

BIODOL Therapeutics Reports on Ongoing Phase 1 Clinical Study in Healthy Volunteers for BDT272, a FTL3 Negative Allosteric Modulator in Development for the Treatment of Pain Disorders

Montarnaud, France, 26 May 2025 – BIODOL Therapeutics, a company dedicated to developing innovative treatments for pain, today reports on the Phase I clinical trial for its lead candidate, BDT272. This novel compound is a Negative Allosteric Modulator (NAM) targeting the interaction between the FLT3 receptor and its ligand FL, and is being developed for the treatment of various pain disorders.

The first-in-human study is currently assessing the safety, tolerability, pharmacokinetics and pharmacodynamics of BDT272 in healthy volunteers. The trial includes single ascending dose (SAD), multiple ascending dose (MAD), and food effect (FE) cohorts. So far, BDT272 is well tolerated at plasma exposures exceeding anticipated therapeutic exposures and has good pharmacokinetic properties.

BDT272 is being developed for two oral treatment modalities:

- As a non-opioid monotherapy for peripheral neuropathies such as Post-Herpetic Neuralgia (PHN), Painful Diabetic Peripheral Neuropathy (PDPN), or Chemotherapy-Induced Peripheral Neuropathy (CIPN).
- As an adjuvant therapy for severe pain requiring opioid treatment including post-surgical pain and mixed nociceptive/inflammatory or inflammatory/neuropathic conditions – by enhancing morphine analgesia while preventing the development of morphine-induced tolerance and hyperalgesia, without exacerbating adverse effects like respiratory depression or constipation.

"Since the inception of BIODOL, our team has been committed to translating this innovation from bench to bedside. Receiving regulatory authorization to begin this first-in-human trial marked a significant milestone after years of dedicated work," said Fabien Granier, Chief Executive Officer of BIODOL Therapeutics. "With the Phase 1 study now underway, its completion will pave the way for proof-of-concept studies — a major source of hope for patients suffering from chronic pain conditions with few safe and effective treatment options".

About BDT272

BDT272 and its chemical series were claimed in a new composition-of-matter patent filed in October 2023 and are part of BIODOL's patent portfolio.

BDT compounds are novel FLT3 inhibitors, acting as a Negative Allosteric Modulator (NAM) of FL binding to FLT3. BDT are not inhibitors of the highly conserved intracellular kinase domain. BDT therefore display a higher selectivity, as compared to kinase inhibitors, and are expected to present better tolerability compared to existing intracellular FLT3 inhibitors. Moreover, as compared to an antagonist, the blocking efficacy of a NAM does not depend on the receptor activation level, possibly limiting response variability and increasing safety.



About Biodol Therapeutics

Biodol Therapeutics (<u>www.biodol.eu</u>), founded in 2015, specializes in developing first-in-class compounds for pain treatment. The company has identified the Receptor Tyrosine Kinase (RTK) FLT3 as a key driver in initiating and sustaining neuropathic pain (Nature Communications, 2018). Its groundbreaking research has also demonstrated that inhibiting FLT3 signaling eliminates opioid tolerance and hyperalgesia while preserving analgesic efficacy (Nature Communications, 2024). Biodol Therapeutics is focused on developing allosteric inhibitors of the FLT3 receptor to address various types of pain. The company holds exclusive rights to a portfolio of four patents and has received support from BPI France, SATT AxLR, Inserm Transfert, Région Occitanie, the French National Research Agency, SEMIA Incubator, and the Montpellier Business and Innovation Centre.

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