

Montis Biosciences Advances First-in-Class Dual-Action C1q Antibody with Strong Preclinical Proof-of-Concept in Neuroinflammatory Diseases

- Lead antibody MB0109 targets C1q and uniquely inhibits both classical complement cascade and C1q-mediated macrophage/microglial activation — two key drivers of neuroinflammation
- MB0109 demonstrated statistically significant disease-modifying activity in relevant in vivo models of demyelinating autoimmune diseases (EAN and EAE)
- Non-human primate PK/tox study showed favorable pharmacokinetics and excellent safety profile
- IND-enabling studies planned to start mid 2026; Phase 1 clinical trial targeted for mid-2027
- Dr. Federico Grossi appointed as clinical advisor and acting CMO to oversee clinical development

Leuven, Belgium – March 3, 2026 (08:30 CET) — Montis Biosciences, a privately held biotechnology company developing first-in-class C1q-targeting antibodies to treat neuroinflammatory diseases, today announced its lead program, MB0109, has demonstrated strong efficacy data in relevant in vitro and in vivo models of neuro-autoimmune diseases, and excellent safety and PK results in non-human primate (NHP) PK/toxicity studies.

Together, this preclinical data package supports further development of MB0109 as a differentiated therapeutic strategy for a broad range of complement- and macrophage-driven neuroinflammatory diseases. Montis is initially focused on establishing clinical proof of concept in demyelinating autoimmune neuropathies such as Guillain-Barré Syndrome (GBS) and Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP), which offer efficient clinical and regulatory development pathways. Additional potential indications include high-C1q subsets of Multiple Sclerosis (MS) and Vascular Dementia.

C1q is the initiating component of the classical complement pathway and plays a critical role in activating macrophages and microglia through receptor-mediated signaling. Dysregulated C1q activity drives both complement- and macrophage/microglia-mediated neuronal damage.

MB0109 is the first antibody known to inhibit both macrophage/microglia and classical complement activation, endowing it with a highly differentiated first-in-class dual mode of action. MB0109 uniquely binds to specific epitopes on the tail region of C1q, thereby blocking receptor-mediated activation of macrophages and microglia, while locking C1q in a conformation that inhibits classical complement activation. By modulating both pathways simultaneously, MB0109 uniquely addresses two key neuroinflammatory disease hallmarks. This differentiates the compound from existing complement therapeutics, known to exclusively focus on blocking complement activation.

“These studies confirm that MB0109 has the potential to offer meaningful relief to patients suffering from these devastating diseases as we pioneer the first ‘*beyond complement*’ class of therapeutics,” said **Gil Beyen, Chief Executive Officer of Montis Biosciences**. “MB0109 is truly a novel approach to modulating C1q and has broad potential for the treatment of complement- and macrophage-driven neuroinflammatory diseases. Its distinctive ability to inhibit both key disease drivers allows us to address what we believe to be the main drivers of these demyelinating disorders.”

Preclinical data from relevant in vitro studies and multiple in vivo studies involving both the experimental autoimmune neuritis (EAN) and the experimental autoimmune encephalomyelitis (EAE) models highlight MB0109’s strong efficacy. These widely used preclinical models are highly relevant for neuroinflammatory indications, including GBS, CIDP and multiple sclerosis.

Top-line data from the NHP assessment of MB0109 show a favorable pharmacokinetics profile and excellent tolerability, based on a dose-escalation study of up to 200 mg/kg.

Montis is submitting the data for presentations at upcoming scientific conferences and for publication in peer-reviewed journals. The start of a Phase 1 clinical trial is targeted by mid 2027.

To initiate and supervise the company’s clinical development, Montis was proud to appoint Dr. Federico Grossi, MD, PhD, as clinical & medical advisor and acting Chief Medical Officer. Federico brings extensive translational and clinical development expertise from his tenure as head of clinical development and CMO at Apellis Pharmaceuticals, where he led multiple complement-targeting programs from discovery through to late-stage development and commercialization.

Montis Biosciences (www.montisbio.com) is developing first-in-class C1q-targeting antibodies for the treatment of neuroinflammatory diseases. Montis’ lead program, MB0109, delivers a unique dual mechanism, potently blocking C1q-driven macrophage/microglial activation and simultaneously inhibiting classical complement activation (CCA). This highly differentiated antibody has generated strong in vitro and in vivo proof-of-concept data in support of its development to treat neuro-autoimmune indications. Montis is backed by a high-quality investor syndicate, including DROIA Ventures, Pfizer Ventures, ALSA Ventures and Polaris Innovation Fund.

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