PRESS RELEASE **April 3, 2013**

ERYTECH Pharma receives FDA IND clearance to initiate a clinical study in Acute Lymphoblastic Leukemia in the U.S.

Lyon, France, and Philadelphia, USA, April 3, 2013 – ERYTECH Pharma SA announced today that it has received clearance of its Investigational New Drug (IND) Application from the United States Food and Drug Administration (FDA) to initiate a Phase I clinical trial of its product ERYASP®, L-asparaginase loaded erythrocytes, in patients 40 years or older with newly diagnosed Acute Lymphoblastic Leukemia (ALL).

L-asparaginase has been a mainstay in the treatment of children suffering from ALL, but its use is limited in older and fragile patients due to its toxicity profile. ERYASP® is a new formulation of L-asparaginase, with a safer and broader range of clinical use than existing forms due to the entrapment and protection of the enzyme inside red blood cells. ERYASP® is intended to satisfy the unmet medical needs of older and fragile, patients suffering relapses and other patient groups for whom the current treatments are not suitable. The added value of ERYASP® relates to its ability, as demonstrated in late stage clinical trials in Europe, to overcome existing limitations associated with conventional L-asparaginase via longer efficacy, reduced doses and a better safety profile. This now needs to be confirmed in the U.S.

“We know L-asparaginase is very important to treat patients with ALL, and we also know the toxicities related to this drug. ERYTECH’s formulation looks quite promising. I am very enthusiastic to start this clinical trial”, said Prof Richard A. Larson, Director of the Hematological Malignancies Clinical Research Program at the University of Chicago and former Chairman of the Leukemia Committee of the Cancer and Leukemia Group B (CALGB). Professor Larson will be the principal investigator of the study and four additional academic medical centers will be participating.

The company plans to start enrollment of ALL patients in the Phase I study in H2 2013. In collaboration with the American Red Cross in Philadelphia, ERYTECH has secured a fully operational manufacturing facility where ERYASP® will be manufactured for the clinical trials. The product holds orphan drug designation in Europe and the US.

“We are very pleased to start the clinical development of ERYASP® in the US, building on the extensive clinical experience with the product in Europe. I would like to take the opportunity to thank all the people involved in this project”, said Dr Yann Godfrin, co-founder and Chief Scientific Officer of ERYTECH.

About ERYTECH Pharma

ERYTECH Pharma SA is a late-stage French biopharmaceutical company developing medicinal products for orphan oncology. The company's proprietary core technology is based on the use of human red blood cells (RBCs) to improve the pharmacokinetic (PK) and pharmacodynamic (PD) properties of therapeutic molecules.

Its lead product, ERYASP®, has completed a Phase IIb clinical trial in patients more than 55 years old and is currently in a pivotal Phase III clinical trial for ALL in Europe. It has recently entered a Phase IIb trial in AML. In Europe, ERYASP® has been licensed to Orphan Europe (Recordati Group) under the GRASPA® brand name for acute leukemia. The product holds orphan designation for ALL in Europe and the US for ALL, and for AML in the US.

The company is expanding the use of its technology in oncology to solid tumors, and outside oncology in rare immunology and hematology indications.

For more information

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