- *Trial will examine administration of Highlight's BO-112 in combination with an anti-PD1 in patients with liver metastasis from colorectal or gastric/gastro-esophageal junction cancers*

- *First cohort of 11 patients already recruited out of ca. 80 planned, despite COVID-19 pandemic challenges*

- *First sites initiated in Spain, Italy & Belgium with additional countries and centers to be added*

- *Click here for hi-res image*

Madrid, Spain, October 21, 2020 – 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 cohort of patients has 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 liver metastasis from colorectal or gastric/gastro-esophageal junction cancers.

This Phase IIa, open-label clinical study is a non-comparative, two-cohort study across four countries. 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 first cohort of 11 patients has already been recruited, with trial centers quickly initiated in Spain, Italy and Belgium, despite the challenges of the COVID-19 pandemic.

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 anti-PD1.

"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. Current treatments do not work for many cancer patients, and we believe BO-112 has the potential to improve outcomes for patients treated with anti-PD1 therapies," said Dr. Marisol Quintero, PhD, CEO of Highlight Therapeutics. "We are encouraged by the progress already made in recruiting patients for this study and we are pleased to be working once again with the highly experienced and dedicated team at Pivotal."

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 approx. 90% to anti-PD1 therapies.

"The know-how and excellence in clinical research of the clinical investigators´ teams, together with Pivotal's 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, Vice President of Regulatory and Clinical Operations at Pivotal. “The challenge of this trial was to swiftly implement the study in a period of time negatively impacted by the COVID-19 pandemic." **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.

For more information, please visit www.highlighttherapeutics.com

About Pivotal

Pivotal was founded in 2001 by Dr. Ibrahim Farr on the principle that strategic medical advice and support should be the backbone of all clinical trials. After working for over two decades in the pharmaceutical industry, Dr. Farr recognized the need for a medium-sized CRO with a solid internal medical franchise that could act not only as the "doers" but also as the “co-thinkers” for their clients, through its strategic scientific advice. To date, we are the trusted adviser and counsellor for many companies to deliver maximum value in their drug and medical devices development programs. We are a leading privately held European CRO and, since inception, we have experienced a fast and steady organic growth in Europe.

Pivotal´s client portfolio spans major pharmaceutical, biotechnological, medical device and nutrition companies, as well as independent investigators and cooperative groups. We have long-standing relations with over 200 clients. Pivotal has extensive experience across major therapeutic areas and phases I to IV. Our highly customized teams bring to each client a combination of broad industry knowledge and operational excellence, to offer our clients fresh perspectives and breakthrough business insights. Additionally, we have built a strong oncology, innovative therapies, rare diseases and early phases hub that enables us to tackle our customers' most difficult challenges, turning recommendations into concrete actions. By remaining true to our core principles and values, our vision is to become our clients' preferred outsourcing solution partner.