CLINICAL TRIAL NEWS

TELIK (TELK)

In two presentations at the annual meeting of the American Society of Hematology in San Diego, Telik reported positive interim data from a Phase 2 trial of its drug Telintra™ (TLK199) for the treatment of myelodysplastic syndrome (MDS). The drug achieved hematologic improvement.

TLK199 (TELINTRA™) is a Novel Glutathione Analog Inhibitor of GST P1-1, in Myelodysplastic Syndrome: Interim Results of a Phase 2 Study (Abstract # 1428, Saturday, December 4, 2004):

At the time of analysis, 34 MDS patients were evaluable for safety and 26 were evaluable for efficacy. Sixteen patients (61.5%) had clinically significant improvement in one or more blood cell lineages (red cells, white cells or platelets). Clinically significant improvement was observed across all major MDS FAB subtypes (RA, RAEB, RAEB-t and RARS) and in all blood cell lineages.

Using the International Working Group (IWG) MDS response criteria, 8 of 17 patients (47%) with white cell dysfunction had Hematologic Improvement -- Neutrophils (HI-N); 6 of 17 patients (35%) with platelet dysfunction had Hematologic Improvement -- Platelets (HI-P); and 8 of 24 patients (33%) with red blood cell dysfunction had Hematologic Improvement -- Erythrocytes (HI-E).

Three of 12 patients (25%) had trilineage improvement and four of 19 patients (21%) had bilineage improvement, meeting the IWG MDS objective response criteria for overall Hematologic Improvement (HI). Clinical responses were associated with decreased red blood cell, platelet and growth factor support requirements, in some cases leading to transfusion independence.

TELINTRA was well tolerated in this predominantly elderly patient population (median age 74 years). Enrollment in the Phase 2 trial is continuing to evaluate alternative dose schedules.

Telintra™ (TLK199) is a Novel Glutathione Inhibitor of GST P1-1. Telik scientists and academic collaborators reported translational data from the ongoing clinical trial demonstrating that Telintra stimulates the formation of bone marrow cells that are precursors to granulocytes and monocytes (white blood cells), erythrocytes (red blood cells) and platelets in MDS patients with abnormally low blood cell counts. These results correlated with clinical improvement in Myelodysplastic Syndrome Patients.

The myelodysplastic syndromes are a group of disorders characterized by the abnormal formation, development and maturation of blood elements. They are associated with a variable incidence of transformation to acute leukemia. The incidence and prevalence of MDS appears to be increasing, perhaps in part due to the aging of the population.

TELIK (TELK) is cruising its way towards putting far-reaching products on the market in steady steps.

FILING

BIOMARIN (BMRN)

Biomarin submitted a Marketing Authorization Application (MAA) to the European Medicines Agency for its investigational enzyme replacement therapy Aryplase™ (galsulfase targeting mucopolysaccharidosis VI (MPS VI). The good news about efficiency is that this filing took place only seven days after filing for Aryplase marketing authorization in the United States.

BioMarin has received orphan medicinal product designation for Aryplase in the European Union.
Aryplase is an investigational enzyme replacement therapy for the treatment of MPS VI. Aryplase is designed to address the underlying deficiency of MPS VI disease and provide the enzyme that people with MPS VI are lacking.

MPS VI, also known as Maroteaux-Lamy Syndrome, is an inherited debilitating, life-threatening disease for which no drug therapies are currently available. MPS VI is caused by the deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B), a lysosomal enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). This enzyme deficiency leads to the accumulation of GAGs in the lysosomes of cells, giving rise to progressive cellular, tissue and organ system dysfunction. Debilitating symptoms can include impaired cardiac and pulmonary function, delayed physical development, skeletal and joint deformities, impaired vision and hearing, sleep apnea, and reduced endurance. The majority of people with MPS VI die from disease-related complications between childhood and early adulthood.

Both Firms’ News is Good.

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