

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

Madrid, Spain - June 26, 2020: Highlight Therapeutics ("Highlight"), a clinical-stage biopharmaceutical company developing RNA-based therapies against cancer, announces the dosing of the first patient in a Phase IIa clinical evaluation of the combination of BO-112, Highlight's lead program, and KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with select advanced stage solid tumors with liver metastases.

The Phase IIa open-label clinical study is a non-comparative, two-cohort study across four countries of intratumoral administration of BO-112 in combination with pembrolizumab in patients with liver metastasis from colorectal cancer or gastric/gastro-esophageal junction cancer. Cohort A will consist of 11 patients with colorectal cancer for part 1, expanding to an additional 15 patients in part 2. Cohort B will consist of 18 patients with gastric or gastro-esophageal junction cancer in part 1, expanding to an additional 25 patients in part 2.

The study will evaluate the safety, tolerability, anti-tumoral activity and systemic exposure of repeated intratumoral injections of BO-112 into a hepatic metastatic lesion in combination with intravenously administered pembrolizumab.

A liver metastasis is a malignant tumor in the liver that has spread from another organ affected by cancer with limited viable treatments. The liver is the most common site for metastatic disease due to its rich, dual blood supply with metastatic tumors in the liver 20 times more common than primary tumors. Between 25-50% of patients with colorectal cancer and 30-50% of patients with gastric/gastro-esophageal junction cancer develop liver metastasis, leading to high morbidity and mortality rates and a non-response rate of ~90% to anti-PD1 therapies.

Marisol Quintero, CEO of Highlight Therapeutics, said: "The initiation of this Phase IIa study of the combination of BO-112 and KEYTRUDA® is an important step in our strategy to develop effective cancer therapies which can be used in combination with checkpoint inhibitors. Current treatments do not work for many cancer patients. However, BO-112 has demonstrated immunological changes in the tumor microenvironment which have the potential to play a key role in turning cold tumors hot, making them visible to the immune system. Liver metastases in particular are notoriously difficult to treat, and we believe that BO-112 has the potential to improve outcomes for patients treated with PD1 therapies."

Bioncotech Therapeutics S.L was renamed Highlight Therapeutics in March 2020.

Institutions participating:

Institut Jules Bordet
UCL St. Luc
University Hospital Antwerp
Universitair Ziekenhuis Gent
Universitaetsklinikum Leipzig, Universitaeren Krebszentrum
Charite Universitaetsmedizin Berlin, Campus Virchow
Klinikum der Universität München, LMU
Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology,
Hospital Universitario Reina Sofia,
Hospital Universitario Ramón y Cajal
Hospital Universitario Gregorio Marañón
Clinica Universidad de Navarra

Hospital Clinico Universitario de Valencia (INCLIVA)
Azienda Ospedaliera Ospedale Niguarda Ca'Granda
Niguarda Cancer Center y IRCCS Ospedale Policlinico San Martino

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Notes to Editors

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.