



Sudo Biosciences Announces Positive Phase 1 Results for Brain-Penetrant Allosteric TYK2 Inhibitor SUDO-550

- SUDO-550 demonstrated favorable safety, tolerability, and once-daily pharmacokinetic profile with full central nervous system (CNS) penetration
- Achieved exposure levels associated with >90% inhibition of TYK2-mediated signaling in both the CNS and peripheral circulation
- Phase 2 study in multiple sclerosis (MS) expected to begin in the first half of 2026

CARMEL, Indiana & LONDON--(BUSINESS WIRE)-- [Sudo Biosciences](#), ("Sudo"), a biopharmaceutical company committed to designing and developing best-in-class precision TYK2 (tyrosine kinase 2) inhibitors, today announced positive topline results from its Phase 1 first-in-human clinical trial of SUDO-550, an oral, CNS-penetrant, allosteric TYK2 inhibitor for the treatment of neuroinflammatory diseases. The study evaluated single and multiple ascending doses of SUDO-550 in healthy volunteers, including participants aged 65 and older.

The Phase 1 results demonstrated that SUDO-550 was safe, well tolerated, and suitable for once-daily dosing across a wide dose range. Pharmacokinetic analyses showed dose-proportional exposure, a long half-life, and equivalent free concentrations in plasma and cerebrospinal fluid (CSF), supporting convenient once-daily dosing. Notably, SUDO-550 achieved concentrations over 24-hours consistent with near complete (>90%) inhibition of TYK2-mediated pathways in the peripheral circulation and CNS, including activity in both microglia and astrocytes. Pharmacodynamic assessments confirmed target engagement in both blood and CSF. Results in participants aged 65 and older were consistent with younger participants, supporting suitability for a broad patient population.

"We believe SUDO-550 represents a new generation of selective TYK2 inhibitors engineered to safely reach the brain and modulate the inflammatory processes driving some of the most challenging autoimmune and neurologic diseases," said Scott Byrd, Chief Executive Officer, Sudo Biosciences. "These results support advancing SUDO-550 into Phase 2 and brings us a step closer to changing the treatment landscape for patients who currently have limited options."

"The ability of SUDO-550 to access the CNS and achieve concentrations providing sustained inhibition of TYK2 pathways is highly encouraging," said Dr. Ian Mills, Chief Medical Officer, Sudo Biosciences. "SUDO-550 demonstrated low peak-to-trough variability following once daily dosing, reducing the risk of adverse effects that can be associated with peak drug concentrations, while providing continuous pharmacological activity over 24 hours. This unique clinical profile differentiates SUDO-550 from other TYK2 inhibitors and highlights its potential to advance the standard of care for patients with MS and other neuroinflammatory diseases."

Sudo Biosciences plans to initiate a Phase 2 study of SUDO-550 in MS in the first half of 2026.

The company is advancing a pipeline of highly selective, small molecule TYK2 pseudokinase inhibitors designed to target the immune and inflammatory pathways that drive autoimmune and neurologic diseases.

About SUDO-550

SUDO-550 is a potential first-in-class and best-in-class, oral, CNS-penetrant allosteric TYK2 inhibitor designed to achieve potent and selective inhibition of TYK2-mediated signaling across both the CNS and peripheral immune systems. In a Phase I clinical study, SUDO-550 was safe and well tolerated and demonstrated a once-daily pharmacokinetic profile with

sustained and equivalent exposure levels in the peripheral circulation and CNS. By precisely modulating pathways driven by interleukin-12 (IL-12), interleukin-23 (IL-23), and Type I interferons, SUDO-550 has the potential to treat a broad range of autoimmune and neuroinflammatory diseases, including MS, ALS, and Alzheimer's disease.

About Sudo Biosciences

Sudo Biosciences is a clinical-stage biopharmaceutical company developing next-generation TYK2 inhibitors to transform the treatment of immune-mediated diseases. Its pipeline includes a potential first- and best-in-class, once-daily oral, brain-penetrant candidate for MS and other neuroinflammatory conditions, as well as a topical candidate for dermatologic diseases. Based in Carmel, IN and London, U.K., Sudo is advancing novel medicines designed to improve patient lives. For more information visit www.sudobio.com.

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