

FOR IMMEDIATE RELEASE**Siena Biotech Announces FDA and EMEA Orphan Drug Designations and Phase I Clinical Study of SEN0014196 for the Treatment of Huntington's Disease.**

Siena, Italy, January 8th, 2010. Siena Biotech S.p.A. announced today that its orally active, selective SirT1 inhibitor SEN0014196 (6-chloro-2,3,4,9-tetrahydro-1*H*-carbazole-1-carboxamide), which is being developed as a disease-modifying therapy in Huntington's disease, has obtained Orphan Drug status both from the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The European Medicines Agency (EMA) granted Orphan Designation to Siena Biotech's SEN0014196 for the treatment of Huntington's disease on October 28, 2009 whereas the Office of Orphan Products Development of the FDA granted Orphan Drug designation for SEN0014196 on December 7th, 2009. The US Orphan Drug Act is intended to assist and encourage companies in the development of new drugs for the treatment of rare diseases and disorders affecting fewer than 200,000 people in the United States, providing economic and regulatory incentives to sponsors, including reduction of fees, protocol assistance and eligibility for seven-year market exclusivity. In the EU, and upon marketing approval, Orphan Drug Designation entitles to ten year's market exclusivity and eligibility for protocol assistance and possible exemptions or reductions from certain regulatory fees.

Siena Biotech also announced that SEN0014196 has entered Phase I clinical studies; the compound is being tested in a combined single- and multiple-dose study with a randomized, double-blind and placebo-controlled design to assess safety, tolerability and pharmacokinetics of SEN0014196 in a total of 96 male and female healthy volunteers.

"The Orphan Drug Designations obtained by this molecule brought into clinical trials by Siena Biotech, reaffirms the commitment of our company and its reference shareholder, the Monte dei Paschi di Siena Foundation, to fight diseases still without a cure", stated Marco Parlangei, Managing Director of the Monte dei Paschi di Siena Foundation and President of Siena Biotech. "We are excited to bring forward SEN0014196 into the clinic as it has the potential to be the first use of this class of molecules in this devastating disease".

In a series of preclinical studies, researchers at Siena Biotech have demonstrated the neuroprotective properties of SEN0014196 in a series of *in vitro* systems as well as its capacity to increase survival and ameliorate psychomotor and histological phenotypes in a widely employed *in vivo* preclinical model of Huntington's Disease, indicative of a disease-modifying activity. Additionally, the product exhibits a biopharmaceutical and preclinical safety profile compatible with chronic treatment of Huntington's Disease.

SEN0014196, also known as EX-527, was in-licensed by Siena Biotech from Elixir Pharmaceuticals Inc., Cambridge, Mass., USA, in 2009. Under the terms of the agreement with Elixir Pharmaceuticals, Siena Biotech has certain exclusive rights to develop and commercialize the compound in all countries of the world.

"We believe that SEN0014196 has all the characteristics to become a breakthrough product for the treatment of this devastating disease, still without a cure." said Giovanni Gaviraghi, M.D., C.Chem., CEO of Siena Biotech, "We are eagerly awaiting the results of the pivotal clinical studies to assess the disease-modification potential of SEN0014196 and confirm our pre-clinical evidence also in patients."

About SEN0014196 and SirT1 Inhibition in Huntington's Disease - The selective SirT1 inhibitor SEN0014196 displays cyto- and neuroprotective activity against toxicity induced by mutant huntingtin in

cellular models of Huntington's Disease increasing survival, amelioration of psychomotor behaviour and improvement in histopathological endpoints in the most widely employed animal models of Huntington's Disease, pointing towards a potential activity of the compound against this disease in humans. SirT1 is a protein deacetylase capable of modulating mutant huntingtin acetylation. Inhibition of SirT1 by SEN0014196 is expected to increase clearance of the mutant huntingtin without affecting levels of the normal protein.

About Huntington's Disease - Huntington's Disease is a monogenetic, autosomal dominant disease that gives rise to progressive neural cell death, characterized by chronic progressive chorea with a degenerative course over a period of 10-25 years, when the patient eventually succumbs to complications such as heart failure or aspiration pneumonia. Huntington's Disease is the most studied and better understood of a class of rare neurodegenerative conditions caused by expansion of CAG repeats in different genes and shares patho-mechanisms with other less studied neurodegenerative diseases. Huntington's Disease is therefore sometimes described as the model for this class of diseases where some degree of sharing in the underlying mechanisms might exist.

About Siena Biotech S.p.A. - Siena Biotech S.p.A. is an innovative, clinical-stage drug discovery company whose R&D efforts are mainly focused on discovering new drugs for therapeutic intervention against neurodegenerative diseases and in oncology. The company, based in Siena, Italy, is structured around drug discovery technology platforms from target validation to clinical studies. The company has developed an internal portfolio of several innovative R&D projects in three therapeutic areas: Alzheimer's Disease, Huntington's Disease and Cancer. The projects are rapidly progressing through the pipeline, in some cases as parts of strategic R&D alliances with major pharmaceutical companies. Siena Biotech has built a wide network of external collaborations, both in the academic and business communities, to add to the scientific excellence of internal R&D, thus creating a sound scientific base for its interactions with patients and physicians. Siena Biotech is the instrumental company of the Monte dei Paschi di Siena Foundation to operate in the field of scientific research and biotechnology, in line with its founding charter and mission.

More information about Siena Biotech available at <http://www.sienabiotech.com>.

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