Paris, November 19, 2025

Bioprojet, in partnership with Harmony Biosciences in the United States, announces the launch of the first-in-human clinical trial of BP1.15205, an orexin receptor type 2 agonist, for central disorders of hypersomnolence.

BP1.15205 is a molecule that has demonstrated high potency and selectivity in preclinical studies, with a favorable safety profile and the potential for once-daily administration.

First clinical data are expected in 2026.

Bioprojet and Harmony Biosciences announce today the start of the Phase 1 clinical trial of BP1.15205, an orexin receptor type 2 (OX2R) agonist currently under development for the treatment of narcolepsy, idiopathic hypersomnia, and other central disorders of hypersomnolence.

The Phase 1 clinical trial is being conducted by Bioprojet Pharma in the European Union. It will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of BP1.15205 in healthy volunteers.

Earlier this year, Bioprojet and Harmony Biosciences presented comprehensive preclinical safety and efficacy data for BP1.15205 at the American Congress (SLEEP 2025) and the World Sleep Congress. Pharmacology studies confirmed that BP1.15205 is a highly potent and selective OX2R agonist. These data showed no potential adverse effects and a favorable safety and pharmacokinetic profile.

The orexin program represents a major expansion of our sleep-wake franchise. Orexin agonists could enhance our portfolio alongside pitolisant, allowing us to offer additional treatment options addressing the complex and individualized needs of patients suffering from narcolepsy and other central hypersomnolence disorders.

BP1.15205 is a molecule originally discovered by Teijin Pharma, for which Bioprojet entered into an exclusive development and commercialization licensing agreement. Additionally, Harmony Biosciences acquired a sublicense for the U.S. territory and committed to co-developing this molecule with Bioprojet.