Press Release

MonTa Biosciences Initiates Expansion Phase with Systemic TLR7 Agonist MBS8 in Checkpoint-Resistant Melanoma Amid Renewed Momentum in the TLR7 Field

Copenhagen, Denmark – February 27, 2026 — MonTa Biosciences, a Copenhagen-based clinical-stage biotech company developing next-generation innate immune modulators for cancer therapy, today announced the expansion of its clinical program with MBS8, a systemically administered second-generation TLR7 agonist, in checkpoint-resistant cutaneous melanoma and metastatic uveal melanoma.

Unlike first-generation systemic TLR7 approaches that were limited by toxicity, MBS8 utilizes a proprietary lipid micelle formulation designed to enable controlled innate immune activation while maintaining systemic tolerability. Phase I evaluation established a favorable safety profile, encouraging tumor effects and a recommended dose for further development

The multi-center expansion study will enroll patients in Denmark and Spain. MBS8 will be evaluated in combination with pembrolizumab (Keytruda®) in patients with acquired resistance to PD-1 therapy, and as monotherapy in uveal melanoma patients previously treated with T-cell engagers.

CEO Statement

“We are very encouraged by the MBS8 phase I data generated and believe systemic TLR7 agonism is entering a new era of clinical validation and investment momentum,” said Simon Skjøde Jensen, CEO of MonTa Biosciences. “With Phase I safety established, we are advancing MBS8, which we believe has Best-in-class potential, into defined resistant melanoma populations where innate immune activation may restore responsiveness to immunotherapy. As capital and clinical momentum accelerate in the TLR7 field, we see a clear opportunity to differentiate through safety, formulation, and rational combination strategies.”

Addressing Checkpoint Resistance

Although immune checkpoint inhibitors have transformed melanoma treatment, up to 40–50% of responding patients ultimately relapse—representing approximately 10-12,000 patients annually across the US and EU—with no broadly effective therapy specifically targeting acquired resistance.

Orphan Opportunity in Metastatic Uveal Melanoma

Metastatic uveal melanoma remains a major unmet need, with approximately 4,000 new cases annually in the US and Europe. The indication qualifies for orphan designation, offering potential regulatory incentives and accelerated development pathways. Checkpoint inhibitors show response rates below 10%, and while a T-cell engager is approved for a subset of patients, durable responses remain limited.

TLR7 Agonism Gains Clinical Validation and Reduces Development Risk

Systemic TLR7 agonism is rapidly re-emerging as a validated immuno-oncology strategy, supported by substantial capital deployment and advancing clinical data. Eikon Therapeutics has raised more than USD 1 billion to advance its TLR7 agonist EIK1001 into Phase II/III development and completed its NASDAQ listing in February 2026. Interim Phase II data in NSCLC demonstrated improved progression-free survival when EIK1001 was combined with chemotherapy and pembrolizumab, reinforcing the clinical relevance of systemic innate immune activation.

In parallel, a landmark *Nature* publication (Grippin et al., 2025) showed that NSCLC and melanoma patients receiving an mRNA COVID-19 vaccine—known to partly activate TLR7 signaling—within 100 days of initiating checkpoint therapy experienced significantly improved survival, including nearly doubled 36-month overall survival in NSCLC.

Collectively, these developments materially reduce development and clinical risk for MBS8 and underscore its potential to enhance checkpoint efficacy.

MonTa's MBS8 is, alongside EIK1001, among the most advanced systemically administered TLR7 agonists with completed Phase I safety data, positioning the company at the forefront of this revalidated therapeutic class.

Read more about MonTa Biosciences here: https://montabiosciences.com/

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