# PRESS RELEASE



# Approval of US pilot clinical trial to evaluate AclarusDx™, the Exonhit investigational test for Alzheimer's Disease diagnosis

- First AclarusDx<sup>™</sup> clinical trial to be conducted in United States
- First patient to be recruited in November

**Paris, France – October, 26 2011** – Exonhit (Alternext: ALEHT) announced today the Institutional Review Board (IRB) approval of Exonhit sponsored pilot clinical trial aimed at evaluating the performance of AclarusDx<sup>™</sup>, a blood based investigational diagnostic test, in US-based patients suffering from memory impairment and newly referred to a reference Memory Center for Alzheimer's Disease (AD) diagnostic workup. This study will be conducted by the Cleveland Clinic Lou Ruvo Center for Brain Health.

Currently, AD diagnosis is based on psychometric tests and behaviour evaluations, as well as brain imaging, at a stage of the dementia where the onset of the disease has already started. Early accurate and reliable diagnostic tools are essential to improve patient management and therapeutic treatments. The use of AclarusDx<sup>™</sup>, a blood based test, could help accelerate the full diagnostic workup.

"This first trial in the U.S. for AclarusDx<sup>™</sup> allows Exonhit to move one step further towards an early diagnosis of the disease", said Loïc Maurel, M.D., President of the Management Board of Exonhit. "Knowing that 5.4 million Americans are living with AD and that AD costs USD 183 billion per year<sup>(1)</sup>, significant efforts have to be made to identify AD at its very early stages to improve the management of the disease. Our ultimate goal is to define the clinical utility of AclarusDx<sup>™</sup> to provide Primary Care Physicians with a diagnostic tool that will help them identify patients at high risk of having AD and to prescribe a complete diagnostic workup".

Patients for this pilot study will be recruited at three Cleveland Clinic sites: the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Nevada; Cleveland Clinic main campus in Cleveland, Ohio, and Lakewood Hospital in Lakewood, Ohio. A total of 160 new patients being seen for memory impairment will be enrolled in the study starting in November. At the end of the study, the blood samples will be sent to Exonhit, Paris facility, for AclarusDx<sup>™</sup> test analysis.

# About AclarusDx<sup>™</sup>

AclarusDx<sup>™</sup> is a blood-based test intended to help in the diagnosis of Alzheimer's disease (AD). This test is based on the compared analysis of AD patients' transcriptome with that of healthy controls. It was developed by identifying a signature gathering biomarkers linked to more than 130 genes including some genes particularly involved in inflammatory and immune mechanisms observed in AD. A French multicenter blind validation study involving 164 individuals, has allowed establishing the assay performance: a sensitivity of 81% and a specificity of 67%<sup>(2)</sup>.

CE marked since March 2011, AclarusDx<sup>™</sup> is being made available progressively to expert memory centers in France prior to wider distribution to specialized memory consultations in France and other European countries. AclarusDx<sup>™</sup> is for investigation use only in United States.

#### About Exonhit

Exonhit (Alternext: ALEHT) is a biotech company, focused on personalized medicine, which develops targeted innovative therapeutic and diagnostic products, in oncology and Alzheimer's disease. Exonhit has a balanced development strategy with internal development programs and strategic collaborations, in particular with Allergan.

Exonhit is headquartered in Paris, France and has a U.S. subsidiary in Gaithersburg, Maryland. The Company is listed on NYSE Alternext in Paris and is part of the NYSE Alternext OSEO innovation index. For more information, please visit http://www.exonhit.com.

#### Disclaimer

This press release contains elements that are not historical facts including, without limitation, certain statements on future expectations and other forward-looking statements. Such statements are based on management's current views and assumptions and involve known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those anticipated.

In addition, Exonhit, its shareholders, and its affiliates, directors, officers, advisors and employees have not verified the accuracy of, and make no representations or warranties in relation to, statistical data or predictions contained in this press release that were taken or derived from third party sources or industry publications, and such statistical data and predictions are used in this press release for information purposes only.

Finally, this press release may be drafted in the French and English languages. In an event of differences between the texts, the English language version shall prevail.

# References

(1) Alzheimer's Facts and Figures 2011, Alzheimer's Association (2) Data on file

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