Opsona Therapeutics Ltd. announces preliminary results from ongoing study in second line lower risk myelodysplastic syndrome (MDS) recently presented at the 58th Annual Meeting of the American Society of Hematology (ASH)

December 20 2016, Dublin, Ireland – Opsona Therapeutics Ltd ('Opsona'), the innate immune drug development company focused on novel therapeutic approaches to treat oncology, autoimmune and other inflammatory diseases, today announces the preliminary results from its ongoing prospective, open label Phase I/II study being conducted with OPN-305 in second-line lower (Low and intermediate-1) risk myelodysplastic syndrome (MDS) which created interest when presented recently at the 58th Annual Meeting of the American Society of Hematology (ASH) in San Diego by Prof Garcia-Manero from the MD Anderson Cancer Center.

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. Opsona has recently received orphan drug designation from the United States Food and Drug Administration for MDS.

The study in patients with lower risk, red cell transfusion dependent, MDS who have failed hypomethylating agents (HMA) ± an erythropoiesis stimulating agent is ongoing in collaboration with MD Anderson Cancer Center in Houston USA with additional sites now being added in the USA.

As of December 2016, 24 eligible patients have been enrolled, 11 at 5 mg dose and 13 at 10 mg/kg. A total of 15 (75%) patients are evaluable for response. Hematological improvement has been seen in 53% (8/15) with 3 (20%) patients achieving transfusion independence and of these 2/5 (40%) were receiving 10 mg/kg while on OPN-305 monotherapy. 12 patients remain on study.

Median age was 72 years (range 42-87). Nine (43 %) patients were classified as Low risk and 15 (63%) as Intermediate-1 risk by IPSS. Thirteen patients (61%) had diploid cytogenetics, 8 (38%) RAEB,5 (23%) RCMD, 3 (14%) RA, 2 (10%) RARS, and 1 (4%) 5q-, RCMD-RS, CMML.

The median number of prior HMA therapies was 2 (range 1-4) with a median duration of prior therapies from time of diagnosis to enrollment of 22.7 months (range 6.3-56.1). The median number of OPN-305 cycles administered is 5 (2-22) with 5 of 9 (55.5%) patients having received azacitidine add-back after 16 weeks of OPN-305 monotherapy. A total of 5 (29%) patients developed AEs related to OPN-305 all grade 1 with gastrointestinal disorders being the most

frequent (23.5%). At this point, no significant drug related toxicity or unexpected infectious complications have been seen and combination with azacitidine has been well tolerated.

To date three (20%) patients were taken off study due to progression to AML and 4 (27%) due to no response all at the 5 mg/kg dose. There is no evidence of treatment related anti-drug antibodies or statistically significant dynamic changes in cytokines in any of the patients.

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 well tolerated, novel therapies in the treatment of MDS which can delay progression, improve patient survival and quality of life and reduce the social and economic burden of transfusion dependence.

Commenting on today's announcement Mary Reilly VP Pharmaceutical Development & Operations said *"OPN-305 data emerging in this heavily pre-treated group of patients is very encouraging, the unmet need for a safe and tolerable product for this patient population is significant and we are happy to be in collaboration with the MD Anderson Cancer Center one of the leading clinical center's in this hematological area"*

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.