## **PRESS RELEASE**



# AclarusDx<sup>®</sup>: launch of observational study in France

- AclarusDx<sup>®</sup> real-life observational study
- First patient should be recruited in December

Paris, France – December 12, 2011 – Exonhit (Alternext: ALEHT) announced today the launch of its observational study in France aimed at evaluating the performance of AclarusDx®, a blood-based test intended to aid in the diagnosis of Alzheimer's disease (AD), in patients consulting for the first time with a specialized memory center for AD diagnostic work-up. This real-life study named DIALOG (Diagnostic Alzheimer cOGnitif) is sponsored by Exonhit and has received all regulatory approvals.

"This AclarusDx® observational study, with first patient recruitment expected in December, allows us to work in close collaboration with French AD experts", said Loïc Maurel, M.D., President of the Management Board of Exonhit. "The study protocol was formulated with the support of a renowned Scientific Advisory Board chaired by Professor Françoise Forette".

"This is an important step in the life-cycle of AclarusDx<sup>®</sup>", added Professor Françoise Forette, President of the Scientific Advisory Board. "This study will allow the medical community to position AclarusDx<sup>®</sup> within the AD diagnostic work-up, while diagnostic criteria are still evolving".

Currently, AD diagnosis is based on clinical examination, psychometric tests, behavior evaluations, as well as brain imaging. Biological markers are also measured in the cerebrospinal fluid but this technique remains invasive. The use of a blood-based test, easy to realize and less traumatic for patients, may thus appear as a major step forward.

#### **About DIALOG**

The main objective of DIALOG (Dlagnostic ALzheimer cOGnitif), a non interventional longitudinal study of the diagnosis of AD, is the evaluation of the positivity of AclarusDx® in AD patients among the population of patients consulting for the first time with French specialized memory centers (Centres Mémoire de Ressources et de Recherche, CMRR, or Consultations Mémoire, CM). This population of newly referred patients includes patients suffering from cognitive disorders and/or memory impairment for whom a specialized exploration using AclarusDx® blood-based test is needed. The study should enroll 600 patients that will be followed by 30 to 50 CMRR or CM for the usual diagnostic workup. A blood sample required for performing the AclarusDx® test will be collected during the first visit, together with other biological samples. Further follow-up data will be collected 6 months and 1 year after the initial visit. This study received the approval of both the CCTIRS on September 15, 2011 and the CNIL on October 14, 2011. On September 22, 2011, the study was also submitted to the CNOM who did not express opposition.

## About AclarusDx®

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>(1)</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 investigational 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.

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.

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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 French language version shall prevail.

#### References

(1) AclarusDx® data on file

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