile in the Phase 1 trial**
- **IFB-088 is advancing into a Multiple Ascending Dose part of the phase 1 trial to support a future Phase 2 trial in Charcot-Marie-Tooth disease**

Nantes, France – May 15th, 2019. 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 favorable results from the Single Ascending Dose (SAD) part of the Phase 1 trial (P188) that evaluated six single doses of IFB-088 administered by oral route. IFB-088, a selective inhibitor of stressed-induced PPP1R15A/PP1c phosphatase complex, is planned to be developed primarily for the treatment of Charcot-Marie-Tooth disease.

The SAD part of the double-blind, randomized, placebo-controlled Phase 1 trial evaluated the safety, tolerability and pharmacokinetics of six doses of IFB-088 in a total of 48 healthy volunteers. Results demonstrated IFB-088 to be well tolerated at doses ranging from 2.5 mg to 60 mg daily, with linear human pharmacokinetics over the dose range tested. IFB-088 was observed to show a favorable safety and tolerability profile with no serious adverse events at all doses tested within the trial.

Based on the favorable results of the SAD part, the Company is preparing to initiate the Multiple Ascending Dose (MAD) part of the Phase 1 study. The MAD will be conducted according to a double-blind, randomized, placebo-controlled, multi oral ascending dose design and will assess the safety, tolerability and pharmacokinetics of three doses of IFB-088 administered to healthy volunteers over 14 days.

Following the successful completion of the Phase 1 study planned by year end, InFlectis BioScience will transition the IFB-088 program into Phase 2 clinical trials to test the drug treatment in patients with Charcot-Marie-Tooth diseases 1A and 1B. 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 for the treatment of Charcot-Marie-Tooth diseases. Additional preclinical data will be presented at Peripheral Nerve Society annual meeting in Genoa, Italy in June 2019 and will highlight the activity of IFB-088 as a potent and selective agent to improve the clinical signs of neuropathy in CMT1A and in CMT1B.

During the remainder of 2019, preparation for the phase 2 program of IFB-088 in Charcot-Marie-Tooth patients will also include a pre-Investigational New Drug meeting with the U.S. Food and Drug Administration and a Protocol Assistance with the European Medicines Agency to discuss the IFB-088 development strategy in CMT.

Anne Visbecq, Chief Medical Officer of InFlectis BioScience SAS said*: "We are pleased with the outcome of the IFB-088 SAD part of Phase 1 trial, which confirms the good tolerance profile of IFB-088. We are planning to initiate the MAD part in healthy volunteers during the summer of 2019 with completion expected in the fourth quarter. This trial will be important in the development plan of IFB-088 in Charcot-Marie-Tooth disease".*

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…) 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 eIF2α. Thus, 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 THE IFB-088 PHASE 1 P188 CLINICAL TRIAL

The Phase 1 P188 clinical trial, which is being conducted in France, is a randomized, double-blind, placebo-controlled, single and multiple ascending dose study of IFB-088, designed to evaluate the safety, tolerability and pharmacokinetics of IFB-088 in healthy subjects. The Phase 1 P188 clinical trial will enrolled 72 healthy adult 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 for 14 days.

ABOUT INFLECTIS BIOSCIENCE (www.inflectisbioscience.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 eIF2α dephosphorylation to restore the cellular homeostasis, is a new frontier pioneered by InFlectis BioScience since 2013, based on many years of academic development. 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 whose etiology lies in different genetic mutations. Thus, the benefit of modulating eIF2α 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.

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