Highlight Therapeutics

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Highlight Therapeutics Presents Positive Phase 2b Topline Results of Intralesional BO-112 in Localized Basal Cell Carcinoma as a Late-Breaker at EADV

- Primary composite endpoint met: 61% of patients achieved visual and pathological response across all treated lesions.
- Complete clinical and pathological response in 56% of high-risk head & neck patients and 62% of patients with lesions in the face.
- BO-112 was well tolerated, with no serious adverse events and no Grade ≥3 treatment-related adverse events reported.
- Results support advancing BO-112 into late-stage development for localized primary basal cell carcinoma.

VALENCIA, Spain, Sept. 30, 2026 (GLOBE NEWSWIRE) -- Highlight Therapeutics, a clinical-stage biotechnology company developing immune activators to transform the treatment of skin tumors, today announced positive results from the multicenter, single-arm Phase 2b SPOTLIGHT-204 clinical trial evaluating BO-112, a novel dsRNA-based intralesional treatment for patients with resectable primary low- and high-risk basal cell carcinoma (BCC). BO-112 is investigational and has not been approved by any regulatory authority. Results will be presented today in a late-breaking presentation at the 35th European Academy of Dermatology and Venereology (EADV) Congress in Vienna.

The study met its primary endpoint of visual and pathological response at week 24 as well as key secondary endpoints, including safety and tolerability.

SPOTLIGHT-204 is believed to represent the largest cohort of high-risk head and neck (H&N) BCC patients treated to date with an intralesional therapy.

“Today marks an important milestone for Highlight Therapeutics as these results represent the first clinical validation of BO-112 in BCC and give us strong conviction to advance into late-stage development,” said Mercedes Diz, Chief Executive Officer of Highlight Therapeutics. “We are excited to bring this potential non-surgical option a step closer to patients, particularly those with high-risk BCC in the head & neck, where the need is greatest. It is precisely in this hardest-to-treat population that SPOTLIGHT-204's results stand out.”

BCC is the most common human malignancy[1], and its incidence continues to rise globally. Demand for treatments that preserve function and appearance keeps growing, but options remain limited. The most urgent need sits in high-risk BCC in cosmetically and functionally sensitive areas, particularly H&N and face, where appearance and function carry lasting emotional weight for patients[2-3]. For these patients, Mohs micrographic and conventional surgery achieve high cure rates but can result in significant scarring and functional compromise[4], and surgery remains the only recommended option for the majority of patients[5-6].

Josep Malvehy, MD, PhD, Professor of University of Barcelona and Director of Skin Cancer Program, Dermatology Department, Hospital Clínic of Barcelona, added, “I am very encouraged by the trial results. Effective non-surgical options remain an unmet clinical need for patients with high-risk BCC in the head & neck, who are also the hardest to manage surgically and carry the greatest concern about the impact of treatment. SPOTLIGHT-204 showed these patients achieved complete response in more than half of cases, and nearly two-thirds of those with facial lesions. These findings support BO-112's potential as a well-tolerated, non-surgical option for this population.”

SPOTLIGHT-204 Key Topline Phase 2b Results
The modified intention-to-treat population comprised 46 patients with 54 evaluable lesions assessed by a central review committee.

- **Primary endpoint met**: 61% (n=28/46) of patients achieved the composite endpoint of visual and pathological response (Grade 3 or better) across all treated lesions, with high visual and histological concordance.
- **Meaningful response rates in both low and high-risk cohorts:** 58% (n=21/36) of high-risk patients and 70% (n=7/10) of low-risk patients achieved visual and pathological response.
- **Strong activity in high-risk H&N:** complete visual and complete pathological response (both Grade 1) achieved in 56% (18/32) of high-risk H&N patients and 62% (16/26) of the patients with lesions in the face.
- **Safety:** BO-112 was well tolerated, with no serious adverse events (AEs), no Grade ≥3 treatment-related AEs, and no treatment discontinuations reported. The vast majority of treatment-related adverse events were mild, with 91% graded as Grade 1, and 88% resolving within three days.

EADV Late-breaking presentation details:

- Abstract ID: LB-309
- Abstract title: SPOTLIGHT-204: Primary Results of Intralesional BO-112 in Resectable Basal Cell Carcinoma
- Presenter: **Prof. M. Teresa Fernández-Figueras** MD, PhD
- Session title: D1T01.1 – Late Breaking News
- Session date and time: Wednesday, 30 September, 15:00-15:15

About the SPOTLIGHT-204 Trial
SPOTLIGHT-204 (NCT06422936) is a Phase 2b, multicenter, single-arm clinical trial evaluating efficacy, safety and tolerability of intralesional BO-112 in patients with resectable primary low and high-risk BCC. The trial enrolled 50 patients, including 40 high-risk (36 presenting with head & neck lesions) and 10 low-risk who received three once-weekly intralesional BO-112 injections followed by complete surgical excision at week 24. The median age was 75 years (range 34–90) and 48% of patients were female. The primary endpoint is visual and pathological response at week 24, assessed by a central review committee. Key secondary endpoints include safety and tolerability as well as visual and pathological response assessed separately by investigator and central review.

About Basal Cell Carcinoma (BCC)

Basal cell carcinoma is the most common human malignancy[1], and its incidence continues to rise globally. Mohs micrographic and conventional surgery achieve high cure rates but can leave significant scarring and functional compromise when lesions arise at cosmetically or functionally sensitive sites, particularly on the head and neck[3]. Effective non-surgical options that can be delivered at the point of care in dermatology practice therefore remain an unmet clinical need.

About BO-112

BO-112 is a double-stranded RNA nanoparticle formulated for intralesional administration. Its immunotherapeutic activity is mediated through activation of innate antiviral sensing pathways, induction of immunogenic tumor cell death, and subsequent development of tumor-specific adaptive immunity.

About Highlight Therapeutics

Highlight Therapeutics is a clinical-stage biotechnology company developing dsRNA-based intratumoral immune activators to transform the treatment of skin tumors, with a lead focus on dermato-oncology. The company's lead asset, BO-112, is a first-in-class agent designed to convert immunologically "cold" tumors into "hot," immune-visible ones, activating both the innate and adaptive immune systems through a multi-target mechanism. Phase 2b results support advancing BO-112 into late-stage development for localized primary basal cell carcinoma.

Highlight is headquartered in Valencia, Spain. To learn more, visit our website at www.highlighttherapeutics.com.

BO-112 is investigational and has not been approved by any regulatory authority.

[1]*Cameron MC, et al. "Basal cell carcinoma: Epidemiology; pathophysiology; clinical and histological subtypes; and disease associations." Journal of the American Academy of Dermatology (JAAD), 2019*

[2] *Martin I, Schaarschmidt ML, Glocker A, Herr R, Schmieder A, Goerdt S, Peitsch WK. Patient preferences for treatment of basal cell carcinoma: importance of cure and cosmetic outcome. Acta Derm Venereol. 2016;96(3):355-360.*

[3] *Stundys D, Ulianskaite G, Stundiene I, Grigaitiene J, Jancoriene L. The Quality of Life in Surgically Treated Head and Neck Basal Cell Carcinoma Patients: A Comprehensive Review. Cancers. 2023;15(3):801.*

[4] *Dika E, Scarfì F, Ferracin M, Broseghini E, Marcelli E, Bortolani B, et al. Basal Cell Carcinoma: A Comprehensive Review. Int J Mol Sci. 2020;21(15):5572. doi: 10.3390/ijms21155572*

[5] *Bichakjian C, Armstrong A, Baum C, et al. Guidelines of care for the management of basal cell carcinoma. J Am Acad Dermatol. 2018;78(3):540-559*

[6]*Basset-Seguin N, Herms F. Update in the Management of Basal Cell Carcinoma. Acta Derm Venereol. 2020;100(11):adv00140. doi: 10.2340/00015555-3495*

Forward-Looking Statements

This release contains forward-looking statements regarding BO-112's development, which involve risks and uncertainties. Topline results include a preliminary analysis as of the data cut-off date and may change upon full analysis. Highlight Therapeutics undertakes no obligation to update these statements except as required by law.

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