

# Highlight Therapeutics announces completion of enrollment for Ph 2b study of BO-112 in large, underserved BCC population

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Highlight Therapeutics ("Highlight"), a private, clinical-stage biopharmaceutical company advancing an innovative RNA-based skin cancer immunotherapy into late-stage development, announces completion of enrollment in its SPOTLIGHT-204, a phase 2b clinical evaluating BO-112, Highlight's lead asset, in patients with basal cell carcinoma (BCC). The completion of enrollment represents a major milestone for the company and highlights the unmet medical need in patients with basal cell carcinoma.



Mercedes Diz, CEO of Highlight Therapeutics, said: "The completion of enrollment in SPOTLIGHT-204 represents an important step in our strategy to develop innovative and scalable dermatology oncology therapies. BCC is a high-incidence disease in which treatment paradigms have remained largely unchanged for decades, particularly for patients with lesions in cosmetically and functionally sensitive areas. By advancing BO-112 in this Phase IIb study, we aim to help redefine the role of intratumoral immunotherapy in BCC."

## About SPOTLIGHT-204

SPOTLIGHT 204 is a multicenter, phase 2b, open-label, non-randomized, clinical trial to evaluate efficacy and safety of intra-lesional BO-112 as monotherapy in 50 patients with resectable

primary low and high-risk BCC currently ongoing in 10 clinical centers in Spain and Israel. The study evaluates BO-112 efficacy in patients with up to 8 BCC lesions, who are treated with 3 weekly intralesional injections of BO-112 followed by complete surgical excision of the injected lesions.

## About BCC

Traditional first line treatment for BCC, the most common human skin malignancy, involves surgical excision. Although surgery remains a standard treatment for BCC, in circumstances where excisional methods are not feasible or could lead to disfigurement or poor cosmetic outcomes, non-surgical therapeutic alternatives may be considered by the treating clinician, based on individual patient circumstances and applicable clinical guidelines. There are approximately 5 million BCC lesions diagnosed yearly in the USA with approximately 70% of BCCs affecting the face, most commonly the nose and eyelid, and therefore may require particular consideration of non-surgical therapeutic approaches in certain patients. As the incidence of BCC continues to increase, there is a need for additional effective alternative treatment options, particularly as our population ages.

## About Highlight Therapeutics and BO-112

Highlight is a private, clinical-stage company dedicated to advancing the potential of immuno-dermato-oncology. Its proprietary dsRNA platform is supported by scientific research, and its lead drug candidate BO-112 is an investigational RNA-based in-office, intralesional immunotherapy. BO-112 is designed to mimic the effects of a viral infection, stimulating the immune system to attack tumor cells through activation of dendritic cells, CD8 T-cell infiltration, induction of interferons (IFNs), induction of apoptosis and enhancement of immunogenic cell death.

BO-112 has been investigated in a range of phase 1 and 2 clinical trials as a monotherapy and in combination with checkpoint inhibitors. BO-112, in combination with KEYTRUDA®, has shown encouraging clinical efficacy in patients with anti-PD-(L)1 relapsed or refractory advanced and metastatic melanoma, including pathological complete responses in patients with non-visceral disease. BO-112 has an observed favorable risk-benefit profile to date in more than 170 patients with dermatology and cancer indications. BO-112 is an investigational product and has not been approved for any indication by any regulatory authority.

Highlight Therapeutics

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