Madrid, Spain 3 July, 2019 – Pivotal , a specialist CRO, has been awarded two clinical trials for a novel investigational immunotherapy drug and patients' enrolment has now started. Pivotal will use its deep knowledge of oncology drug development to address a critical need for the expansion of immunotherapy programmes for Metastatic Melanoma (MM) and Non-Small Cell Lung Cancer (NSCLC) patients.

Immunotherapy has shown very promising results in the treatment of some solid tumours. This therapeutic approach has become available for more cancer patients but, despite these advances, there are still many of these patients with unmet medical needs. The current programme for these trials will be supported by Pivotal as CRO and is focused on the clinical development of an investigational immunotherapy drug which mobilises the patient's innate and adaptive immune systems to try to defeat cancer.

The incidence of malignant MM is estimated to impact 3-5/100,000 individuals in European countries and 5/100,000 in the US, and NSCLC is the most frequent tumour in both sexes, with 80-100/100,000 individuals in both USA and Europe.

Activating therapeutic anti-tumour immunity by the modulation of the host immune system has become a key approach for treating several solid tumours. Antagonistic monoclonal antibodies (mAb) against immune inhibitory molecules such as cytotoxic T-lymphocyte associated protein 4 (CTLA-4) and programmed death receptor-1 (PD-1) have improved survival of patients with MM and are already a standard of care. NSCLC immunotherapy has also been incorporated into the standard approaches in several settings, used either as monotherapy or combined with chemotherapy, depending on PD-L1 status, in the first line setting or, as monotherapy, in already pretreated patients.

This investigational immunotherapy drug will be tested under two different approaches (as monotherapy and as a combined treatment with an anti-PD1) in two different phase II clinical trials, the first one in MM patients and the second one in combination with an anti-PD1 in second line MM and NSCLC patients. Both trials will include up to 200 patients from 25 sites across the EU and US and will assess clinical benefit in terms of overall response rate and survival benefit as a primary objective.

"The power of partnerships, such as the one we are embarking on here brings together the best minds and capabilities to accelerate this dynamic area of research and bring therapies to patients with high unmet needs," said Dr Lourdes Huarte, VP Regulatory and Clinical Operations at Pivotal. "We are delighted to have started enrolment of patients in these two crucial trials and to have been able to deploy our capabilities to accelerate the development of medicines in such a difficult-to-treat area."

Pivotal is working in close partnership with a sponsor in the execution of this development programme across the US and EU, providing its resources to increase and streamline operational efficiency, including Start-up, Regulatory, Clinical Operations, Medical Monitoring, Data Management and Biostatistics among other operational services.