

PRESS RELEASE

osteomiR[™]: wordwide first miRNA-based test for early detection of osteoporosis

Vienna/Atlanta September 16th, 2016: The Austrian spin-off TAmiRNA develops biomarker solutions, which significantly improve early detection of serious age-related illnesses such as osteoporosis. At this years ASBMR meeting in Atlanta (Georgia) TAmiRNA presents the new osteomiR[™] test kit – a unique molecular diagnostic kit for detection of osteoporosis.

Every year more than 3 million bone fractures occur in Europe due to osteoporosis. The resulting costs are estimated at 40 billion Euro. Worldwide, the number of osteoporotic fractures is just under 10 million. Osteoporosis has become a major socio-economic challenge and burdens patients as well as public and private health insurances, and based on the steady increase in life expectancy the incidence of osteoporosis will continue to rise. Therefore, tools for early diagnosis coupled with targeted therapeutic intervention are required to prevent fractures and to counteract this trend. "Due to the heterogeneity of osteoporosis, we are convinced that early and personalized diagnosis are essential for a timely and successful therapeutic prevention of bone fractures, which are associated with great pain, immobility and unfortunately even mortality," said Matthias Hackl (32), director and co-inventor of this microRNA based diagnostic procedure.

Since 2013 TAMIRNA has developed a minimal-invasive molecular diagnostic test to estimate fracture-risk in postmenopausal women as well as other subgroups at risk of osteoporosis. The results of the clinical development, which have been published in peer-reviewed journal journals in 2015 and 2016, show that serum concentrations of specific microRNAs are significantly associated with osteoporosis and the risk of fractures. Using multivariate diagnostic algorithms a significant improvement of the classification performance of bone densitometry and other risk-score can be achieved. The osteomiRTM kit has been developed to standardize both laboratory and data analysis of these microRNAs ("osteomiRs") in patient serum samples. For now, the osteomiRTM kit is for research-use only, but in the near future the clinical utility of will be investigated in multiple clinical research centers for musculoskeletal disease.

microRNAs are a class of non-coding RNA molecules, which regulate gene expression and correct cell function. Abnormal microRNA expression can be a consequence or even cause of onset and progression of disease. Since microRNAs are constantly released from cells through specific mechanisms, their composition in blood changes during disease development. The innovative team of TAmiRNA has taken advantage of this effect within their very successful research studies. "On the basis of several studies in more than 1,000 patients, we were able to show that certain microRNAs are strongly associated with the progression of osteoporosis and the risk of fractures. From these data, we were able to develop diagnostic algorithms based on microRNAs and clinical parameters to allow a more accurate patient classification." Says Johannes Grillari, professor at the University of Natural Resources and Life Sciences, Vienna, co-founder and scientific advisor of TAmiRNA.

TAmiRNA was founded in 2013 as a biopharmaceutical research and development company and as a spin-off company of the University of Natural Resources and Life Sciences, Vienna, to promote the discovery and development of

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microRNAs (miRNAs) substantially as tools for diagnosis and treatment of age-related diseases such as osteoporosis, cardiovascular and neurodegenerative diseases. The aim of the research work is to advance early risk assessment of age-associated diseases, and thus to give physicians a tool for timely initiation of counteractive measures. This should result in increasing the quality of life for older patients

and people. Furthermore, tests for personalized medicine will be developed to

support the choice of the best treatment options for patients and also may reflect the therapeutic success.

Publications:

[1] Heilmeier U, Hackl M, Skalicky S, Weilner S, Schroeder F, Vierlinger K, et al. Serum microRNAs Are Indicative of Skeletal Fractures in Postmenopausal Women with and without Type 2 Diabetes and Influence Osteogenic and Adipogenic Differentiation of Adipose-Tissue Derived Mesenchymal Stem Cells In Vitro. J Bone Miner Res 2016.
[2] Hackl M, Heilmeier U, Weilner S, Grillari J. Circulating microRNAs as novel biomarkers for bone diseases – Complex signatures for multifactorial diseases? Mol Cell Endocrinol 2016;432:83–95.

[3] Kocijan R, Muschitz C, Geiger E, Skalicky S, Baierl A, Dormann R, et al. Circulating microRNA signatures in patients with idiopathic and postmenopausal osteoporosis and fragility fractures. J Clin Endocrinol Metab 2016:jc.2016-2365.

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