



Opsona Therapeutics Ltd. receives orphan designation for myelodysplastic syndrome (MDS) with OPN-305, a first-in-class monoclonal antibody that blocks Toll-Like Receptor 2

October 25 2016, Dublin, Ireland – Opsona Therapeutics Ltd ('Opsona'), the innate immune drug and development company focused on novel therapeutic approaches to treat oncology, autoimmune and other inflammatory diseases, today announced that it has received orphan drug designation (ODD) from United States Food and Drug Administration for myelodysplastic syndromes (MDS).

Myelodysplastic syndromes are a complex and heterogeneous group of bone marrow failure disorders characterized by ineffective hematopoiesis, and poor prognosis. There is an urgent need for the development of novel therapies in the treatment of MDS which can delay progression, improve patient survival and quality of life, and which have fewer adverse effects.

OPN-305 is a novel proprietary humanized IgG4 monoclonal antibody (MAb) against Toll-Like Receptor 2 (TLR2), a key target within the innate immune system.

Evaluation of OPN-305 in MDS is the first of a range of oncology indications that the company is exploring with its leading drug in development, OPN-305. A study in patients with lower risk MDS who have failed hypomethylating agents is ongoing in collaboration with MD Anderson Cancer Center in Houston USA. Opsona believes that OPN-305 has the potential to be first and best-in-class while also providing a novel treatment option for a wide variety of oncology, autoimmune and other inflammatory diseases.

Commenting on today's announcement, **Mary Reilly, VP Pharmaceutical Development and Operations at Opsona Therapeutics**, said: *"We are pleased to receive FDA Orphan Drug Designation for OPN-305 in MDS. This is an important regulatory milestone for the company and a significant step forward in our clinical development of OPN-305 targeting this rare disease associated with an unmet medical need for safe and effective therapeutics."*

ENDS

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About Opsona Therapeutics

Opsona is a leading immunology drug development company, focused on novel therapeutic approaches to key targets of the innate immune system associated with a wide range of major human diseases, including cancer, autoimmune and other inflammatory diseases. The company was founded in 2004 by three world-renowned immunologists at Trinity College, Dublin. Opsona has a strong international investor consortium including: Amgen Ventures, BB Biotech Ventures, EMBL Ventures, Enterprise Ireland, Fountain Healthcare Partners, Inventages Venture Capital, Novartis Venture Fund, Omnes Capital, Roche Venture Fund, Seroba Life Sciences, Shire and Sunstone Capital.