

CONSILIENT HEALTH LAUNCHES GHRYVELIN™ (macimorelin), A NOVEL ORAL DIAGNOSTIC TEST FOR ADULT GROWTH HORMONE DEFICIENCY

FOR UK/EUROPEAN MEDICAL AND TRADE MEDIA ONLY

DUBLIN, IRELAND, May 26, 2022 /EINPresswire.com/ -- [Consilient Health](https://www.consilienthealth.com) has today announced the launch of Ghryvelin™ (macimorelin), the first oral test licensed for diagnosing Growth Hormone Deficiency (AGHD) in adults.



Ghryvelin™ is now available to healthcare professionals across Europe, subject to reimbursement. Ghryvelin™ is a simple, well-tolerated, reproducible diagnostic test for AGHD with accuracy comparable to that of the insulin tolerance test (ITT).¹ Consilient Health will be hosting a Hub session to discuss advances in AGHD testing, including Ghryvelin™ at the European Congress of Endocrinology (ECE) in Milan (21st to 24th May).

AGHD is a rare disease affecting around 200 – 300 people per million across Europe.² It is a debilitating disease that affects psychological, physical, cognitive, and energy aspects of patients' lives.³

"Growth Hormone Deficiency (GHD) in adults can develop insidiously; therefore, diagnostic testing of appropriate patients is important to prevent long-term health-related issues," commented Sherwin Criseno, Consultant Nurse in Endocrinology, University Hospitals Birmingham and Chair of the ESE Nurse Committee. "An oral test to diagnose GHD in adults, like macimorelin, offers a well-tolerated and time-efficient alternative to commonly used labour-intensive tests, such as the insulin tolerance test (ITT). The use of this new oral test could increase patient throughput in diagnostic clinics, which in turn can facilitate timely treatment."

Ghryvelin™, a ghrelin agonist, is an orally active small molecule that stimulates the secretion of growth hormone from the pituitary gland. Stimulated growth hormone levels are measured in blood samples after oral administration of Ghryvelin™ for the assessment of AGHD. Ghryvelin™ is the only EMA approved oral diagnostic for adult growth hormone deficiency.⁴

Pat McBride, Head of Patient and Family Services at The Pituitary Foundation said, "Our research shows that Insulin Tolerance Testing can be a challenging and difficult experience, often causing patients to be fearful and anxious. We urgently need innovative testing approaches that provide accurate results, while minimising the overall impact on patient health and wellbeing."

EMA approval of Ghryvelin™ was granted in 2019, based on Phase III data showing that oral Ghryvelin™ provides accuracy comparable to that of standard insulin tolerance testing (ITT), but has a considerably more favourable safety profile compared to ITT. Oral Ghryvelin™ also reduces false positive test results, helping to avoid unnecessary treatment of patients.^{1,4}

Christian J. Strasburger, M.D., Professor of Medicine, Charité Universitätsmedizin, Berlin commented, "It is important for testing approaches for Adult Growth Hormone Deficiency to provide both sensitivity and specificity, to support effective diagnosis and treatment decisions."

The Phase III study included a total of 166 participants (137 had suspected AGHD and 29 were healthy matched controls); 157 underwent at least one GHST and 154 underwent both GHSTs at least once. The study showed that after the first test, 99% of Ghryvelin™ and 82% of ITTs were evaluable. Using growth hormone cut off levels of 2.8 ng/mL for Ghryvelin™ and 5.1ng/mL for ITTs, the negative agreement was 95.38% (95 CI, 87% to 99%), the positive agreement was 74.32% (95% CI, 63% to 84%), sensitivity was 87%, and specificity was 96%. On retesting, the reproducibility was 91% for Ghryvelin™ (n=33). Adverse events were mild and transient.¹

Glenn Darley, Head of European Speciality Products, Consilient Health said, "We are delighted to be making oral Ghryvelin™, a novel active substance for diagnostic testing of AGHD for clinicians and patients across Europe, as part of our specialist endocrinology portfolio We hope that this new test can significantly reduce the burden of testing for adult GHD. Profoundly improving the testing experience for both health care professionals and patients alike."

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