

## PRESS RELEASE

### **ExonHit and Institut Gustave Roussy announce the signing of a license agreement for novel breast cancer diagnostic assay**

- Exclusive rights licensed from Institut Gustave Roussy
- New assay to improve accuracy of breast cancer diagnosis through FNA sampling based on research from Institut Gustave Roussy
- Research Use Only product available within 12 months

**Paris, France – May 27, 2009** – ExonHit Therapeutics (Alternext: ALEHT) and Institut Gustave Roussy (IGR) today announce the signing of a license agreement for a novel breast cancer diagnostic assay. ExonHit Therapeutics strengthens its diagnostic pipeline through this worldwide license of Institut Gustave Roussy's tissue-based breast cancer signature.

As recently published in *Lancet Oncology*, Institut Gustave Roussy in collaboration with the CNRS unit FRE 2939 identified a novel breast cancer signature, with an accuracy of over 95%, based on ExonHit's proprietary SpliceArray™ platform (1). This new signature allows for the discrimination between malignant tumors and benign lesions from cells sampled through fine-needle aspiration (FNA). This research was conducted by Dr. Fabrice André and his team at the IGR.

*"Institut Gustave Roussy pioneered the routine use of FNA in replacement of the more invasive core biopsy. This diagnostic method is specifically used in breast pathology routine exams during "the consultations and diagnosis in a day" program,"* said Professor Gilles Vassal, Head of Clinical and Translational Research at Institut Gustave Roussy, Villejuif France. *"The assay that ExonHit is planning to develop could be an excellent tool to improve accuracy of FNA result, making it possible for more medical centers to adopt a practice which is less invasive and less traumatic for the patient."*

*"The license of such a promising signature for breast cancer diagnosis is in line with our strategy to reinforce our diagnostic portfolio with simple, accurate and patient-friendly tests,"* stated Dr. Loïc Maurel, President of the Management Board of ExonHit Therapeutics. *"As our first non blood-based diagnostic, this is a different and complementary approach to our ongoing cancer diagnostic programs with bioMérieux."*

This signature may be used for all cases where FNA sampling is performed and is especially useful for "gray zone" cases where FNA results are inconclusive and either a surgical biopsy or an exploratory surgery is required to get a definitive answer. Today, it is estimated that a cytologist is unable to provide a definitive diagnosis in 10 to 20% of cases where FNA samples are taken (2).

As part of the license, ExonHit will further validate the signature identified by Institut Gustave Roussy. This includes conducting multicenter evaluations, i.e. confirming the validity of the signature in a larger population and that the assay may be performed at different sites. For these validation studies, ExonHit will be able to use samples from Institut Gustave Roussy's biobank.

Assuming successful clinical validation, ExonHit will first launch the test as a Research Use Only product within 12 months. Then, following further validation, the test will be launched as a clinical diagnostic.

Under the terms of the agreement, Institut Gustave Roussy granted ExonHit an exclusive worldwide patent license to develop and commercialize a breast cancer molecular diagnostic. In return, Institut Gustave Roussy will receive an upfront payment as well as development milestones and royalties on future sales. Detailed financial terms were not disclosed.

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

A fine needle aspiration (FNA) is a quick procedure which is performed in the outpatient clinic. Using a very thin needle and syringe, the doctor removes either fluid from a cyst or clusters of cells from a solid mass. This sample of cells from the breast lump is sent to a laboratory for microscopic analysis to see if any cancer cells are present. Should the FNA results be uncertain, the diagnosis is pursued with a surgical biopsy or exploratory surgery.

Each year, an estimated 370,000 FNA procedures are performed in Europe (3).

### **About breast cancer**

Breast cancer is the leading cause of death by cancer in women with 465,000 estimated deaths worldwide in 2007 (4). Early detection of breast cancer significantly increases survivorship.

If a breast abnormality is detected with mammography or physical exam, a woman will typically be referred for additional breast imaging with diagnostic mammography, ultrasound, or other imaging tests. Depending on the results of these follow-up tests, she may be referred for FNA or a breast biopsy to confirm whether the tissue change is malignant or benign.

### **About Institute Gustave Roussy**

The Institut Gustave Roussy (IGR, Villejuif, France), one of Europe's leading Comprehensive Cancer Centers, 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 center wholly patient-oriented with a global expertise and the mission to fight cancer. Located South of Paris on an unique site, IGR employs 2,000 professionals working in care, research and teaching. Some IGR figures: 368 beds and places for day-cases, 159 certified physicians, 751 professional caregivers, 161,000 consultations and 43,000 patients cared per year, 14 basic research units, 300 research scientists, and 260 students, researchers and physicians trained per year. For more information, please visit <http://www.igr.fr>.

### **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 blood based diagnostic tests and therapeutics for neurodegenerative 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. 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 Therapeutics, 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) André F, Michields S, Dessen P, Scott V, Suci V, Uzan C, Lazar V, Lacroix L, Vassal G, Spielmann M, Vielh P, Delaloge S. Exonic expression profiling of breast cancer and benign lesions: a retrospective analysis. The Lancet Oncology, Early Online Publication, 26 February 2009
- (2) Compiled from literature
- (3) Breast Disease Diagnosis and Therapy Markets 2007 – Life Science Intelligence
- (4) Global Cancer Facts & Figures 2007:  
[http://www.cancer.org/downloads/STT/Global\\_Facts\\_and\\_Figures\\_2007\\_rev2.pdf](http://www.cancer.org/downloads/STT/Global_Facts_and_Figures_2007_rev2.pdf)

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