Press Release

EADV: Sanofi's brivekimig achieved positive results in hidradenitis suppurativa in phase 2a study

- In phase 2a study, brivekimig led to clinically meaningful improvements in primary and key secondary endpoints in biologic-naïve patients compared to placebo at week 16
- Dual-target Nanobody® VHH inhibiting TNF and OX40L being explored across a range of immune-mediated diseases
- Reaffirms Sanofi's commitment to addressing underlying inflammation across complex, heterogeneous chronic skin diseases

Paris, September 17, 2025. New data from the HS-OBTAIN phase 2a study (clinical study identifier: NCT05849922) show that treatment with brivekimig led to clinically meaningful improvements in the primary endpoint of Hidradenitis Suppurativa Clinical Response (HiSCR50) in patients naïve to biologics with moderate-to-severe hidradenitis suppurativa (HS). Brivekimig was well tolerated, with no serious adverse events. The results will be shared in an oral presentation at the European Academy of Dermatology and Venereology (EADV) 2025 Congress in Paris.

HS is a chronic and debilitating inflammatory skin disease characterized by painful cutaneous nodules, abscesses and draining tunnels. Approximately 196,000 adults in the EU live with HS.

> *"Despite the debilitating impact of HS, treatment options are unfortunately limited," said **Alexa B. Kimball**, MD, MPH, Professor of Dermatology, Harvard Medical School. "The phase 2a results presented at EADV indicate targeting TNF and OX40L pathways together with brivekimig may offer a promising strategy to reduce underlying inflammation, leading to improvement in HS symptoms."*

Key results

The HS-OBTAIN phase 2a study is a randomized, double-blind, placebo-controlled, proof-of-concept study assessing the efficacy and safety of brivekimig in adults with moderate-to-severe HS. The primary analysis population included biologic-naïve HS patients who were randomized 2:1 to receive brivekimig 150 mg or placebo subcutaneously every two weeks. The following was observed at 16 weeks:

- HiSCR50, defined as ≥50% reduction in total abscess and inflammatory nodule count with no increase in abscess or draining fistula count relative to baseline, median response rates were **67% in the brivekimig arm** (n=48) versus 37% (n=23) in the placebo arm (Bayesian primary analysis with estimated difference of 29%; 90% credible interval: 10%–47%; probability of superiority: 99.28%).
- **Clinically meaningful improvements were also seen in more stringent secondary efficacy endpoints** of HiSCR75 and HiSCR90 for brivekimig versus placebo.
- **54% of patients treated with brivekimig achieved HiSCR75** versus 22% with placebo (estimated difference of 29%; 90% confidence interval [CI]: 11%–48%; p=0.0171).
- **HiSCR90 was achieved by 31% of patients treated with brivekimig** versus 9% with placebo (estimated difference of 20%; 90% CI: 5%–34%; p=0.0576).
- The mean percent change from baseline in **draining tunnel count was -56.0% for brivekimig** versus +10.9% for placebo (estimated difference of -67.0%; 90% CI: -105.2% to -28.8%; p=0.005).

The most frequent adverse events (occurring in >10% of participants, and more frequent with brivekimig than with placebo) were nasopharyngitis and headache.

*"The positive early-stage results for brivekimig in HS presented at EADV exemplify our deep understanding of pathway biology and commitment to exploring novel platforms and technologies with the goal of delivering new treatment options that can address the complex, heterogeneous nature of chronic inflammatory skin diseases," said **Alyssa Johnsen**, MD, PhD, Global Therapeutic Area Head, Immunology and Oncology Development at Sanofi. "We are encouraged by these results and look forward to continuing to explore brivekimig, and the impact of dual TNF and OX40 ligand inhibition, on the inflammation driving the burdensome symptoms of HS."*

The use of brivekimig to treat HS is investigational and has not been evaluated by any regulatory authority.

About brivekimig

Brivekimig is a dual-target Nanobody® molecule inhibiting the tumor necrosis factor and OX40-ligand, key immune regulators. It is being investigated for potential uses across a range of immune-mediated diseases and inflammatory disorders.

About the HS-OBTAIN Study

HS-OBTAIN (clinical study identifier: NCT05849922) is a randomized, double-blind, placebo-controlled, proof-of-concept phase 2a study assessing the efficacy and safety of brivekimig in adults with moderate-to-severe HS.

Patients were randomized 2:1 to receive brivekimig 150 mg or placebo subcutaneously every two weeks for 16 weeks, followed by a 12-week open-label period and an 8-week safety follow-up. The primary efficacy endpoint was the percentage of biologic-naïve participants achieving HiSCR50 at week 16. The primary analysis was based on a Bayesian logistic regression model adjusted for Hurley Stage. Additional endpoints included HiSCR75, HiSCR90, and draining tunnel count at week 16 (with adjusted estimates and nominal p-values).

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Sanofi forward-looking statements

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Dr. Kimball receives compensation for consulting and unpatented licensing fees from Sanofi.