Oncopeptides Receives EMA and FDA Orphan Drug Designation for Melflufen in the Treatment of Multiple Myeloma

Stockholm, Sweden
March 23, 2015

Oncopeptides AB, a clinical stage company developing a novel alkylator - melflufen - today announced that the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have both granted Orphan Drug Designation to its lead candidate, melflufen, in the treatment of multiple myeloma.

Multiple myeloma is the second most common hematological cancer and worldwide more than 230,000 people are living with the disease, with approximately 114,000 new cases diagnosed annually (ref: International Agency for Research on Cancer, GLOBOCAN 2012 database).

Phase I/ II clinical data were presented at the American Society of Hematolgy annual meeting in December 2014, with results supporting the potential of melflufen to offer significant clinical benefit to patients with multiple myeloma.

Jakob Lindberg, CEO of Oncopeptides said: "Multiple myeloma is a devastating disease with a recognised unmet need for more effective therapies. These orphan designations are important regulatory milestones in taking melflufen to patients in both the EU and the US".

Orphan Drug Designation will provide Oncopeptides with a number of benefits during the development and commercialization process of melflufen, including a period of marketing exclusivity in both the US and EU, pending regulatory approval.

About Oncopeptides AB
Oncopeptides is a clinical stage pharmaceutical development company working to enhance oncology therapies by creating cytosuperiors of existing cytotoxic compounds. The company is targeting multiple myeloma as a first indication with its lead compound, named melflufen, which is a chemotherapeutic alkylator.

Oncopeptides is currently in the closing stages of a Phase II clinical trial (carried out across six centers; in Europe – in Sweden, Italy, the Netherlands and Denmark – together with Dana Faber Cancer Institute, Boston, MA and Chapel Hill, NC in the USA. Data from the trial is anticipated in Q2 of this year).

A family of enzymes that are overexpressed at very high levels in cancer cells, such as plasma cells in multiple myeloma, cleave melflufen so that the alkylating moiety accumulates at high concentrations within the diseased cells. This results in partially targeted delivery of the chemotherapeutic compound to the cancer cells and thereby better treatment of the disease.

For further information please contact:
Jakob Lindberg CEO
Oncopeptides AB, Stockholm, Sweden
Tel: +46 (0) 705 695 471
Email: jakob.lindberg@oncopeptides.se
Web: www.oncopeptides.se
----------END----------