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BO-112: a non-coding double-stranded ribonucleic acid (dsRNA)

Highlight Therapeutics

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HIGHLIGHT THERAPEUTICS: PRIVATE BIOTECH ADVANCING AN INNOVATIVE SKIN CANCER THERAPY INTO LATE STAGE DEVELOPMENT

Highlight Therapeutics

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LEAD DEVELOPMENT CANDIDATE BO-112: A POTENT IMMUNE MODULATOR

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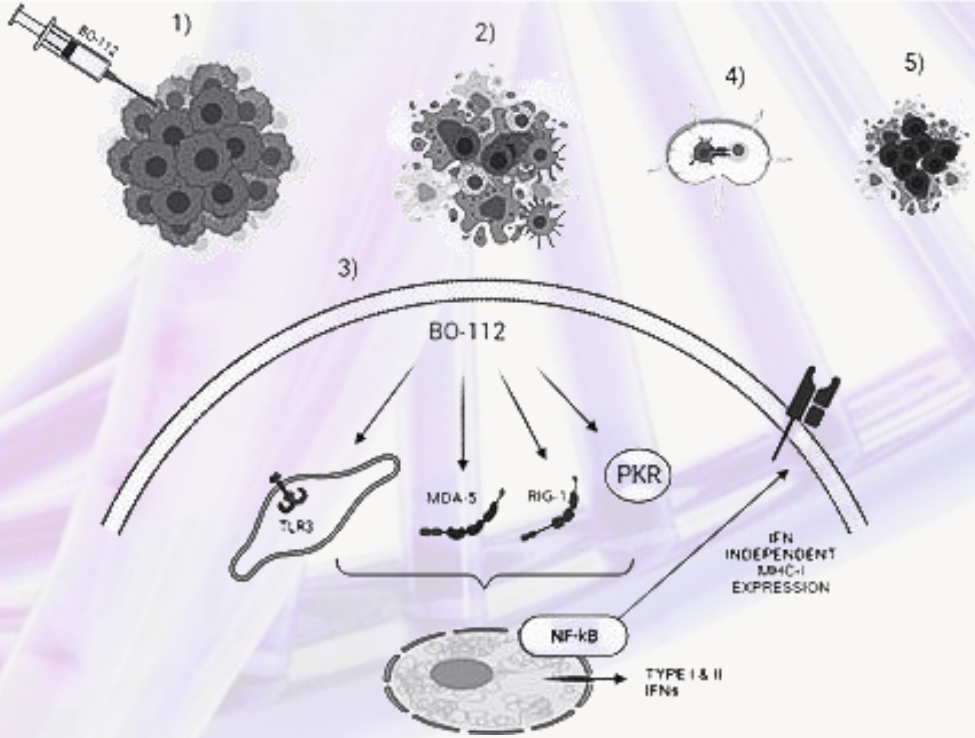
BO-112 is a non-coding double-stranded ribonucleic acid (dsRNA) based on **Polyinosinic Acid • Polycytidylic Acid** (Poly I:C) formulated with polyethyleneimeine (PEI).

It is an analog of double-stranded viral RNA thereby mimicking effects of a viral infection.

Mechanism of Action includes innate and adaptive **immune system activation** mediated by TLR3, MDA5, RIG-I, and PKR and **direct tumor cell death** creating a long-lasting immune response.



Aznar MA et al. J Immunother Cancer. 2019 May 2;7(1):116.
Kalbasi A et al Sci Transl Med. 2020 Oct 14;12(565).

BO-112 AVAILABLE DATA: END TO END PACKAGE

Highlight Therapeutics

Chemistry, manufacturing, and controls

Robust and up-scalable manufacture / Seven GMP batches.
Storage at 4ºC.

Non-clinical data

Non-clinical pharmacology covered by extensive in vitro and in vivo data.
Comprehensive toxicology package according to ICH S9 and M3(R2) requirements.

Clinical Efficacy and Safety

Outstanding efficacy in advanced a-PD-1 R/R melanoma (25% ORR).
Preliminary monotherapy efficacy in high-risk basal cell carcinoma (lead indication).
Mild and transient safety profile in more than 130 patients & various indications.

Fast to market development strategy

With limited competition: potential for use as monotherapy for non-melanoma skin tumors.

Intellectual Property

Robust IP and technical protection in support of a full and effective lifecycle.

Cost of Goods

Attractive cost of goods

PHASE II SPOTLIGHT-203: BO-112 PLUS PEMBROLIZUMAB FOR PATIENTS WITH ANTI–PD-1–RESISTANT ADVANCED MELANOMA, ORR 25%

Highlight Therapeutics

- 42 participants with unresectable stage III (9.52%) or stage IV (90.48%) melanoma with confirmed progression on prior anti-PD/L1 per SITC criteria were enrolled in the study.

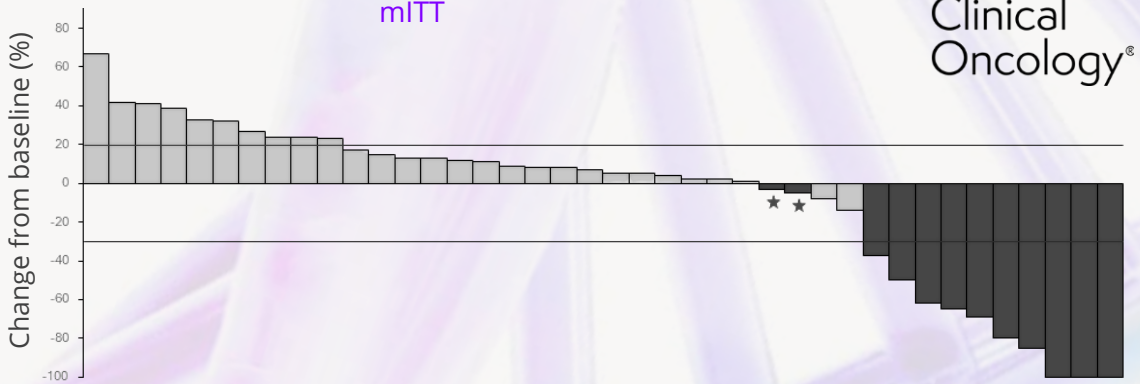
- **Efficacy:** 40 patients were evaluable and assessed by an Independent Review Committee according to RECIST 1.1.

  - **Objective Response Rate 25%** (95% CI: 12.69%, 41.20%, p=0.0008).
    - Four (10%) patients achieved complete response and six (15%) partial response.
    - Abscopal responses observed.
  - **Disease Control Rate 67.5%** (95% CI: 50.87%, 81.43%).
    - Seventeen (42.5%) patients achieved stable disease
  - Median PFS was 3.7 months (95% CI, 2.2 to 9.2)
  - Median OS was not reached (95% CI, 9.9 to NA), with 54% patients alive at 24 months.

- **Safety:** combination was well tolerated: 16 patients (38.1%) experiencing ≥G3-4 adverse events with four of them (9.5%) drug-related, and no deaths related to treatment.

Waterfall plot of best overall responses by IRCR in mITT

Journal of Clinical Oncology®



* Two patients with skin disease only, despite having a RECIST SD, achieved a pCR as evaluated by DMC

Waterfall plot of best overall responses in non-injected lesions (abscopal effect)

PHASE IIB SPOTLIGHT-204: BO-112 MONOTHERAPY IN BCC (LEAD INDICATION)

Highlight Therapeutics

Multicenter, Phase 2b, open-label, non-randomized, clinical trial to evaluate safety, tolerability and preliminary efficacy of **intra-lesional BO-112 as monotherapy** in patients with resectable primary LOW and HIGH -risk basal cell carcinoma (NCT06422936).

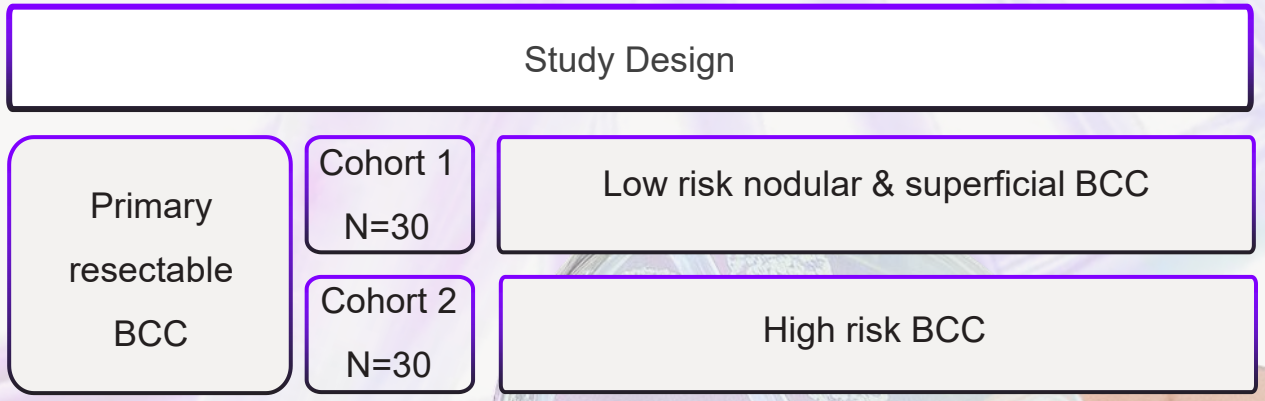
Enrollment planned to complete in Q4 2025

Eligibility

- Up to 8 injectable and resectable primary BCC lesions.
- Patients with Gorlin's syndrome are excluded.

Primary endpoint

- Composite visual and pathological response [at surgery] on patient level assessed by central review.

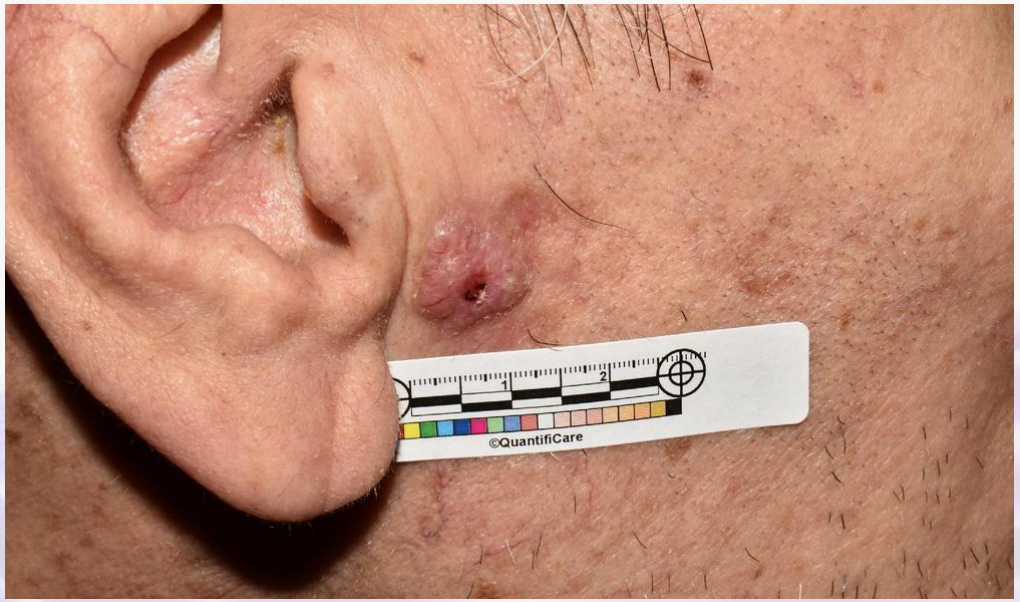


BO-112 EFFICACY IN BCC – CASE REPORT

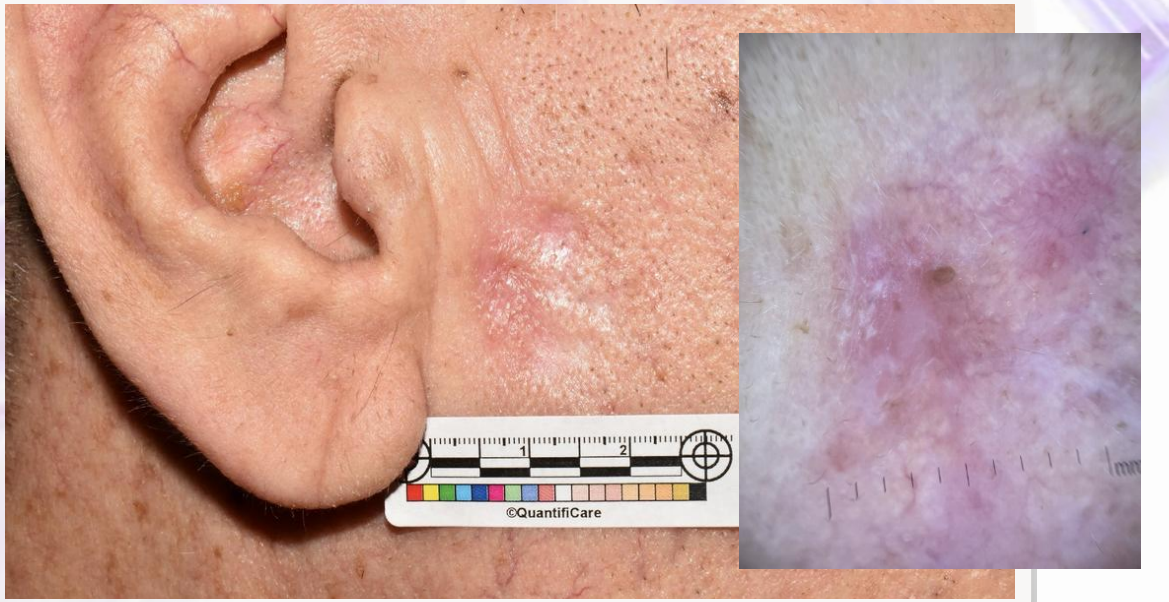
Highlight Therapeutics

A 75 years old male presented with 14 mm **high-risk mixed infiltrative BCC** in the right periauricular area.

Patient achieved complete visual and pathological response



Baseline

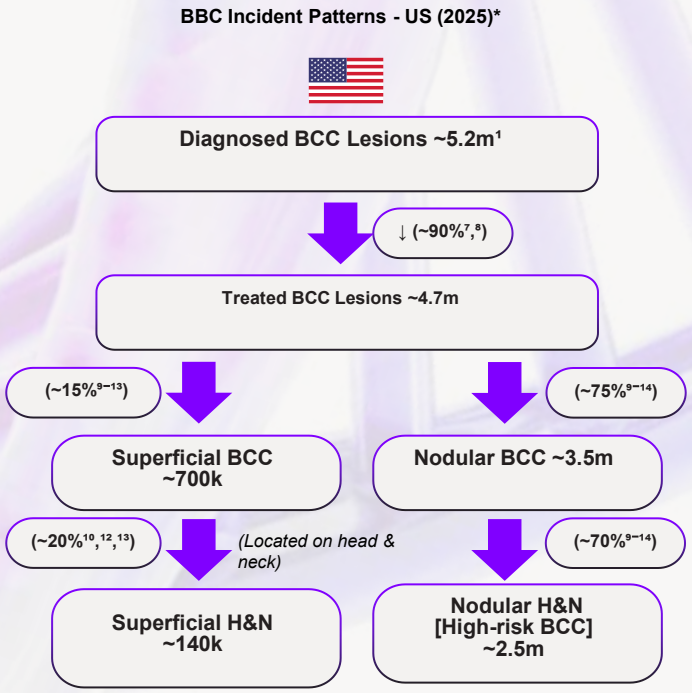


Prior to surgery (Week 24)

LARGE BCC MARKET AND RISING INCIDENCE

Highlight Therapeutics

- There is an **unmet medical need for non-surgical options** in patients with high-risk BCC lesions in cosmetically sensitive areas (i.e. Head & Neck) and multiple lesions.
- Estimated market of high-risk BCC in Nodular Head & Neck to be ~ **2.5 million lesions** in the US.
- Market amenable to **intralesional therapy.**
- **Physician dispensed.**
- BO/112 to be positioned as a product to treat **cosmetically sensitive high risk BCC lesions** as alternative option to (Mohs) surgery or as complementary treatment to minimize surgical risks.



*Literature based sources

KEY TAKEAWAYS
BO-112 AT THE FOREFRONT OF SKIN TUMOR CARE

Highlight Therapeutics

Novel efficacious solution for local treatment of skin tumors

Differentiated MOA capable of killing tumor cells and activating immune cells

Protected technology & well-established IP strategy. Global rights granted until 2041

Robust Clinical data

Proven efficacy in advanced melanoma

Promising efficacy in monotherapy in BCC

Manageable favorable safety profile in combination and monotherapy

Attractive commercial opportunity

Ideal combination partner for immuno-dermato-oncology treatments

Unique competitive advantage as loco-regional monotherapy with potential to cure BCC

Fast-to-market opportunity

Potential to expand to other indications