Halo Biosciences Announces Thorax Publication of Phase 2a SATURN Study Results in PH-ILD

- Positive results in key clinical outcomes for patients with pulmonary hypertension and interstitial lung disease (PH-ILD) with a novel extracellular matrix (ECM) modulator -

PALO ALTO, Calif. – June 4, 2025 — Halo Biosciences ("Halo"), a clinical-stage biotechnology company developing extracellular matrix-targeted therapies, today announced publication of results from the Phase 2a SATURN study in *Thorax*. The study, conducted at Stanford University, evaluated 4-methylumbelliferone (4-MU) in patients with pulmonary hypertension, a highly progressive disease with significant unmet needs.

The SATURN study, a Phase 2a randomized, double-blind, placebo-controlled trial, enrolled 16 patients with pulmonary hypertension. 4-MU was safe and well-tolerated throughout the 24-week treatment period. The primary hemodynamic measurement of change in pulmonary vascular resistance was not statistically significant. Among patients with PH-ILD, prespecified exploratory efficacy signals showed a mean improvement of 66 meters in six-minute walk distance and enhanced quality-of-life scores. These findings support further clinical evaluation of 4-MU as a potential disease-modifying therapy for inflammatory and fibrotic lung diseases.

"These clinical data reinforce the scientific rationale for targeting hyaluronan in fibrotic and inflammatory lung disease and highlight 4-MU's potential as a first-in-class, disease-modifying ECM-modulator for patients with serious conditions like PH-ILD," said Paul Bollyky, M.D., professor of medicine at Stanford University and scientific co-founder of Halo Biosciences. "This represents a meaningful step forward for individuals living with PH-ILD, a condition with limited treatment options and a high burden of disease."

HB-1614, Halo's lead investigational therapy, is a proprietary, oral formulation of 4-MU optimized for improved bioavailability and long-term use in patients with chronic lung conditions such as PH-ILD. By inhibiting hyaluronan synthesis, HB-1614 targets a key driver of extracellular matrix (ECM) remodeling involved in inflammation and fibrosis—processes central to disease progression in several debilitating diseases, including PH-ILD.

"We are proud to see the SATURN study featured in *Thorax*, validating our translational approach and marking a key milestone in our development of HB-1614," said Anissa Kalinowski, chief executive officer of Halo Biosciences. "We are thankful to Stanford University and sponsor investigators Roham Zamanian, M.D., and Vinicio de Jesus Perez, M.D., for their leadership of the SATURN trial, unlocking the potential of this new mechanism of action."

Halo Biosciences is progressing clinical development of HB-1614 and exploring partnership opportunities to accelerate its work in PH-ILD and other fibrotic conditions. The company holds exclusive intellectual property for its formulation and is positioned to optimize drug delivery, bioavailability and regulatory strategy.

The full manuscript is now available online. To access the paper, visit:
https://thorax.bmj.com/content/early/2025/05/31/thorax-2024-222725

ABOUT HB-1614

HB-1614 is Halo Biosciences' lead investigational therapy, a proprietary formulation of 4-methylumbelliferone (4-MU) designed to inhibit hyaluronan synthesis, a key driver of inflammation and fibrosis in the ECM. By targeting this dysregulated pathway, HB-1614 offers a novel, disease-modifying approach for conditions like pulmonary hypertension associated with interstitial lung disease (PH-ILD).

ABOUT PULMONARY HYPERTENSION

Pulmonary hypertension (PH) is a progressive condition caused by elevated blood pressure in the arteries of the lungs, leading to reduced oxygen exchange, right heart strain, and eventual heart failure.[i] Symptoms include breathlessness, fatigue, and dizziness[ii]. PH diagnosis is often delayed and accompanied by comorbidities, with most patients diagnosed between the ages of 60 and 70[iii]. When PH is associated with interstitial lung disease (PH-ILD), the course of disease is often more accelerated, with these patients facing a median survival of just 2 to 5 years.[iv]

Currently, there is only one FDA-approved therapy for PH-ILD,[iv] leaving a significant unmet need for therapies that target the underlying mechanisms of disease progression. New approaches are urgently needed to improve outcomes and quality of life for this vulnerable patient population.

ABOUT HALO BIOSCIENCES

Halo Biosciences is a clinical-stage biopharmaceutical company targeting the extracellular matrix (ECM) to transform the treatment of diseases characterized by inflammation and fibrosis. It is headquartered in Palo Alto, CA. For more information, visit www.halobiosciences.com.

MEDIA CONTACT:
Nancie Steinberg
The Grace Group
nancie@gracegroup.com

[i] Pulmonary Fibrosis Foundation. *Pulmonary Hypertension Related to Interstitial Lung Disease (for Patients)*. Retrieved from https://www.pulmonaryfibrosis.org/researchers-healthcare-providers/clinical-resources/position-statements/pulmonary-hypertension-related-to-ild-for-patients

[ii] Pulmonary Hypertension Association. *Diagnosing Pulmonary Hypertensio*n. Accessed on June 3, 2025 from https://phassociation.org/patients/diagnosis/

[iii] Mount Sinai Health System. (n.d.). *Idiopathic pulmonary fibrosis*. Mount Sinai Health Library. Retrieved June 3, 2025, from https://www.mountsinai.org/health-library/diseases-conditions/idiopathic-pulmonary-fibrosis

[iv] Nathan, S. D., Stinchon, M. R., Atcheson, S., Simone, L., & Nelson, M. (2025). Shining a spotlight on pulmonary hypertension associated with interstitial lung disease care: The latest advances in diagnosis and treatment. Journal of Managed Care & Specialty Pharmacy, 31(1-a Suppl), S2–S29. https://doi.org/10.18553/jmcp.2025.31.1-a.s2