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For Immediate Release

**ACUPATH LABORATORIES, INC. ANNOUNCES  
NEW High Quality PNH testing according to the ICCS Guidelines Implemented**

**Plainview, NY, May 2011** -- Paroxysmal nocturnal hemoglobinuria (PNH) is a rare but progressive and destructive disease that can cause chronic hemolysis, thrombosis, and end organ damage.<sup>1</sup> About 35% of patients die in the first five years and the median survival is 15 years.<sup>2</sup> Common PNH symptoms such as abdominal pain, dyspnea, and chest pain are predictive of thrombosis in this disease.<sup>3</sup>

Patients with unexplained low blood cell counts, hemolysis, thrombosis and bone marrow failure disorders should be tested for PNH.<sup>4</sup> Definitive diagnosis can be made from a peripheral blood test that examines the presence of certain proteins on the red and white blood cells along with a full clinical workup of the patient.

Acupath Laboratories, a leader in hematopathology is currently the only private laboratory in New York State that is certified by the New York State Department of Health to perform PNH testing and one of the few labs in the tri-state area to use the new FLAER reagent for the diagnosis of (PNH). The laboratory recently modified their testing according to the recommendations by the International Clinical Cytometry Society published in their 2010 Guidelines, and is now recognized as a dedicated leader in delivering high quality PNH testing in the world of innovative diagnostics.

Dr. Zsuzsanna Vegh-Goyarts, Ph.D., Assistant Director of Flow Cytometry at Acupath Laboratories explains that PNH is a hematopoietic stem cell disorder caused by a somatic mutation of a single gene. "This mutation occurs in PNH, as well as in some other bone marrow failure disorders. In certain types of Myelodysplasia or Myelodysplastic syndrome (MDS) and in Aplastic Anemia (AA), small size PNH clones may also be identified. In these cases the detection of PNH cells have prognostic and therapeutic implications.<sup>5</sup> Early diagnosis can positively impact long term outcomes for patients," she comments.

PNH patients with the defective gene have a partial or complete deficiency of the glycosylphosphatidylinositol (GPI) anchor, that bind proteins to the outer cell membrane -for example CD55 and CD59-, that are protecting cells from complement mediated lysis," Dr Vegh-Goyarts explains. "These proteins are not present in the cells of PNH clones, so the cells are not protected from lysis, causing the destruction of the red blood cells."

In 2007, Soliris® (eculizumab) was approved by the FDA for the treatment of PNH. The drug is a monoclonal antibody that specifically inhibits uncontrolled complement activation by targeting C5 in the complement pathway. Soliris® (eculizumab) is the only approved treatment to reduce hemolysis and its harmful effects in PNH patients.<sup>6</sup>

For the diagnosis of PNH flow cytometry is the “gold standard,” says Dr Vegh-Goyarts. “The lack of these GPI-linked cell surface molecules is detectable by flow cytometry, although to show the absence or partial expression of molecules is technically challenging. Since this test is a “home brew”, procedures varied significantly by laboratory, she explains. In 2010 a panel of experts constructed consensus guidelines and recommendations for the detection of PNH by flow cytometry.<sup>4</sup>

Traditionally the red blood cells CD55 and CD59 were the diagnostic targets, however testing only the red blood cells will lead to false negative results, since these cells are eliminated. Recent transfusion also affects the accuracy of the testing. The detection of clone size is very important, so testing of a second or even a third lineage of cells is recommended, that can be granulocytes and/or monocytes. One can test for CD55, CD59, CD24, CD14 and other GPI-linked proteins on the white blood cells, but today there is a new and more specific reagent on the market, FLAER (fluorescent aerolysin). FLAER that binds to the GPI anchor itself will give more accurate results.

“The FLAER molecule that reacts with all GPI-linked proteins on the white blood cells is the most reliable reagent to diagnose PNH because it is more specific and the test has greater sensitivity. “FLAER has as another advantage: If combined with other antibodies, like CD24 or CD14 and lineage specific antibodies, such as CD45, CD15 or CD33, test accuracy is further enhanced,” says Dr Vegh-Goyarts. “When we say small PNH clones are detectable, we are actually talking about 1%, or in some cases less than 1% PNH cells that are detectable with the routine method. With multiparameter gating the definition of cell populations is more precise. The high sensitivity method that tests a larger number of cells can be used to identify even smaller (>0.01) PNH positive cell populations. The high sensitivity PNH test is recommended for myelodysplasia and aplastic anemia cases,” explains Dr. Vegh-Goyarts.

“The absence or partial expression of a GPI-linked molecule (CD59) on the red blood cells and the absence or partial expression of FLAER and another GPI-linked molecule on the granulocytes (CD24) or monocytes (CD14) is the diagnostic requirement for positive PNH,” adds Dr. Vegh-Goyarts. Recently published research through an International PNH Registry has confirmed that patients experience fatigue and impaired quality of life regardless of clone size, again reinforcing the importance of early detection using flow cytometry in this disease.<sup>7</sup>

*Acupath Laboratories, Inc. located in Plainview, New York, is an anatomic pathology and cancer genetics laboratory. Acupath's mission is to deliver fast, accurate anatomic pathology, flow cytometry, molecular and cytogenetic analysis in a way that enhances the quality of medical care provided by practitioners while minimizing the risk of error. The research and development team continuously innovates, designing up to date methodologies for testing and new ways for doctors to access, exchange, record and analyze medical information. Acupath is committed to improve efficiencies of practice, superior service and greater patient knowledge and satisfaction. Acupath is accredited by the College of American Pathologists (CAP), the Occupational Safety and Health Administration (OSHA), the Joint Commission, and certified by the New York State Department of Health (DOH). [www.acupath.com](http://www.acupath.com).*

*About Zsuzsanna Vegh-Goyarts, Ph.D. With ample experience in the field of tumor biology and immunology, Dr. Zsuzsanna Vegh-Goyarts serves as the assistant director of the Flow Cytometry department and as a member of the research and development team. Prior to Acupath, she worked as an assistant professor in immunology research at the State University of*

*New York (SUNY) at Stony Brook and served as a consulting assistant director of flow cytometry at Enzo Clinical Laboratories, Inc. She spent her postdoctoral years in prestigious research institutes, including the Immunology Department of Albert Einstein College of Medicine, NY and Tumor Biology Department of the Karolinska Institute in Stockholm, Sweden. Dr. Vegh-Goyarts' research has appeared in an extensive list of peer reviewed publications in various scientific journals, including Cancer Research, Cancer Immunology and Immunotherapy, Molecular Immunology and Cellular Immunology. In addition, she currently holds a Certificate of Qualification in Oncology-Sera and Soluble Tumor Markers, Diagnostic Immunology and all four areas of Cellular Immunology/Flow cytometry from the New York State Department of Health (NYSDOH).*

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