Highlight Therapeutics announces first patient dosed in Phase IIa study in liver metastasis

Second collaboration with MSD to evaluate combination of BO-112 and KEYTRUDA®

- New research studies may further accelerate delivery of novel treatment strategies for melanoma

Madrid, Spain – September 2, 2020: Highlight Therapeutics ("Highlight"), a clinical-stage biopharmaceutical company developing RNA-based therapies against cancer, announces it has entered into a second Phase II trial collaboration with a subsidiary of Merck & Co., Inc., Kenilworth, New Jersey, U.S.A., known as MSD outside the U.S. and Canada.

The collaboration will focus on the Phase II evaluation of the combination of BO-112, Highlight's lead program, and KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients that have progressed on anti-PD-1-based therapy in refractory advanced malignant melanoma.

The incidence of malignant melanoma is estimated to be 3-5 cases per 100,000 individuals in Europe. Activating therapeutic anti-tumor immunity by the modulation of the host immune system has become a key approach for treating melanoma. Antagonistic monoclonal antibodies (mAb) against immune inhibitory molecules such as CTLA4 (cytotoxic T-lymphocyte associated protein 4) and PD-1 (programmed death receptor-1) have improved the prognosis of patients with malignant melanoma and have been incorporated into oncology treatment guidelines as a standard of care. However, most patients treated in this way do not achieve a clinical response and many of those who do respond eventually develop progressive disease.

The trial, named Spotlight 203, will evaluate the combination of stimulation of the innate immune system by direct intra-tumoral administration of BO-112, combined with systemic administration of pembrolizumab, based on Response Evaluation Criteria in Solid Tumors (RECIST) 1.1, defined as the percentage of patients achieving a complete response or partial response as primary endpoint.

Spotlight 203 will also seek to further characterize the clinical activity of intra-tumoral BO-112 in combination with pembrolizumab by evaluating disease control rates, duration of response, progression-free and overall survival, as well as safety, tolerability and pharmacokinetics. A total of 40 patients are planned to be enrolled. The sample size for a subsequent randomized portion of the study will be determined based on efficacy results.

Marisol Quintero, CEO of Highlight Therapeutics, commented: "Spotlight 203 is designed to address the high unmet need of patients with unresectable stage III or IV melanoma who have failed anti-PD-1 therapy. Phase 1 data suggest the potential of BO-112 to sensitize the immune system against the tumor, including enhanced sensitivity to anti-PD-1 treatment. Based on clinical and pre-clinical studies, we believe intra- tumoral BO-112 has the potential to overcome resistance to anti-PD-1 therapy. We are pleased to build on our fruitful collaboration with MSD, whose extensive expertise in immune-oncology makes them the ideal partner.

"This partnership seeks to accelerate the development of therapies for patients with malignant melanoma. We are delighted to commence Spotlight 203 and to be able to combine our capabilities to accelerate the research of medicines in diseases with such a poor prognosis."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ. A Phase 2 clinical study of intra-tumoral BO-112 in combination with pembrolizumab in patients with liver metastases from colorectal or gastric/gastro-esophageal junction cancer is also currently underway.

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Notes to Editors

About melanoma

Almost 288,000 new cases of melanoma and more than 60,000 deaths were estimated worldwide in 2018 [Ferlay 2019]. In North America, melanoma is the fifth most common cancer in males and sixth most common cancer in females [Siegel 2018]. In the U.S, it is estimated that more than 100,000 patients will be diagnosed with melanoma in 2020, with almost 7,000 deaths recorded. Advanced or metastatic melanoma (unresectable Stage III, Stage IV) remains a lethal disease with a high proportion of patients resistant to approved therapies. There are currently limited treatment options for patients who progress on targeted therapy or immunotherapy, creating a high unmet need for novel therapies for advanced melanoma patients who have failed existing treatments.

About Highlight Therapeutics

Highlight, formerly known as Bioncotech Therapeutics S.L, is a private, clinical-stage company dedicated to unlocking the full potential of immuno-oncology. Its lead drug candidate BO-112 is a best-in-class RNA-based therapy which has been demonstrated to initiate a powerful immune response, leveraging a unique multi- target approach to turn 'cold' tumors 'hot' and therefore visible to the immune system. It has the potential to rescue patients who are resistant to current checkpoint inhibitor therapy, a very large market opportunity. BO-112 is currently being investigated in a range of clinical trials as a monotherapy and in combination with checkpoint inhibitors. In addition to in-house research, Highlight Therapeutics has a number of external collaborators, including Merck & Co and UCLA.