

## ExonHit announces successful completion of the first phase of EHT Dx14 ongoing clinical validation

- Second phase will be the signature validation for use on indeterminate samples expected in July 2011
- Introduction as an Investigational Use Only product in major cancer centers planned for second half of 2011

**Paris, France – March 29, 2011** – ExonHit Therapeutics (Alternext: ALEHT) today announced successful completion of the first phase of the validation study of EHT Dx14, a new transcriptomic signature allowing to differentiate, at molecular level, benign breast tumors from malignant ones.

*“These very promising first results confirm EHT Dx14 capability to reliably classify breast tumor type in benign and malignant fine-needle aspiration (FNA) samples. Hence, they confirm the initial performances of the test obtained in a previous study. Our goal is now to evaluate EHT Dx14 performances in making the molecular diagnosis of breast tumors in indeterminate FNA samples,”* said Loïc Maurel, M.D., President of the Management Board of ExonHit Therapeutics.

*“If these good results are confirmed, this new molecular diagnostic test could potentially become, in association with cytopathological analysis, a credible alternative to the systematic use of the more traumatic breast biopsies. It could also contribute to strengthen the role and confirm the interest of cytology use in the diagnostic process of breast tumors. At IGR, we organize once a week a diagnostic day for breast nodules during which we use FNA,”* added Philippe Vielh, M.D., Head of the Cytopathological Unit in the Department of Biopathology at the Institut Gustave Roussy in Villejuif (France).

EHT Dx14 was developed using ExonHit’s Genome-Wide SpliceArray™ platform and was licensed from the Institut Gustave Roussy in May 2009. This molecular biology test is intended when assessing a suspicious tumor discovered during mammography to allow the accurate reading of samples obtained by FNA especially in cases where the standard analysis returns an indeterminate result. EHT Dx14 was able during the initial study to differentiate benign breast tumors from malignant ones in 96% of the cases (1).

EHT Dx14 clinical validation is a two-step process. The first step consisted in confirming the initial performances of the test, as published earlier in *Lancet Oncology* (1), in an independent set of malignant and benign FNA samples coming from the Institut Gustave Roussy biobank. In a second step, it will be necessary to demonstrate the added value of the test in the discrimination of indeterminate cytological samples. The first part of the validation which was just completed showed a 91.5% specificity and a 97.9% sensitivity in a panel of 94 cytological samples (47 benign and 47 malignant ones).

On the basis of these excellent results, ExonHit will be starting the second phase of the validation study and the results are expected in July 2011. At the end of this second step, ExonHit plans to offer EHT Dx14, as an Investigational Use Only product, to major cancer centers in France, in the second half of 2011.

The use of EHT Dx14 in association with FNA could contribute to improve and standardize FNA performances at a level equivalent to those of a biopsy while offering the following advantages:

- Replace the use of a more invasive procedure
- Reduce the time to results for the patients.

This could eventually contribute to expand FNA use.

### **About fine-needle aspiration (also called needle biopsy)**

A fine needle aspiration (FNA) is a non traumatic and quick procedure which is performed in the outpatient clinic. Using a very thin needle and a syringe, the physician removes the biological material from the breast lesion (cells, fluid, ...) which is then spread on a layer for a cytopathological analysis under the microscope. This analysis allows to identify the possible presence of malignant cells. If the results of the cytopathological study do not allow to conclude, a biopsy or an exploratory surgery are necessary to make a precise diagnosis.

Each year, an estimated 370,000 FNA procedures are performed in Europe (2).

### **About breast cancer**

Breast cancer is the leading cause of death by cancer in women with 465,000 estimated deaths worldwide in 2007 (3). Early detection of breast cancer thanks to national screening practice significantly increases survival.

If a breast abnormality is detected with mammography or physical exam, the patient undergoes a diagnostic procedure with standard exams. The benign or malignant nature of the tumor is determined by a morphological examination of the breast tissue. Depending on the results of the tests, of the profile of the patient and of the centers expertise, the analysis of the lesion is performed using an FNA and/or a breast biopsy.

### **About ExonHit Therapeutics**

ExonHit Therapeutics (Alternext: ALEHT) is a fast emerging healthcare player active in both therapeutics and diagnostics. The Company is applying its proprietary technology, based on the analysis of alternative RNA splicing, to develop innovative molecular diagnostic tests and therapeutics for Alzheimer's disease and cancer indications. ExonHit has a balanced investment strategy with internal development programs and strategic collaborations, in particular with bioMérieux and Allergan.

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

### **About the Institut Gustave Roussy**

The Institut Gustave Roussy (IGR, Villejuif, France), leading European Comprehensive Cancer Center, is a non profit academic entity belonging to the French public hospital service and that is authorized to receive donations and legacies. IGR is a wholly patient-oriented centre with global expertise and the mission to fight cancer. Located South of Paris on a single site, IGR employs 2,500 professionals working in care, research and teaching. Some IGR figures: 337 beds and 83 places for day-cases, 210 certified physicians, 880 professional caregivers, 162,000 consultations and 43,000 patients cared for per year, 27 basic research teams, 300 researchers, and 2800 students, researchers and physicians trained per year. [www.igr.fr](http://www.igr.fr)

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*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**

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- (2) Breast Disease Diagnosis and Therapy Markets 2007 – Life Science Intelligence
- (3) Global Cancer Facts & Figures 2007:  
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