2023 SITC Regular / ESMO LBA Titles: Quick IO Takes

September 28, 2023

Bottom Line: Numerous LBA presentations at ESMO are important for Merck (MRK, OP), including a session on belzutifan, (potentially) frontline bladder cancer data, competitor data in non-small cell lung cancer (NSCLC), and clinical correlate data with INT (with Moderna [MRNA, UP: Foroohar]). BioNTech (BNTX, OP) has several presentations at SITC across their portfolio with additional anti-CTLA4 data the most important, in our view. Werewolf (HOWL, OP) has first-in-human data for their tumor-selective, native IL-2 (WTX-124), which could provide proof-of-mechanism (PoM) and, maybe, an early glimpse at efficacy. Compugen (CGEN, OP) has several clinical updates at SITC that we do not expect to be stock-moving, but supportive to their core CD226-axis thesis. We are more excited about a preclinical oral at SITC on their novel approach to IL-18.

What happened: Regular abstract titles for the upcoming Society for Immunotherapy of Cancer (SITC) meeting (Nov. 1-5) were released yesterday (search HERE). The European Society for Medical Oncology (ESMO) released “almost all late-breaking” titles for their annual meeting (Oct. 20-25) and, given that multiple open “LBA” slots remain in the ESMO schedule, we expect more LBAs to come (ESMO Twitter; search HERE). In this report, we offer our initial reactions to SITC regular and ESMO LBA titles and highlight those clinical presentations most relevant to our covered companies.

What’s next: SITC titles do not include late-breaking abstract (LBA) titles, which will be released on Wednesday, 10/25, at 9am EDT. Some additional regular abstract titles “Part 2” will also be released on Wednesday, 10/18, at 9am EDT. Abstracts for all regular and LBA presentations will be made public (along with embargo lifting) on Tuesday, 10/31, at 9am EDT. Our usual formal conference preview and accompanying sortable Excel planner will be published in a future report.

See within for a discussion of SITC and ESMO LBA presentations for our covered companies (MRK, BNTX, HOWL, CGEN, MOLN, AFMD, TSBX) and an outline of select SITC presentation titles (clinical oral and poster presentations) that caught our attention…

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Contents

Merck: INT (with Moderna), ADCs, HIF-2α (readthrough to Arcus), and peri-adj NSCLC

BioNTech: CTLA-4, cancer vaccine, ex vivo expanded T cell therapy, and CAR-T

Werewolf and IL-2/IL-15 cytokines

Compugen and PVRIG / TIGIT, IL-18

CD40-targeting bispecifics from Molecular Partners and Roche

SITC preclinical presentations from our coverage, of note (Turnstone and Affimed)

Select SITC titles of interest – clinical only
Merck: INT (with Moderna), ADCs, HIF-2α (readthrough to Arcus), and peri-adj NSCLC

Merck and partner Moderna have additional data with their individualized neoantigen therapy (INT) in adjuvant melanoma on Monday, 10/23: ESMO LBA49 - mRNA-4157 (V940) individualized neoantigen therapy + pembrolizumab vs pembrolizumab in high-risk resected melanoma: clinical efficacy and correlates of response.

Thus far data from the KEYNOTE-942 trial have been clinical and we have been eagerly awaiting biomarker and correlate data that support the positive clinical signal, given some misbalances in the arms of KEYNOTE-942 that may have favored the active arm. It looks like these biomarker data could be coming at ESMO. The read-out might be from the parallel Ph 1 study, KEYNOTE-603, which Moderna management has said has more intense biomarker collection possible in a smaller study.

At ESMO, we see a couple of LBA antibody-drug conjugate (ADC) / anti-PD1 + chemotherapy read-outs that are important for Merck: (1) TROP2 ADC read-through in NSCLC; (2) successful EV-302 (speculating that it will be at ESMO) and CheckMate-901 in 1L bladder cancer; (3) increased competition in early-stage NSCLC with success of BMY’s (MP: Risinger) CheckMate-77T, with Merck answering with OS data teed up from their own KEYNOTE-671. See HERE for discussion of PRs on several of these datasets last week.

- **ESMO LBA12** - Datopotamab deruxtecan (Dato-DXd) vs docetaxel in previously treated advanced/metastatic (adv/met) non-small cell lung cancer (NSCLC): results of the randomized phase 3 study TROPION-Lung01 from AZN (OP: Berens) on Monday, 10/23
- **ESMO One LBA TBC** (Sunday, 10/22, Presidential 2) that we are speculating is EV-302
- **ESMO LBA7** - Nivolumab plus gemcitabine-cisplatin versus gemcitabine-cisplatin alone for previously untreated unresectable or metastatic urothelial carcinoma: results from the phase 3 CheckMate 901 trial on Sunday, 10/22
- **ESMO LBA1** - CheckMate 77T: Phase 3 study comparing neoadjuvant nivolumab (NIVO) plus chemotherapy (chemo) vs neoadjuvant placebo plus chemo followed by surgery and adjuvant NIVO or placebo for previously untreated, resectable stage II–IIIB NSCLC on Saturday, 10/21
- **ESMO LBA56** - Overall survival in the KEYNOTE-671 study of perioperative pembrolizumab for early-stage non-small-cell lung cancer (NSCLC) on Friday, 10/20
Merck has a trio of belzutifan (hypoxia-inducible factor 2α [HIF-2α], Welireg) inhibitor presentations at ESMO in a genitourinary tumor Proffered Paper session on Saturday, 10/21 (LBA87, LBA88, 1881O):

- **ESMO LBA87**: Phase 2 LITESPARK-003 Study of Belzutifan in Combination With Cabozantinib for Advanced Clear Cell Renal Cell Carcinoma (ccRCC)
- **ESMO LBA88**: Belzutifan versus everolimus in participants (pts) with previously treated advanced clear cell renal cell carcinoma (ccRCC): randomized open-label phase 3 LITESPARK-005 study
- **ESMO 1881O**: Safety and Efficacy of Two Doses of Belzutifan in Patients (pts) With Advanced RCC: Results of the Randomized Phase 2 LITESPARK-013 Study

**LITESPARK-005** is Merck’s first broad ccRCC registration trial for belzutifan with an active control (everolimus) in patients who progressed on anti-PD(L)1 and a VEGFR TKI. We are looking for a strong progression-free survival (PFS) benefit and a trend toward overall survival (OS) benefit. The company press-announced that the trial met its PFS endpoint, and OS data is immature (PR), and the FDA has accepted an NDA for priority review based on the data (PR). Previously, belzutifan showed a 25% ORR in 55 heavily pre-treated (median three prior therapies) RCC patients at 120mg once-daily dose, with median DoR not reached (median 28mo follow-up, Bauer et al., 2021 ASCO-GU). We very much like that belzutifan targets a driver (HIF-2α) of RCC cancers—defective pVHL that in normal, oxygenated cells holds HIF-2α from transcription of pro-angiogenic genes (Kaelin, W, Keynote Lecture, 2021 ASCO-GU).

**Updated outcomes from LITESPARK-03** are important for Merck’s expansion plans for belzutifan, which include combination with Merck’s VEGFR multi-tyrosine kinase inhibitor (MKI), lenvatinib (len). Merck has two ongoing trials of belzutifan + len, one versus cab in r/r RCC (LITESPARK-011) and one that adds pembro to the combination and compares the triplet to pembro + len in 1L RCC (LITESPARK-012). LITESPARK-03, which combines belzutifan with another VEGFR MKI, cabo, in two cohorts—treatment naïve and patients who progressed on anti-PD(L)1 and a VEGFR MKI—was presented previously at ESMO 2022 and ASCO-GU 2021. Prior LITESPARK-03 read-outs did not convince us the combination is offering more efficacy than each drug alone. In 1L, overall response rate (ORR) was 57% (n=35), which is similar to lenvatinib + everolimus outcomes in 1L (55% ORR, CLEAR ph3). Though Belzutifan + cabo did have an impressive duration of response (DoR) of 28.6 months (vs 16.6 with lenvatinib + everolimus and 26.7 with lenvatinib + pembro, CLEAR ph3), this was probably skewed by the high proportion of favorable risk patients enrolled in LITESPARK-03 (60% vs 27% in CLEAR). In the data update at ESMO, we expect more patients from the 1L cohort and more follow-up for both cohorts. We will be looking for evidence that the combination is additive to synergistic, comparing outcomes the CLEAR trial and the recently failed CONTACT-03 study that
provides a modern benchmark for cabo alone in patients who progressed on anti-PD(L)1—41% ORR, 12-15 month DoR, 12-mo PFS of 48% (Choueiri et al., ASCO 2023).

Merck’s LITESPARK-013 presentation (#1881O) may prove especially relevant for Arcus (RCUS, OP) and the company’s wholly owned HIF-2α inhibitor, AB-521. The Ph 2 randomized study is comparing two doses of belzutifan monotherapy (standard vs. high dose) in 154 patients with advanced RCC to determine if higher dose exposures result in superior efficacy (i.e., ORR). Arcus’ central hypothesis for AB-521 is that belzutifan has inferior PK due to absorption limitations and is underdosed in the tumor, thereby resulting in suboptimal efficacy. A strong LITESPARK-013 scenario for Arcus is that higher dose belzutifan indeed results in superior efficacy. On the other hand, comparable efficacy between the two dose levels would challenge Arcus’ hypothesis that belzutifan is underdosed, and therefore, that AB-521 offers a differentiating value proposition.
BioNTech: CTLA-4, cancer vaccine, ex vivo expanded T cell therapy, and CAR-T

At SITC, updated clinical readouts on single-agent efficacy for next-generation anti-CTLA-4 targeting gotistobart (ONC-392 / BNT316) in PD-(L)1 resistant metastatic NSCLC (oral #599) will be important for BioNTech and partner OncoC4 (private): SITC Oral 599: Single-agent safety and activities of target-preserving anti-CTLA-4 antibody gotistobart (ONC-392/BNT316) in PD-(L)1 resistant metastatic NSCLC and population PK analysis in patients with solid tumors

These data were first presented at ASCO this year where we were impressed by the monotherapy activity of ORR of 22-30% on 27 patients. Gotistobart looks to improve on therapeutic window of first-generation anti-CTLA-4, which may underly its impressive efficacy (LINK, see Figure 1). We believe finding the right dose for gotistobart as a single-agent and in combination with anti-PD1 is critically important. Anti-CTLA-4 efficacy (and toxicity) increases with dose and finding the ideal balance for your molecule could prove differentiating. To this end, we are looking for evidence in the SITC dataset, which looks to focus on pharmacokinetics (PK), that supports the go-forward doses in the Stage I dose-confirming lead-in to their ongoing Ph3, PRESERVE-003 (6 mg/kg with 2 loading doses of 10 mg/kg OR 3 mg/kg, Q3W).

Figure 1. Durable responses with ONC-392 (anti-CTLA-4) in PD-(L)1 & chemo r/r NSCLC

Source: He et al., 2023 ASCO

We will also see two posters from BioNTech on fixed antigen RNA vaccine (FixVac) BNT116 in NSCLC (Poster #597) and non-engineered, ex vivo expanded neoantigen T
cell product BNT221 (Poster #769), though these updates have a low likelihood of being stock-moving.

- **SITC Poster 597**: Preliminary results from LuCa-MERIT-1, a first-in-human Phase I trial evaluating the fixed antigen RNA vaccine BNT116 in patients with advanced non-small cell lung cancer
- **SITC Poster 769**: Interim clinical and translational data from NTC-001, a phase I study to evaluate the non-engineered neoantigen-specific T cell product BNT221 in patients with advanced or metastatic melanoma

On BNT221, we will be seeing data first at ESMO (see [HERE](#) for our thoughts). Given that the titles between ESMO and SITC presentations are practically identical, we expect the poster at SITC will have some incremental biology.

We were surprised that BioNTech has an LBA at ESMO for their Claudin-6-targeting (CLDN6) CAR-T, BNT211, + CLDN6-encoding mRNA vaccine (CARVac) and would like to learn more about durability of response at ESMO: **ESMO LBA35: BNT211-01**: Interim results from a repeat dose escalation study of CLDN6 CAR-T cells manufactured with an automated process ± a CLDN6-encoding CAR-T cell-Amplifying RNA Vaccine (CARVac)

At the ASCO meeting this year, we were encouraged by the promising efficacy signal with BNT211 in ovarian cancer patients (Figure 2). Durability of responses, safety profile, and contribution of each CLDN6 component remain question marks (see [HERE](#) for our thoughts post-AACR). At ESMO, we would like to see a continued trend of efficacy in ovarian cancer patients in addition to early data on duration of response.
Figure 2. Waterfall plots for BNT211 + / - CARVac with automated process (left) or manual process (right)

Source: Mackensen, et al., 2023 ASCO

BNT211-01: Efficacy

Change in target sum (best response) after CLDN6 CAR-T(A) ± CLDN6 CARVac administration

ORR = 41%
DCR = 65%

ESMO 2022

Data cut-off: 10/1/2022
* Two patients died prior to op and one patient was lost to follow-up before achieving optimal sample size

ORR = 33%
DCR = 67%

Source: Mackensen, et al., 2023 ASCO
Werewolf (HOWL) and IL-2/IL-15 cytokines

HOWL will have a robust presence this SITC with six poster presentations showcasing their tumor-activated or prodrug cytokine platform (INDUKINE) and pipeline candidates WTX-124 (native IL-2), WTX-330 (IL-12), and WTX-712 (IL-21) (PR).

Headlining will be our first look at Ph 1 dose escalation data for lead candidate WTX-124 in patients with IO-sensitive tumors (poster #737): SITC poster 737 - A phase 1/1b study of the tumor-activated IL-2 prodrug WTX-124 alone or in combination with pembrolizumab in patients with immunotherapy-sensitive locally advanced or metastatic solid tumors.

If successful, this trial could provide proof-of-mechanism (PoM) for WTX-124 and the company’s broader INDUKINE platform, and is also, potentially, a significant catalyst for HOWL shares. In a previous note following the company’s recent R&D day on WTX-124, we summarized our perspective on the program’s potentially differentiating attributes relative to the broader IL-2 space and outlined our expectations for the initial Ph 1 readout (LINK). Given that Werewolf management has guided only to safety, pharmacokinetic (PK) / pharmacodynamic (PD), and biomarker data, but no efficacy, we generally anticipate a muted stock reaction to the data. Even with demonstration of PoM (which we expect and define as PK/PD evidence of IL-2 release and activation in the TME without meaningful peripheral immune activation and favorable safety), we believe most investors remain too grounded in the negative historical precedent of next-gen IL-2 therapies for HOWL to get early credit. That said, management has long maintained that WTX-124, like high dose aldesleukin (recombinant human IL-2), should exhibit monotherapy activity, and we see a possibility for an upside surprise for HOWL shares should the company report compelling individual case studies of anti-tumor activity (even if no RECIST response data) in conjunction with PoM.

Other early clinical readouts at SITC for competing next-gen IL-2 and IL-15 therapies will provide additional competitive context and read-through to WTX-124. Of these, the most directly relevant to WTX-124 is Xilio’s (XLO, Not Rated) Ph 1 dose escalation update for their similar tumor-activated IL-2 prodrug, XTX202, in advanced solid tumors (poster #717). Xilio has guided to updated data, including preliminary anti-tumor activity, in ≥20-evaluable patients across advanced solid tumors at dose levels ≥1 mg/kg. This update will likely be more robust than Werewolf’s (commensurate with XTX202’s longer time in clinic), and we believe that encouraging anti-tumor activity would read positively to WTX-124 and HOWL. However, although both molecules are designed to unmask in the tumor, XTX202 utilizes a “not alpha” IL-2 variant that we expect sacrifices potency (and efficacy) relative to WTX-124’s use of native IL-2 that retains alpha binding.

Other clinical IL-2 / IL-15 presentations (all posters) are for programs with “not alpha” design and are likely incremental to previously reported updates. These include Ph 1 updates for Alkermes’ (ALKS, MP, Goodman) nemvaleukin alfa, Medicenna’s (MDNA, Not Rated) MDNA11, Aulos’ (private) AU-007, and Sotio’s (private) nanrilkefusp alfa (see below for abstract numbers and titles and LINK for last year’s SITC discussion on these programs).
**Compugen and PVRIG / TIGIT, IL-18**

Compugen will have two clinical presentations (both posters) at SITC for lead candidate COM701 (anti-PVRIG mAb) in patients with metastatic breast cancer (mBC) and platinum-resistant ovarian cancer (prOC), respectively (#640 and #669; PR). Together, we anticipate these data will provide encouraging, incremental support for the company’s scientific hypothesis. We are especially interested in the prOC readout, given it is one of two currently prioritized indications and it allows potential interrogation of anti-TIGIT contribution to clinical and pharmacodynamic (PD) benefit (albeit with BMY’s recently discontinued BMS-986207 instead of Compugen’s COM902). However, these datasets are also unlikely to be significant stock-moving catalysts, as investors await important Ph 1 dose expansion readouts in prioritized indications and regimens later this year, i.e., COM701 + COM902 + pembrolizumab (anti-PD-1) read-outs in microsatellite stable colorectal cancer (MSS-CRC) and prOC (see [LINK](#) for further discussion).

**Compugen oral presentation of preclinical COM503 data (SITC #550), the company’s first-in-class anti-IL-18 binding protein (BP) mAb that recently entered the clinic, is quite interesting to us (and possibly, to prospective development partners).** The first-in-class program is unique in its mechanism of leveraging IL-18’s known immunostimulatory properties. Unlike engineered IL-18 cytokine approaches, which require an effective decoy-resistant design (i.e., resistant to IL-18BP), by targeting the BP directly Compugen also inherently confers greater tumor selectivity given BP tumor-specific expression. Regarding this competitive class, it’s possible we get initial Ph 1 data from Simcha Therapeutics’ (private) decoy-resistant IL-18 cytokine, ST-067, in a poster presentation (FPI was in 3Q21), though it’s unclear if this is only a trials-in-progress poster (SITC #736).
CD40-targeting bispecifics from Molecular Partners and Roche

We expect data for Molecular Partners' (MOLN, MP) MP0317 (FAP x CD40 DARPin) at SITC this year to have limited stock-moving impact: SITC poster 721: Ongoing Phase 1 study of MP0317, a FAP-CD40 DARPin, shows a favorable safety profile and early evidence of tumor-localized CD40 activation in patients with advanced solid tumors.

Management has already indicated that they do not expect meaningful single-agent clinical activity and are still looking to find a partner to bring this program into combination studies (see HERE for 1H23 note). We believe the SITC update will include additional patients and deeper analysis to that presented at ASCO '23 and SITC '22 (LINK for our thoughts). The company previously reported signals of dose-dependent pharmacodynamic (PD) effects including evidence of FAP / CD40 co-localization, in line with our expectations of the product.

From Roche (RHHBY, not rated), we expect outcomes from a meaningful patient sample for FAP x CD40 agonist RO7300490, which is likely to have read-through to Molecular Partners and BioNTech: SITC poster 617: A Phase I study of a tumor-targeted, fibroblast activation protein (FAP)-CD40 agonist (RO7300490) in patients with advanced solid tumors.

For Molecular Partners, a good showing from RO7300490 could reinvigorate investor and corporate sentiment on CD40-targeting and help Molecule secure a licensor for their DARPin candidate.

We were impressed by early clinical signals for BioNTech and Genmab’s (GMAB, MP: Chang) GEN1042 (BNT312, CD40 x 4-1BB). At ESMO-IO ’22, the companies presented early outcomes for patients in first-line squamous cell carcinoma of the head and neck (SCCHN): two complete responses and two deep partial responses in a total of four patients (Figure 3). It is difficult to draw conclusions given the low evaluable patient number (5 enrolled, 4 evaluable), limited follow-up (~18-30 weeks), and combination on top of two other active agents (pembro and chemo) (see HERE for our thoughts). The partners plan to enroll 10-40 patients with SCCHN to confirm this early signal. BioNTech management said they have other expansion cohorts enrolling—non-small cell lung cancer (NSCLC), melanoma, and pancreatic ductal adenocarcinoma (PDAC).
Figure 3. Change in target lesions in SCCHN patients treated with GEN1042 + pembrolizumab + cis/carboplatin + 5-FU

Source: Melero et al., ESMO IO 2022
Preclinical presentations at SITC from our covered companies, of note

Turnstone next-generation TIL therapy

One of the key differences between Turnstone’s (TSBX, MP) two lead clinical programs (TIDAL-01 and TIDAL-02) is neoantigen selection, and we look forward to learning more about this novel methodology at SITC. *SITC poster 900: TBio BFX 4101: a neoantigen prioritization pipeline for selected tumor-infiltrating lymphocyte therapy.*

With TIDAL-02, Turnstone is aiming for meaningful process improvements to their first-generation selected TIL, TIDAL-01 (see TSBX initiation, slide 46 [HERE: LINK] to poster from AACR ’23). This catalyst pales in comparison to the initial clinical data we expect in 2024 for TIDAL-01.

On the selected TIL competitive front, we did not see any presentations with clinical outcomes / data in melanoma and NSCLC from Achilles (ACHL, Not Rated). They do have a poster on manufacturing process (SITC #437).

Affimed comparison of NK cell engagers vs CAR-NK

*SITC poster 329: Redirecting NK cell cytotoxicity by Innate Cell Engagers: A differentiated and innovative approach compared to CAR-NK cells*

We believe that this poster will dive deeper into the company’s thesis that C16A shedding facilitates serial tumor-cell killing. At the American Association for Cancer Research (AACR) meeting this year, Affimed’s (AFMD, OP) collaborators presented a poster ([LINK]) showing *in vitro* data using CD30-targeting innate cell engager AFM13. CD16A shedding appears to be important for AFM13’s potency, which may confer an advantage for the combination of Affimed’s innate engagers + NK cells over the CAR-NK programs that genetically engineer CD16A to prevent shedding. Adding a CD16A shedding inhibitor reduced serial killing and induced NK cell death (see [HERE] for our thoughts).
Select SITC titles of interest – clinical only
Possibly includes trial-in-progress presentations; at SITC, the “Clinical Trials in Progress” sessions includes both actual clinical data and TiP presentations

Covered Company Titles

- **CGEN**
  - Poster - 669 - Durable responses with triple blockade of the DNAM-1 axis with COM701 + BMS-986207 + nivolumab in patients with platinum resistant ovarian cancer.

- **BNTX**
  - Oral - 599 - Single-agent safety and activities of target-preserving anti-CTLA-4 antibody gotistobart (ONC-392/BNT316) in PD-(L)1 resistant metastatic NSCLC and population PK analysis in patients with solid tumors
  - Poster - 597 - Preliminary results from LuCa-MERIT-1, a first-in-human Phase I trial evaluating the fixed antigen RNA vaccine BNT116 in patients with advanced non-small cell lung cancer
  - Poster - 769 - Interim clinical and translational data from NTC-001, a phase I study to evaluate the non-engineered neoantigen-specific T cell product BNT221 in patients with advanced or metastatic melanoma

- **HOWL**
  - Poster - 737 - A phase 1/1b study of the tumor-activated IL-2 prodrug WTX-124 alone or in combination with pembrolizumab in patients with immunotherapy-sensitive locally advanced or metastatic solid tumors
    - XLO presentation: Poster - 611 - XTX202-01/02-001, Phase 1/2 First-in-Human Study of XTX202, a Masked, Tumor-Activated IL-2βγ, in Patients with Advanced Solid Tumors: results from Phase 1

- **RCUS**
  - Poster - 660 - Phase 2 Study to evaluate the triplet combination of pemetrexed plus etrumadenant and zimberelimab in patients with previously treated advanced or MTAP-deficient metastatic urothelial carcinoma (mUC)
    - TiP
  - Poster - 773 - A phase I/II study to evaluate the safety, tolerability and preliminary efficacy of GLS-012 monotherapy and in combination with zimberelimab in patients with advanced melanoma (Triumph-01)
    - Gloria-sponsored China trial using zim with their LAG-3

- **IPHA**
  - Poster - 700 - A phase II trial of MOnaliZumab plus durvAlumab plus platinum-based chemoTherapy for first-line Treatment of extensive stage small cell lung cancer (MOZART): A Hoosier Cancer Research Network study
    - TiP
BOLT
- Poster - 716 - Phase 2 study of the HER2-targeting TLR7/8 immune stimulating antibody conjugate (ISAC) BDC-1001 monotherapy +/- nivolumab in patients with HER2+ colorectal, endometrial, or gastroesophageal cancer
  - TiP
- Poster - 720 - A Phase 1/2 study of BDC-3042, a novel Dectin-2 agonistic antibody, in patients with advanced cancers
  - TiP

MOLN
- Poster - 721 - Ongoing Phase 1 study of MP0317, a FAP-CD40 DARPin, shows a favorable safety profile and early evidence of tumor-localized CD40 activation in patients with advanced solid tumors

MRK
- Poster - 722 - Evaluation of the effects of pembrolizumab alone and in combination(s) with MDSC-targeting agents MK-0482 and MK-4830 on the native cancer patient TME via functional spatial profiling (CIVO®)

Select Notable Titles by Target / Mechanism – not exhaustive

Cytokines
- IL-2 / IL-15
  - Poster - 737 - A phase 1/1b study of the tumor-activated IL-2 prodrug WTX-124 alone or in combination with pembrolizumab in patients with immunotherapy-sensitive locally advanced or metastatic solid tumors
  - Poster - 611 - XTX202-01/02-001, Phase 1/2 First-in-Human Study of XTX202, a Masked, Tumor-Activated IL-2βγ, in Patients with Advanced Solid Tumors: results from Phase 1
  - Poster - 717 - A phase 1/2 study of AU-007, a monoclonal antibody (mAb) that binds to IL-2 and inhibits CD25 binding, in patients with advanced solid tumors: Interim results from dose escalation
  - Poster - 760 - Interim PK/PD, safety and efficacy data of monotherapy dose escalation of a Phase 1/2 study with MDNA11 in patients with advanced solid tumors
  - Nemvaleukin alfa
    - Poster - 724 - Subcutaneous nemvaleukin alfa in combination with pembrolizumab in patients with refractory solid tumors (ARTISTRY-2)
    - Poster - 740 - Pattern of natural killer (NK) cell (CD16+CD56+) expansion correlates with response outcomes with nemvaleukin alfa treatment
    - Poster - 744 - Assessment of safety and immunologic activity of nemvaleukin alfa in patients with advanced solid tumors treated with less frequent intravenous dosing (ARTISTRY-3)
  - Poster - 713 - Nanrilkefusp alfa, a high-affinity IL-15Rβγ agonist, promotes an innate and adaptive anti-tumour inflammatory
environment as single agent or combined with anti-PD-1 in patients with advanced cancers

- New name for Sotio's SOT101
- Poster - 674 - A phase 1 dose-escalation and expansion study of CUE-101, given as monotherapy in 3L and in combination with pembrolizumab in 1L recurrent/metastatic HPV16+ head and neck cancer patients.
- Poster - 710 - Keynote-B59: Dose escalation of a phase 1/2 first-in-human, open-label study of GI-101, a novel immunocytokine combining CD80-IL2v, in combination with pembrolizumab in advanced solid tumors
- Poster - 729 - A first-in-human, open-label, multicenter, phase 1/2a, dose escalation and expansion study of GI-102, a novel immunocytokine combining CD80-IL2v3, in patients with advanced or metastatic solid tumors
  - Appears like a 2nd gen version of GI-101 above
- Poster - 728 - A Phase 1/2 Study of JK08, an IL-15 antibody fusion protein targeting CTLA-4, in Patients with Advanced Solid Tumors
- Poster - 750 - A phase 1 trial of CUE-102, a novel WT1-pHLA-IL2-Fc fusion protein in HLA-A*0201 positive patients with WT1-positive recurrent/metastatic cancers
- Poster - 753 - An open-label, phase 1a/b study of AB248, a CD8+ selective IL-2 mutein fusion protein, alone or in combination with pembrolizumab in patients with advanced solid tumors
  - TIP (PR)
- Poster - 767 - Pre-clinical and first-in-human studies of HCW9218, a bifunctional TGF-β antagonist/IL-15 protein complex, in advanced solid tumors
- Poster - 771 - A Phase 1 Study to Assess Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Intratumoral CLN-617 (IL2/IL12 Fusion Protein) Combined with Pembrolizumab in Patients with Advanced Solid Tumors
- Poster - 779 - A Phase 1/2, open label, first-in-human, dose escalation and expansion study of SAR445877 administered as monotherapy in adults with advanced solid tumors
  - Kadmon's PD-1 x IL-15

**IL-18**
- Oral - 550 - Harnessing natural IL-18 activity through IL-18BP blockade reshapes the tumor microenvironment for potent anti-tumor immune response
- Oral - 1070 - "Decoy-resistant” IL-18 in combination with CTLA-4 blockade enhances anti-tumor efficacy in preclinical models of renal cell carcinoma
- Poster - 736 - A Phase 1/2 open-label, dose-escalation study of ST-067, a decoy-resistant IL-18 cytokine, given as a monotherapy and with pembrolizumab in advanced solid tumor malignancies

**IL-7**
- Poster - 652 - NT-I7 (efinpeptakin alfa), a long-acting IL-7, in combination with pembrolizumab improves T cell fitness in heavily pretreated subjects with gastrointestinal tumors
Cell therapy

Oral - 636 - BASECAMP-1: A master prescreening study to identify patients with high-risk or metastatic solid tumors with HLA loss of heterozygosity (LOH) in preparation for Tmod CAR T-cell therapy trials


Poster - 621 - A Phase I Study of Autologous Activated NK Cells ± rhIL15 in Children and Young Adults with Refractory Solid Tumors

Poster - 634 - EVEREST-1: A seamless phase 1/2 study of CEA logic-gated Tmod CAR T-cell therapy (A2B530) in patients with solid tumors associated with CEA expression also exhibiting HLA loss of heterozygosity (LOH)

Poster - 635 - A Phase 1, First in Human (FIH) study of autologous macrophages engineered to express an anti-HER2 chimeric antigen receptor (CAR) in participants (pts) with HER2 overexpressing solid tumors.

Poster - 654 - A Phase 1/II trial investigating safety and efficacy of autologous TAC01-HER2 in relapsed or refractory solid tumors

Poster - 644 - A Phase 1 Dose Escalation Study of GCC19CART – A Novel CoupledCAR® Therapy for Subjects with Metastatic Colorectal Cancer

Poster - 659 - Repeated Dosing of Anti-Claudin 18.2 CAR-T in Metastatic Gastrointestinal Cancer

Poster - 738 - A phase 1/2 study investigating the safety and efficacy of autologous TAC T cells in subjects with unresectable, locally advanced or metastatic claudin 18.2+ solid tumors

Poster - 723 - Metabolically reprogrammed autologous Th1/Tc1 cell therapy (RAPA-201) yields promising safety and efficacy in post-PD-(L)1 solid tumor patients without lymphodepleting host conditioning

Poster - 735 - Peripheral and tissue persistence of agetN-797, an allogeneic iNKT cell-based cell therapy for the treatment of cancer

Poster - 739 - Emerging proteomic and safety analysis of blood from solid tumor patients receiving TILT-123 (Ad5/3-E2F-d24-hTNFa-IRES-hIL2) monotherapy in TUNIMO phase 1 clinical trial

Poster - 754 - Phase 1 trial of LYL797, a ROR1-targeted CAR T-cell therapy enhanced with genetic and epigenetic reprogramming, in advanced triple-negative breast cancer (TNBC) and non-small cell lung cancer (NSCLC)

Poster - 684 - Assay development and quantitative detection of ADI-001, a CD20-targeted γδ1 CAR T therapy, using AlloCell, a universal assay for monitoring of off-the-shelf allogeneic cell therapies

Poster - 769 - Interim clinical and translational data from NTC-001, a phase I study to evaluate the non-engineered neoantigen-specific T cell product BNT221 in patients with advanced or metastatic melanoma

TIL

Poster - 643 - A first in human Phase I/IIa trial of personalized Tumor-Trained Lymphocytes, pTTL, derived from regional lymph nodes for treatment of colorectal cancer
- Poster - 747 - Phase 1 trial of LYL845, an autologous tumor-infiltrating lymphocyte (TIL) therapy enhanced with epigenetic reprogramming, for the treatment of advanced solid tumors
- Poster - 776 - Long-term efficacy and safety of lifileucel tumor-infiltrating lymphocyte (TIL) cell therapy in patients with advanced melanoma: A 4-year analysis of the C-144-01 study
- Poster - 778 - TILVANCE-301, a phase 3 study of lifileucel tumor-infiltrating lymphocyte (TIL) cell therapy combined with pembrolizumab (pembro) vs pembro alone in treatment-naïve unresectable or metastatic melanoma

- CPI extension - PD-(L)1, CTLA-4, LAG-3
  - NSCLC - CPIs
    - Oral - 596 - AMBER, Part 2B: a Phase 1 study of cobolimab plus dostarlimab in patients with advanced/metastatic non-small cell lung cancer (NSCLC) previously treated with anti-PD(L)-1 therapy
      - Anti-TIM-3 combo
    - Oral - 606 - IMpower110: Tertiary lymphoid structures (TLS) and clinical outcomes in advanced non-small cell lung cancer (NSCLC) treated with first-line atezolizumab or chemotherapy
    - Poster - 600 - Objective response impact on patient reported outcomes (PROs) in patients with aNSCLC with PD-L1 ≥50% receiving cemiplimab versus chemotherapy: EMPOWER-Lung 1
    - Poster - 601 - Identification of non-squamous NSCLC molecular subtypes and association with outcomes in the phase 3 IMpower150 study of 1L atezolizumab ± bevacizumab + carboplatin-paclitaxel in metastatic NSCLC
    - Poster - 602 - A Phase I Trial of Atezolizumab and Varlilumab in Combination with Radiation in Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC)
      - Anti-CD27 combo
    - Poster - 607 - TTFields therapy with an immune checkpoint inhibitor in metastatic non-small cell lung cancer (mNSCLC) with progression on/after platinum-based therapy: histology subgroups in the pivotal LUNAR study
  - Misc. PD-(L)1
    - Poster - 585 - Phase I/II Study to Evaluate the Safety and Tolerability of Avelumab in Combination with Other Anti-cancer Therapies in Patients with Advanced Malignancies
    - Poster - 616 - Pharmacokinetics and safety of a subcutaneous formulation of nivolumab (NIVO SC) monotherapy: updated results from the phase 1/2 CheckMate 8KX study
    - Poster - 774 - NeoPOWER: a Phase II Study of Neoadjuvant PD-1 Blockade with Cemiplimab in High Risk Localized, Locally Recurrent and Regionally Advanced Cutaneous Squamous Cell Carcinoma
  - CTLA-4
    - Poster - 624 - Longitudinal scRNAseq profiling of PBMCs from melanoma patients treated with anti-CTLA4 or anti-PD1/CTLA4 combination elucidates mechanisms of immunotherapy resistance
  - Next-gen CTLA-4
Oral - 599 - Single-agent safety and activities of target-preserving anti-CTLA-4 antibody gotistobart (ONC-392/BNT316) in PD-(L)1 resistant metastatic NSCLC and population PK analysis in patients with solid tumors

Poster - 770 - ADU-1604, a novel CTLA-4 blocking antibody modulates pharmacodynamic markers in PD1 relapse/refractory melanoma patients

LAG-3 / sLAG-3

- Poster - 703 - Single Cell Analysis of Phase II Study of Nivolumab and Relatlimab in Metastatic Uveal Melanoma Reveals Tumor and Immune Response to Dual PD-1 and LAG-3 Inhibition
- Poster - 773 - A phase I/II study to evaluate the safety, tolerability and preliminary efficacy of GLS-012 monotherapy and in combination with zimberelimab in patients with advanced melanoma (Triumph-01)
- Poster - 595 - Biomarker results from the 1st line non-small cell lung cancer cohort of TACTI-002: pharmacodynamic effects of combining efutilagimod alpha (soluble LAG-3) and pembrolizumab

Other select IO targets

CD226 axis (TIGIT, PVRIG)

- Poster - 669 - Durable responses with triple blockade of the DNAM-1 axis with COM701 + BMS-986207 + nivolumab in patients with platinum resistant ovarian cancer.

TGF-beta

- Poster - 666 - Safety, efficacy, and biomarker results of SRK-181, a latent TGFβ1 inhibitor, in anti-PD-1 resistant metastatic ccRCC patients
- Poster - 726 - Establishing Proof of Mechanism in Patients: Preliminary Biomarker Data of SRK-181 (a latent TGFβ1 inhibitor) from DRAGON Study
- Poster - 631 - Pharmacokinetics and Pharmacodynamics study of TU2218, TGFβRI and VEGFR2 dual inhibitor in patients with advanced solid tumors
- Poster - 642 - TGFβ-based Immune Modulatory Vaccines

NKG2A

- Poster - 700 - A phase II trial of MOnaliZumab plus durvAlumab plus platinum-based chemotheRapy for first-line Treatment of extensive stage small cell lung cancer (MOZART): A Hoosier Cancer Research Network study

HPK1

- Poster - 741 - TWT-101: A First-In-Clinic Study of CFI-402411, a Hematopoietic Progenitor Kinase-1 (HPK1) Inhibitor, as Single Agent or Combined With Pembrolizumab in Subjects With Advanced Solid Malignancies
• Poster - 751 - Monotherapy Results From an Ongoing Phase 1a Dose Escalation Study of NDI-101150, a Highly Selective Oral Hematopoietic Progenitor Kinase 1 (HPK1) Inhibitor
  ○ Siglec-15
    • Oral - 463 - Targeting a novel myeloid checkpoint Siglec-15 in GBM generates an extremely durable response with Zika virus oncolytic therapy
    • Poster - 756 - First-in-human, open-label, multicenter, phase 1 clinical study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of anti Siglec-15 PYX-106 in subjects with advanced solid tumors
  ○ CD47/SIRPa
    • Poster - 650 - Neoadjuvant ezabenlimab or pembrolizumab in combination with an anti-SIRPa antibody in resectable colorectal cancer
    • Poster - 685 - A first-in-human Phase 1/2 clinical trial of SIRPαlow activated macrophages (SIRPant-M) for the treatment of R/R-NHL
    • Poster - 675 - Safety and tolerability of magrolimab combination therapy in patients with recurrent or metastatic head and neck squamous cell carcinoma (RM-HNSCC)
    • Poster - 698 - Safety and tolerability of magrolimab in combination with taxanes in patients with solid tumors
  ○ Adenosine
    • Poster - 759 - ADPORT-601 (TT-10-101): First-in-Human Study of Adenosine 2A (A2A) and Adenosine 2B (A2B) receptor antagonists in Participants with Selected Advanced Solid Tumors
  ○ VISTA
    • Poster - 780 - VISTA-101 – A phase 1/2 clinical trial of KVA12123, an engineered IgG1 targeting VISTA, alone and in combination with pembrolizumab in advanced solid tumors.
  ○ Co-stim / non-bispecific
    • CD40
      • Poster - 617 - A Phase I study of a tumor-targeted, fibroblast activation protein (FAP)-CD40 agonist (RO7300490) in patients with advanced solid tumors
      • Poster - 721 - Ongoing Phase 1 study of MP0317, a FAP-CD40 DARPin, shows a favorable safety profile and early evidence of tumor-localized CD40 activation in patients with advanced solid tumors
      • Poster - 765 - NG-350A, a tumor-selective anti-CD40 agonist expressing therapeutic, gemcitabine/nab-paclitaxel and ipilimumab for untreated metastatic pancreatic adenocarcinoma: Cohort C of the REVOLUTION trial
      • Oral - 1361 - Neoadjuvant CD40 agonism remolds the tumor immune microenvironment in locally advanced esophageal/gastroesophageal junction cancer
    • OX40
      • Poster - 748 - Phase 1/2 study of the hexavalent OX40 agonist INBRX-106 alone and in combination with pembrolizumab in select solid tumors
- **Bispecifics**
  - **TCEs**
    - Poster - 689 - Pharmacodynamic results with talquetamab and daratumumab in patients with relapsed/refractory multiple myeloma in TRIMM-2
    - Poster - 764 - A phase 1, first-in-human (FIH), open-label, dose-finding and expansion study of XmAb808, a B7H3 x CD28 bispecific antibody, in combination with pembrolizumab in patients with advanced solid tumors
  - **IO x IO**
    - Poster - 742 - Phase 1/2 study of the bispecific 4-1BB and PD-L1 antibody INBRX-105 alone and in combination with pembrolizumab in select solid tumors
    - Poster - 775 - Phase Ib/II Study of XmAb23104 (PD1 X ICOS) and XmAb22841 (CTLA-4 X LAG3) Combination in Metastatic Melanoma Refractory to Prior Immune Checkpoint Inhibitor Therapy with and without CNS Disease

- **Innate agonists / ISACs**
  - Poster - 647 - PERIO-03: Pressure Enabled Intrapancreatic Delivery of SD-101 With Checkpoint Blockade for Locally Advanced Pancreatic Adenocarcinoma – Initial Safety and Feasibility Experience
  - TLR9 agonist
  - Poster - 715 - ICT01 plus Low Dose SC IL-2 Produces a Robust Anti-Tumor Immune Activation in Advanced Cancer Patients (EVICTION-2 Study)
  - Poster - 743 - INCLINE-101: Preliminary Safety, Tolerability, Pharmacokinetics (PK), and Pharmacodynamics (PD) of TAC-001 (TLR9 agonist conjugated to a CD22 mAb) in Patients with Advanced or Metastatic Solid Tumors
    - ISAC comp and relevant for BOLT
  - Poster - 763 - INITIAL RESULTS FROM PHASE I DOSE ESCALATION TRIAL OF CAN1012 IN PATIENTS WITH SOLID TUMOR MALIGNANCIES
    - TLR7 agonist
  - Poster - 782 - TransCon TLR7/8 Agonist Induces Sustained Local and Systemic Immune Activation in Patients with Solid Tumors

- **Oncolytic virus**
  - Oral - 777 - Initial results from an open-label phase 1b/2 study of RP1 oncolytic immunotherapy in solid organ and hematopoietic cell transplant recipients with advanced cutaneous malignancies (ARTACUS)
  - Poster - 585 - Ofranergene obadenovec (VB-111) in combination with nivolumab in patients with microsatellite stable colorectal liver metastases: a single-center, single-arm phase II trial
  - Poster - 586 - Phase II study of Telomelysin (OBP-301) in combination with pembrolizumab in gastroesophageal (GEA) adenocarcinoma
Poster - 649 - Phase 1a open-label, non-randomized, multi-center clinical trial of intratumoral IVX037 in patients with advanced microsatellite stable (MSS) colorectal, gastroesophageal or ovarian cancer

Poster - 705 - Biodistribution and shedding analysis following RP1 oncolytic immunotherapy dosing in patients from the IGNYTE clinical trial

Poster - 711 - Development of oncolytic adenovirus Ad5/3-E2F-D24-hTNFa-IRES-hIL2 (TILT-123) for the treatment of solid tumours - from preclinical testing to Phase I clinical trials

Poster - 730 - A Phase I Safety and Tolerability Study of VAXinia (CF33-hNIS), a Novel Chimeric Oncolytic Poxvirus, Administered Intratumorally or Intravenously in Adults with Metastatic or Advanced Solid Tumors.

Poster - 739 - Emerging proteomic and safety analysis of blood from solid tumor patients receiving TILT-123 (Ad5/3-E2F-d24-hTNFa-IRES-hIL2) monotherapy in TUNIMO phase 1 clinical trial

Poster - 745 - Immune cell profiling of advanced-stage solid tumors patients treated with an oncolytic adenovirus encoding for TNF-a and IL-2 (TILT-123)

Poster - 749 - Early phase oncology experience on the use of an oncolytic adenovirus encoding for TNFa and IL-2 for the treatment of solid tumors – Interim results

Poster - 766 - A Clinical Trial to Evaluate the Safety, Tolerability and Preliminary Efficacy of VG161 in Combination with Nivolumab in Patients with Advanced Pancreatic Cancer

Cancer vaccines

Poster - 597 - Preliminary results from LuCa-MERIT-1, a first-in-human Phase I trial evaluating the fixed antigen RNA vaccine BNT116 in patients with advanced non-small cell lung cancer

Poster - 693 - SQZ-AAC-HPV-101: Initial data from a phase I dose escalation/expansion study of SQZ-AAC-HPV, a red blood cell-based therapeutic cancer vaccine for HPV16+ solid tumors

Poster - 692 - COMMANDER-001: Safety data from a phase I/II dose escalation/expansion study of SQZ-eAPC-HPV, a cell-based mRNA therapeutic cancer vaccine for HPV16+ solid tumors

Poster - 641 - A pilot study of a DNAJB1-PRKACA fusion kinase peptide vaccine combined with nivolumab and ipilimumab for patients with fibrolamellar hepatocellular carcinoma

Poster - 656 - ELI-002 Immunotherapy Induces Broad Polyfunctional T Cell Responses in Subjects with High Relapse Risk KRAS Mutated Pancreatic Ductal Adenocarcinoma and Colorectal Cancer
  - KRAS vaccine
  - Poster - 679 - Tumor CD8+ T cell responses in patients with recurrent/metastatic HPV16 positive head and neck cancer receiving HB-200 monotherapy as second or later line treatment in a Phase 1 study

Treg-targeted

Oral - 608 - Results of a phase 1 study investigating camidanlumab tesirine as monotherapy and in combination with pembrolizumab in patients with selected advanced solid tumors
  - Anti-CD25 ADC

Poster - 704 - Biological activity of FLX475, an oral CCR4 antagonist, as monotherapy and in combination with pembrolizumab in advanced cancer
• **TME-targeted**
  - Poster - 714 - Phase 1a trial of PLN-101095, an integrin αvβ8 and αvβ1 inhibitor, as monotherapy and in combination with pembrolizumab, in treatment-resistant patients with advanced or metastatic solid tumors
  - Oral - 472 - Anti-VEGF treatment amplifies immune checkpoint inhibitor induced immune responses by targeting B and regulatory T cells

• **Misc. novel targets / mechanisms**
  - Poster - 630 - EO2401, a new peptide immunotherapy against cancer, in combination with nivolumab, induces a strong and durable immune response in patients from the EOADR1-19/SPENCER Study
    - Poster - 638 - Characterisation of the immune response to EO2401, a new immunotherapy approach against cancer, plus nivolumab in recurrent glioblastoma: The EOGBM1-18/ROSALIE study
  - Poster - 633 - A Phase 1a/1b, Dose-Escalation/Dose-Expansion Study of NPX267 in Subjects with Solid Tumors Known to Express HHLA2
    - First-in-class KIR3DL3 blocking antibody
  - Poster - 719 - Phase 1 clinical trial design of ZM008, a first-in-class anti LLT1 antibody, is a promising therapy for multiple solid cancers
  - Poster - 752 - Developing Biomarkers for Bexmarilimab, a novel macrophage-guided immunotherapy, in advanced solid tumors to select patients and confirm mechanism of action
  - Poster - 757 - Phase 1/2a Clinical Trial of BI-1808, a Monoclonal Antibody to Tumor Necrosis Factor Receptor 2 (TNFR2) as Single Agent and in Combination with Pembrolizumab
  - Poster - 619 - First-in-class anti-CD200R1 antibody 23ME-00610 in Patients with Advanced Solid Malignancies: Updated Phase 1 Results
    - Poster - 609 - Phase 1/2a dose selection of 23ME-00610, a first-in-class anti-CD200R1 antibody, in patients with advanced solid malignancies
Disclosures Appendix

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