Press release

OWL Metabolomics and Sagimet Biosciences closed an agreement to use OWL´s services in Sagimet´s Phase 2b FASCINATE-2 Clinical Trial

- *In a recent Phase 2a trial, TVB-2640 improved serum biomarkers of liver injury in patients with nonalcoholic steatohepatitis (NASH)*
- *OWL has worked since 2019 as the provider of metabolomics services for TVB-2640 development showing a clear metabolomics signature of the drug*

(Bilbao, 27 May 2021). – The Spanish biotech and the American clinical-stage biotechnology company have recently entered into an agreement to use OWL's Metabolomics Technology in Sagimet´s TVB-2640 Phase 2b Clinical NASH Trial FASCINATE-2.

Non-alcoholic fatty liver disease (NAFLD) is a highly-prevalent progressive chronic disease and very common in the diabetics and obese populations. It starts with fat accumulation in the liver in patients who do not consume alcohol or take it in insignificant amounts, but have risk factors such as overweight or obesity, diabetes mellitus (high blood sugar), hypertension (high blood pressure) or dyslipidemia (abnormal blood lipids).

Metabolomics is the comprehensive characterization of small molecules in biological systems. It can provide an overview of the metabolic status and global biochemical events associated with a cellular or biological system. Studying the metabolome highlights changes in networks and pathways and provide insights into physiological and pathological states, resulting in a particularly useful probe of an individual's phenotype.

Recently, in March 2021, Sagimet received Fast Track designation from U.S. Food and Drug Administration (FDA) for fatty acid synthase (FASN) inhibitor TVB-2640 for NASH.

In a recent Phase 2 randomized placebo-controlled trial (FASCINATE-1), TVB-2640 demonstrated statistically significant improvement across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH.

Through this agreement, OWL will provide its expertise in metabolomics technology to support the drug effect. After the relevant lipidomic changes observed in Phase 2a, the company will start a Phase 2b trial to confirm these findings in a long term biopsy study. OWL will also provide in this Phase 2b a complete lipoprotein profile through NMR in order to detect improvement in parameters related to cardiovascular risk due to TVB-2640. This is of great importance as cardiovascular disease is the first cause of mortality among NASH patients.

Joint Collaboration for NASH and NAFLD

OWL and Sagimet have been collaborating since 2019 both in Phase 2a clinical and preclinical studies and have reinforced this relationship for the Phase 2b FASCINATE-2 Clinical Trial.

Both companies intend to maintain their collaboration by keeping OWL services through data mining and metabolomics, this time adding cardiovascular risk and genetic variants sub-analysis assessment.

About OWL

OWL is a global service provider of metabolomics technologies for the pharmaceutical industry whose main focus is on supporting clinical trials for liver diseases and other highly prevalent diseases, as well as research in indications where metabolomics plays a key role.

OWL also develops and commercializes diagnostics tools and has marketed the first NASH diagnostics in the market. For more information, please visit www.owlmetabolomics.com.

For further information, contact:

Eider Lazkano - GUK	eider@guk.es	+34 620 807 344
Miriam Pérez – OWL	mperez@owlmetabolomics.com	+34 688 641 824