Unlocking the potential of IO

Overcoming anti-PD1 resistance to create best-in-class intra-tumoral immunotherapy
• BO-112 differentiated from other intratumoral innate immune activating agents
  - Unique single agent activity demonstrated in pre-clinical studies
  - Addresses two main mechanisms mediating resistance to anti-PD1 therapies
  - 50% of anti-PD1 resistant melanoma patients had clinical benefit after a few BO-112 injections - similar trends in other solid tumors
  - Compares favorably with lack of clinical efficacy for STING/RIG agonists, potentially superior to TLR9 agonists

• Three opportunities of success in the Phase 2 trials to prove BO-112’s superior efficacy in reversing anti-PD1 resistance

• Strong and growing IP through 2036 and beyond in US and EU

• Raising €22M to help deliver results from three Phase 2 / POC studies by 2022 (latest trial)

• Multiple potential strategic exits and options guided by Internationally-experienced management team and advisers

BO-112 offers potential solution to anti-PD1 resistance to transform cancer immunotherapy
The Company
Management, Boards and who we are
Executive Team and Board

Marisol Quintero, PhD, MBA
CEO/Board Member

- Head Biotech and Medicinal Chemistry at Spanish National Cancer Research Centre
- BD and Tech Transfer at Spanish Cancer Research Centre, Fundación Botín, Life Length
- Pharmacy degree (University of Valencia), PhD in Pharmacology (UCL), Executive MBA (Instituto de Empresa)

Carlos Paya MD PhD
Executive Chairman of the Board

- Leading physician-scientist at the Mayo Clinic
- Leadership track record in pharma, biotech, and start-ups
- Strategy, pipelines development, global launches and product life cycle
- Executed Company growth plans, successful fundraising in private/public markets, and via BD and M&A

Mark Branum, PhD
CMC & Manufacture

- Executive Director of CMC at Immune Design, until acquisition by Merck
- Senior CMC roles at OncoResponse and Theraclove Sciences
- Led academic R&D collaborations
- Ph.D. in biological chemistry (University of Minnesota), post-doctoral studies in biochemistry with Nobel Laureate Aziz Sancar (University of North Carolina)

Michael Doherty
Regulatory Strategy

- Led Global Regulatory Affairs at Roche
- Launch No.1 oncology portfolio with a franchise of monoclonal antibodies and targeted medicines
- Member of the Roche portfolio committee from 2002 to 2016
- Prior positions: Global Head, Pharma Regulatory Affairs, Hoffmann La-Roche and Genentech

Non-Executive Members:
Janwillem Naesens (DROIA), Damia Tormo (COLUMBUS), Shahzad Malik (ADVENT), Matthias Van Woensel (DROIA)
Scientific Advisory Board

Ralph R. Weichselbaum; MD

- Professor of Radiation and Cellular Oncology Chair, Department of Radiation and Cellular Oncology, University of Chicago
- Made discoveries in basic signal transduction after ionizing radiation exposure and, in separate studies, discovered mechanisms of radiation resistance/sensitivity are mediated by cytokine activation in tumors
- Currently investigating the relationship between radiotherapy and immunotherapy

Antoni Ribas, MD, PhD

- Professor of Medicine, professor of Surgery and professor of Molecular and Medical Pharmacology at UCLA
- Director of Tumor Immunology Program at Jonsson Comprehensive Cancer Center; Director of Parker Institute for Cancer Immunotherapy Center, UCLA
- Chair of SWOG Melanoma Committee; member of American Society of Clinical Investigation
- Recipient of AACR Richard and Hinda Rosenthal Award and NCI Outstanding Investigator Award

Ignacio Melero, MD, PhD

- Professor of Immunology of the University of Navarra
- Leads a group working in translational tumor immunotherapy with emphasis on cell therapy, cytokine gene therapy, and immune-stimulatory monoclonal antibodies
- Earlier in his career, contributed to seminal discoveries in the function of Natural Killer cells, and T-cell costimulation via CD137 (4-1BB)

Michael Doherty

- Led the Global Regulatory Affairs function at Roche through the important growth years where Roche launched the number one oncology portfolio with a franchise of monoclonal antibodies and targeted medicines. Member of the Roche portfolio committee from 2002 to 2016
- Prior positions: Global Head, Pharma Regulatory Affairs, Hoffmann La-Roche Ltd., Basel/Genentech, San Francisco
Clinical-stage oncology company maximizing potential of checkpoint therapy

Targeting anti-PD1 resistance to transform cancer immunotherapy

- Phase 2 asset BO-112 offers a unique and superior solution to anti-PD1 resistance
- Sound clinical strategy including three Phase 2 / POC trials with Merck
- Primary and acquired resistance a major barrier to successful cancer immunotherapy
- Series B with potential for three significant, parallel inflection points
Clinical-stage oncology company maximizing potential of checkpoint therapy

Targeting anti-PD1 resistance to transform cancer immunotherapy

Phase 2 asset BO-112 offers a unique and superior solution to anti PD1 resistance

- Unique multi-target approach to turn cold tumors hot and visible to immune system
- BO-112 activates selected signaling pathways in tumor microenvironment and specifically and uniquely in tumor cells
- Pre-clinically & clinically superior to other innate immune activators in clinical development (TLRs, RIGI, and STING agonists)
- Backed by robust and growing IP to 2036 and beyond in US and EU

Primary and acquired resistance a major barrier to successful cancer immunotherapy

- Most tumor types don’t respond to checkpoint therapy with only 20-40% response rate for single agent in the best cases
- **Primary** resistance - mainly due to lack of T-cells trafficking to tumor ("cold" tumor)
- **Acquired** resistance – due to reduced MHC1 in tumor cell
Development program designed to maximize chances of success

Three clinical programs underway with Merck

Sound clinical strategy including three Phase 2 / POC trials with Merck

- Three separate Phase 2/POC trials being initiated in collaboration with Merck & Co. in patients with anti-PD1 resistance using ORR as primary endpoint
- Additional independent Investigator-led studies including UCLA Phase 1 at the UCLA Jonsson Comprehensive Cancer Center, US
- Proven safety and activity in Phase 1 as monotherapy and in combination with anti-PD1’s
- Focus on indications with unmet medical need and where intra-tumoral therapy has advantages over systemic therapies

Series B with potential for three significant, parallel inflection points

- Three opportunities of success in the Phase 2 trials to prove BO-112’s superior efficacy in reversing anti-PD1 resistance
- Multiple potential strategic exits
- Highly experienced international management, Board and SAB to drive success
Clinical Development strategy

Maximizing chances of success of BO-112 to unlock the full potential of anti-PD1 therapies
Unlocking the full potential of checkpoint inhibitors

Turning cold tumors hot

BO-112 in combination with anti-PD1 antibodies shows potent & durable clinical responses in patients not responding to anti-PD1 antibodies

Stimulation of immune system using anti-PD1 antibodies significantly improves survival in some cancers e.g. melanoma, NSCLC

Most tumor types don’t respond to checkpoint therapy - best case single agent response rate 20-40%

Activating immune system can stimulate tumor neoantigens and priming of T cells Turning cold tumors hot

STING, RIG1/MDA5, TLR9 trigger tumor cell death, expression of type I IFNs and pro-inflammatory cytokines and recruitment of immune cells
BO-112 multi-pathway approach has a duel positive effect

Targeting different dsRNA sensors confers superiority to achieve potent immune modulation of tumor micro-environment.

Multi-pathway approach combines activation of immune system to improve effectiveness with direct effect on tumors to make them more sensitive to T-Cell recognition and attack.

Vanpouille- Box et al, Nat. Reviews Drug Discovery. Sep 2019
Unlocking a large potential oncology market opportunity
Addressing Primary and Acquired immunity

Reverse Acquired anti-PD1 resistance
Positive signal in solid tumors especially melanoma for ORR

Enable anti-PD1 primary resistance in cold tumors
Target liver metastasis which dictate prognosis in two GI malignancies

SPOTLIGHT 202
Phase 2 liver metastasis from CRC (MSS)- 2nd L
Phase 2 liver metastasis from GC (MSS)-3rd L

SPOTLIGHT 203
Melanoma Phase 2 trial-2nd L
No treatment
The tumor is not detected by the immune system and grows without interference.

TUMOR
They do not express MHC-1, which needs to be detected by the immune system.

IMMUNE SYSTEM
Macrophages: They see the tumor in a neutral mode; they ignore the tumor and allow it to grow.

Dendritic cells: Without MHC-1 they cannot detect the tumor and remain inactive.

Lymphocytes: Not present or not properly activated to detect and attack the tumor.

Mode of action

TUMOR
BO-112 activates a series of intracellular cascades that trigger immunogenetic cell death, leading to TCR-dependent cell death in MHC-1-deficient tumor cells.

IMMUNE SYSTEM
Dendritic cells: They recognize the antigens presented by MHC-1 and present them to lymphocytes.

Lymphocytes: BO-112 increases the expression of MHC-1 peptides, making the tumor easier to detect and attack.

TUMOR RECOGNITION
BO-112 fragments of double-stranded RNA injected directly onto the tumor.

TUMOR DEATH
Lymphocytes anti-tumor effect.

Treatment with BO-112
The double-stranded RNA simulates a viral particle. It makes tumor cells more sensitive and detectable by the immune system, which is also more active.

BO-112
Lymphocytes anti-tumor effect +

IMMUNE SYSTEM
Dendritic cells: They recognize the antigens presented by MHC-1 and present them to lymphocytes.

Lymphocytes: They are activated to the tumor and begin to attack it due to MHC-1 and dendritic cells. Also activated directly by the presence of BO-112.

TUMOR DEATH
Lymphocytes anti-tumor effect.

COMBINABLE
This treatment can be combined with other different therapies to achieve a higher anti-tumor effect.

MUTIPLE ACTIVATION
BO-112 activates several complementary intracellular cascades, thus enhancing its effect.
<table>
<thead>
<tr>
<th>Phase 1/1b</th>
<th>Phase 2</th>
<th>Indication</th>
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<tbody>
<tr>
<td><strong>SPOTLIGHT 101</strong></td>
<td>BO-112 mono</td>
<td>Melanoma, leiomyosarcoma, breast cancer</td>
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<tr>
<td><strong>SPOTLIGHT 102</strong></td>
<td>BO-112 + anti-PD1</td>
<td>NSCLC, SCCHN, melanoma, RCC</td>
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<td><strong>SPOTLIGHT 202</strong></td>
<td>BO-112+ pembro</td>
<td>Colorectal cancer with liver mets</td>
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<td><strong>SPOTLIGHT 203</strong></td>
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<td>Melanoma*</td>
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<tr>
<td><strong>IST</strong></td>
<td>BO-112 + nivolumab</td>
<td>Resectable soft tissue sarcoma pre-surgery*</td>
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SPOTLIGHT

CLINICAL TRIALS

| SPOTLIGHT 101 | Phase 1 BO-112 monotherapy |
| SPOTLIGHT 102 | Phase 1b BO-112 + anti-PD1 combination in anti-PD1 resistant patients |
| SPOTLIGHT 202 | Phase 2 BO-112 + pembrolizumab combination in Liver Metastases |
| SPOTLIGHT 203 | Phase 2 BO-112 + pembrolizumab combination in melanoma |
SPOTLIGHT

C L I N I C A L T R I A L S

SPOTLIGHT 101 Phase 1
SPOTLIGHT 102 Phase 1b
Study design

- BO-112 (0.6 mg and 1mg) administered intratumorally up to 3 sequential times into a single lesion (median lesion size 4 cm) to patients with solid tumors:
  - melanoma, leiomyosarcoma, and breast cancer
- Primary endpoint: safety and tolerability
- Secondary endpoint: tumor biomarkers of biological activity (apoptosis/necrosis & T-cell infiltrate)
- 16 patients in 3 Study cohorts
  - 6 patients: 0.6 mg single IT administration
  - 3 patients: 0.6 mg three consecutive IT administrations (same lesion)
  - 7 patients: 1.0 mg three consecutive IT administrations (same lesion)

Results

- Tumor Biomarkers post treatment demonstrate clear clinical benefit:
  - Increases in tumor cell death observed in 15/16 patients (despite only 1-3 injections)
  - Increases in CD4+ and CD8+ T cell infiltrates observed in 6 and 3 patients, respectively
  - non-injected lesions show increased tumor necrosis
  - 52 different genes associated with immune response were upregulated in the tumor
- Increased peripheral blood biomarker activity post treatment:
  - Increased (>15% vs. baseline) CD8+, CD4+ T cells, CD4+ T regs, NK, DC, pDC, monocytes and B cells in PBMNCs from 14/16 subjects
- Safety and tolerability well tolerated with mild flu-like symptoms

Pre and post-treatment images from multiplex analysis of a tumor biopsy.
**Highlight Therapeutics**

Unlocking the potential of immuno-oncology

### SPOTLIGHT 101

**Phase 1**

**BO-112 monotherapy**

**Abscopal effects observed with BO112 monotherapy**

Increased necrosis in non-injected metastatic lesions from 46 year-old female with stage IV leiomyosarcoma and progressive disease after several lines of chemotherapy including an anti PD1/LAG 3 combination.

**Pre and post images from CT-scans**

- **Pre-treatment**
  - Injected
  - Non-Injected
- **Post-treatment**
  - Injected
  - Non-Injected
Phase 1b
BO-112 + anti-PD1 combination in anti-PD1 resistant patients

Study design
- Regimen: Addition of intratumoral BO-112 to anti-PD1 therapy
- Inclusion criteria: anti-PD1 resistance (Radiological progression while on anti-PD1 therapy) - toughest to treat
- Sample size: 28 patients with metastatic disease
  - NSCLC 13, SCCHN 4, melanoma 10, & RCC 1
  - 71% had visceral (39% lung, 25% liver) or bone lesions
  - 43% of patients had received 2 or more prior lines of treatment
- 20/28 (71%) patients had only 1 lesion injected throughout the study
- Primary objective: safety and tolerability of combination
- Secondary objectives: immune responses, evidence of clinical benefit
- First efficacy assessment performed early: after only 4-5 injections

Results
- Increased anti-tumor CD8+ T lymphocytes and genes associated with T cell cytotoxic effects and antigen presentation post-BO-112 correlates with ORR
- Evidence of Clinical Benefit:
  - BO-112 reversed primary anti-PD1 resistance in:
    - 50% (5/10) of Melanoma patients: 20% ORR (PR) & 30% SD³
    - 100% (1/1 RCC pt: ORR (PR)
    - 47% (8/17) of NSCLC & SCCHN patients: SD
  - Systemic tumor reduction also observed in non injected distal lesions
  - One patient (characterized as a SD) is a PR based on best response in target lesions
- No additional side effects
Injection frequency & relevance vs competition in melanoma

- 2/10 and 3/10 of anti-PD1 primary resistant melanoma patients showed durable PRs or SD, respectively with BO-112 injected only up to 4-5 injections before the efficacy assessment (12 weeks)
- Combination of CMP-001 (TLR9 agonist, Checkmate) + pembro in a similar population reported*
- ORR of 7.7% 4 injections first 12 weeks
- ORR 22.5% 8 injections first 12 weeks
- *Abstract CT144. Milhem et al. AACR 2018

77% (17/22) of patients progressing to anti-PD1 became durable SD or ORR; melanoma: 50% DCR; (20% ORR*)

Changes in CD8 T cell infiltrates in the tumor correlates with clinical benefit
Conclusions

**Monotherapy**
- Favorable safety, clinical & biomarker activity observed after single intratumoral injection
- Abscopal effects with monotherapy very hard to observe in solid tumors

**BO-112+ anti-PD1 in anti-PD1 resistant patients**
- 77% clinical benefit in patients from different solid tumors with up to 30% ORR in melanoma
- Clinical signal across all studied indications, meaningful responses in melanoma and patients with liver metastases
- Post-treatment changes in CD8+ T cell infiltrate in tumor is a biomarker to predict responses

**Next steps**
- Focus on melanoma and patients with liver metastases
- ORR as primary endpoint
- Unmet medical need in 2L in CRC, 3L Gastric, and 2L melanoma
- Potential for accelerated approval if ORR similar or superior to Spotlight 001 & Spotlight 002
- 3 separate Phase 2/POC trials (liver metastases in patients with CRC, liver metastases in patients with GC, and melanoma)
Spotlight 202 Phase 2
Spotlight 203 Phase 2
Rationale for liver metastasis indication

- Liver metastasis is the most common metastasis in colorectal (CRC) and gastric cancer (GC)
  - Poor prognosis; high unmet need; rapid read out
  - Variable levels of immune cell infiltration (associated with treatment outcomes), usually “cold”
  - Single organ type for injections minimizes organ-specific heterogeneity of tumor microenvironment
- Evidence of safety and activity from SPOTLIGHT 101 and 102 in anti-PD1 resistant patients:
  - Monotherapy: Increase in necrosis observed in liver metastases from patient with adenoid cystic carcinoma after 2 injections of BO-112

Study overview

1. Open-label, non-comparative, two-stage study of BO-112 in combination with pembrolizumab in up to 26 3rd line anti-PD1 naïve patients with liver metastases from CRC
   - Trial started enrolment June 2020
   - Sites: Belgium, Germany, Italy, Spain
   - Primary endpoints: ORR and AEs grade 3
   - Secondary endpoints: disease control rate (DCR), duration of response, PFS, OS at 6 months, AEs all grades
2. Open-label, non-comparative, two stage study of BO-112 in combination with pembrolizumab in up to 43 2nd line anti-PD1-naïve patients with liver metastases from Gastric/GEJ cancer
   - Primary endpoints: ORR and AEs grade 3
   - Secondary endpoints: disease control rate (DCR), duration of response, PFS, OS at 6 months, AEs all grades

- Collaboration with Merck & Co.
Study overview

- Phase 2/POC, open-label, single arm clinical study to evaluate the efficacy and safety of intra-tumoral administration of BO-112 in combination with pembrolizumab in patients that have progressed on anti-PD1-based therapy as first line in refractory unresectable malignant melanoma stage III or IV
- Indication: 2nd line melanoma
- Q4 2020 start
- 40 patients
- Sites: France, Germany, Italy, Spain (UK, US, Netherlands, Israel, Belgium to follow)
- Primary endpoint: ORR
- Secondary endpoints: disease control rate (DCR), duration of response (DOR), progression-free survival (PFS), overall survival (OS), and iRECIST ORR, DCR, DOR and PFS

2L MELANOMA
anti-PD(L)1 resistant

BO-112 QW for 7 weeks then Q3W plus pembrolizumab Q3W
N=40

ORR
Investigator-led studies

UCLA Phase 1 Sarcoma Clinical Trial
Study overview

- Phase 1 clinical trial to study side effects of Nivolumab + BO-112 before surgery for treatment of resectable soft tissue sarcoma

- Rationale:
  - Immunotherapy with mAb (e.g. nivolumab) may help immune system attack the cancer and may interfere with ability of tumor cells to grow and spread
  - Immunotherapy with BO-112 may induce changes in immune system and may interfere with ability of tumor cells to grow and spread; giving nivolumab + BO-112 before surgery may work better in treating patients with soft tissue sarcoma compared to nivolumab alone

- Q4 2020 start
- 25 patients
- Sites: US
- Primary endpoint: frequency and severity of AEs and dose-limiting toxicities
- Secondary endpoints: immune-oncologic impact of combined regimen of nivolumab and BO-112 and pathologic treatment effect
Use of proceeds
Series B Use of Proceeds

€22 million raise to complete and follow through three separate Phase 2/POCs

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<td>Q1</td>
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<td>Current financial status</td>
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Series B funding

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<td>Stage 1 CRC 11 patients</td>
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<td>Stage 2 CRC 15 patients</td>
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Increasing sector focus underlines significant potential value

Developing a competitive position

• Checkmate and Idera (TLR9 agonist) targeting solid tumors
• Clinical package shows BO-112 uniquely able to modify immune pathway, making tumor cells more susceptible to therapy
  - BO-112 demonstrated similar efficacy with fewer injections
  - Potentially superior efficacy combining tumor intrinsic pathways with innate immunity activation
  - Lower injection requirement = barrier to entry for competitors

Rigontec acquired by MSD for $137m, up to $553m milestones (2017)

IFM Therapeutics acquired by BMS for $300m upfront, up to $2.3bn milestones (2017)

Aduro BioTech co-development with Novartis - $200m upfront, up to $750m milestones (2015)

Immune Design acquired by MSD for $300m (2019)

Significant deals for RIG1/MDA5 STING, TLR9 agonists

Bristol-Myers Squibb

Novartis
• BO-112 differentiated from other intratumoral innate immune activating agents
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BO-112 offers potential solution to anti-PD1 resistance to transform cancer immunotherapy
Highlight Therapeutics
Unlocking the potential of immuno-oncology

Marisol Quintero, CEO
info@highlighttherapeutics.com
www.highlighttherapeutics.com