

### Bioncotech Therapeutics Announces Oncology Clinical Trial Collaboration with MSD

#### Phase II Trial with Combination of BO-112 and Pembrolizumab

Madrid, Spain – December 10, 2019: Bioncotech Therapeutics ("Bioncotech"), a clinical-stage biopharmaceutical company developing RNA-based therapies against cancer, announces it has entered into a Phase II clinical trial collaboration with a subsidiary of Merck & Co., Inc., Kenilworth, New Jersey, U.S.A., known as MSD outside the U.S. and Canada.

The collaboration will focus on the Phase II clinical evaluation of the combination of BO-112, Bioncotech's lead program, and KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with select advanced stage solid tumors with liver metastases. The trial will evaluate if the combination of stimulation of the innate immune system by direct intra-tumoral administration of BO-112, combined with systemic administration of pembrolizumab, shows safety and efficacy in patients with tumors that are poorly or only moderately responsive to monotherapy with an anti-PD1 agent.

"This collaboration is an important next step in the clinical development of BO-112 and the potential of the innate immune system and intra-tumoral route of administration to provide improved outcomes for cancer patients," said Marisol Quintero, CEO of Bioncotech. "We consider MSD, with its extensive expertise in immune-oncology, as the ideal partner for Bioncotech to complete this study."

"Early clinical data suggest BO-112 induces immunological changes in the tumor microenvironment and beyond, which may render previously anti-PD1 refractory tumors susceptible to checkpoint inhibition," added Dominique Tersago, CMO of Bioncotech. "Cancers that have metastasized to the liver present a significant therapeutic challenge. By targeting the metastatic liver lesions as the site for intra-tumoral injection we aim to reduce organ-related variability of the injection site, and also evaluate if BO-112 has potential to break through the generally immune tolerant hepatic environment and trigger or improve responsiveness to anti-PD1 therapy."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

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### **Notes to Editors**

#### **About Bioncotech**

Bioncotech is a Spanish biopharmaceutical company focusing on the development of RNA-based therapies against validated and novel targets in cancer and immune cells.

# **About BO-112**

Bioncotech's lead candidate, BO-112, is a formulated non-coding double stranded RNA (dsRNA) that acts as an agonist to toll-like receptor 3 (TLR-3), and the cytosolic helicases melanoma differentiationassociated gene 5 (MDA5) and retinoic acid-inducible gene I (RIG-I). It is a stimulator of the innate immune system, activates dendritic cells and induces interferons (IFNs), and also has been shown to trigger apoptosis and cause immunogenic cell death in tumor cells. BO-112 is being evaluated in combination with anti-PD1 treatment in a Phase I clinical trial. For information on clinical trials, please visit www.clinicaltrials.gov.