Madrid, Spain, March 2, 2021 – Highlight Therapeutics , ("Highlight"), a clinical-stage biopharmaceutical company developing RNA-based therapies against cancer, and Pivotal , a Europe-wide full-service CRO, today announced that the first patients have been recruited in a Phase IIa study to assess Highlight's lead program BO-112 in combination with an anti-PD1 therapy, in patients with unresectable or metastatic melanoma that have previously progressed to checkpoint inhibitors.

Melanoma is the most malignant tumor of the skin although it can be seldom found in other organs. Incidences of this tumor are rapidly increasing in western countries and, once disseminated, it has been considered an incurable disease with limited therapeutic options. Recently, immunotherapy with anti-PD1 (checkpoint inhibitors) showed encouraging results with 30-36% patients alive at 5 years. Unfortunately, the median PFS (progression free survival) is less than 12 months, mainly due to primary or acquired resistance to anti-PD1 treatment, and most of those patients will die due to the tumor or its complications.

"This Phase IIa study is an important step forward in our strategy to develop effective cancer therapies which can be used in combination with checkpoint inhibitors. We are looking to produce a better immunological response in anti-PD1 therapy-sensitive patients, and to induce or maintain responses for those patients that progress or are initially treatment-resistant. BO-112 has the potential to be employed from the beginning of disease treatment and we believe it offers patients a resistant status after immunological treatment," said Dr. Marisol Quintero, PhD, CEO of Highlight Therapeutics. "We are encouraged by the effectiveness already seen in previously treated melanoma patients in the phase I study with BO-112 and we are pleased to be working once more with the highly experienced and dedicated team at Pivotal."

This Phase IIa, open-label clinical study is a non-comparative trial implemented in 19 sites across Spain and France. The protocol will include a minimum of 40 non-resectable melanoma patients. This is the third trial with BO-112, following initiation of the the phase I trial in 2016. In 2020, a second trial was initiated in gastrointestinal tumors from which the first cohorts have already been successfully completed, and the recruitment of this Phase IIa trial has now been initiated in melanoma despite the obstacles presented due to the COVID-19 pandemic.

The study will evaluate the anti-tumoral activity and systemic exposure of repeated intratumoral injections of BO-112 into a tumoral lesion, in combination with intravenously administered anti-PD1. BO-112 has intrinsic anti-tumoral effects, but interestingly acts on several mechanisms involved in resistance to checkpoint inhibitors.

"The excellence in clinical research of the clinical investigators´ teams, together with Pivotal's infrastructure and vast experience in the implementation and performance of innovative early phases clinical trials, will allow us to accelerate the research and to quickly test this new treatment regimen," said Dr. Lourdes Huarte, PhD, Senior Vice President of Regulatory and Clinical Operations at Pivotal. "The challenge of this trial was to swiftly

implement the study and activate its recruitment in a period negatively impacted by the COVID-19 pandemic. We are delighted to have diligently achieved our first milestone with the recruitment of the first patients in this trial."

About Highlight Theraputics

Highlight Therapeutics, formerly known as Bioncotech Therapeutics, is a private, clinical-stage company dedicated to unlocking the full potential of immuno-oncology. Our 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.