

## Highlight Therapeutics and Pivotal work together on Melanoma therapy and launch a Phase IIa trial to examine BO-112 efficacy and safety

- Trial will examine administration of Highlight's BO-112 in combination with an anti-PD1 in unresectable or metastatic melanoma patients
- Recruitment has already begun across 19 top-level centers in Spain and France
- No delays to recruitment despite the persistent challenges encountered during the COVID-19 pandemic

Madrid, Spain, 2 March, 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 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 Therapeutics

*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](http://www.highlighttherapeutics.com); or

Contacts: Dr. Marisol Quintero CEO at Highlight Therapeutics [info@highlighttherapeutics.com](mailto:info@highlighttherapeutics.com)

Mo PR Advisory

Tel: +44 (0) 7876 444977 / 07860 361746

Mo Noonan/Jonathan Birt

## 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, infectious diseases, vaccines, 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 client's preferred outsourcing solution partner.*

For more information, please visit [www.pivotalcr.com](http://www.pivotalcr.com); or

Contact Ms Natalia Farr at Pivotal [natalia.farr@pivotalcr.com](mailto:natalia.farr@pivotalcr.com)