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Clinical update on SPiReL Phase 2 with Merck's Keytruda® in relapse/refractory Diffuse Large B-cell Lymphoma (r/r DLBCL)

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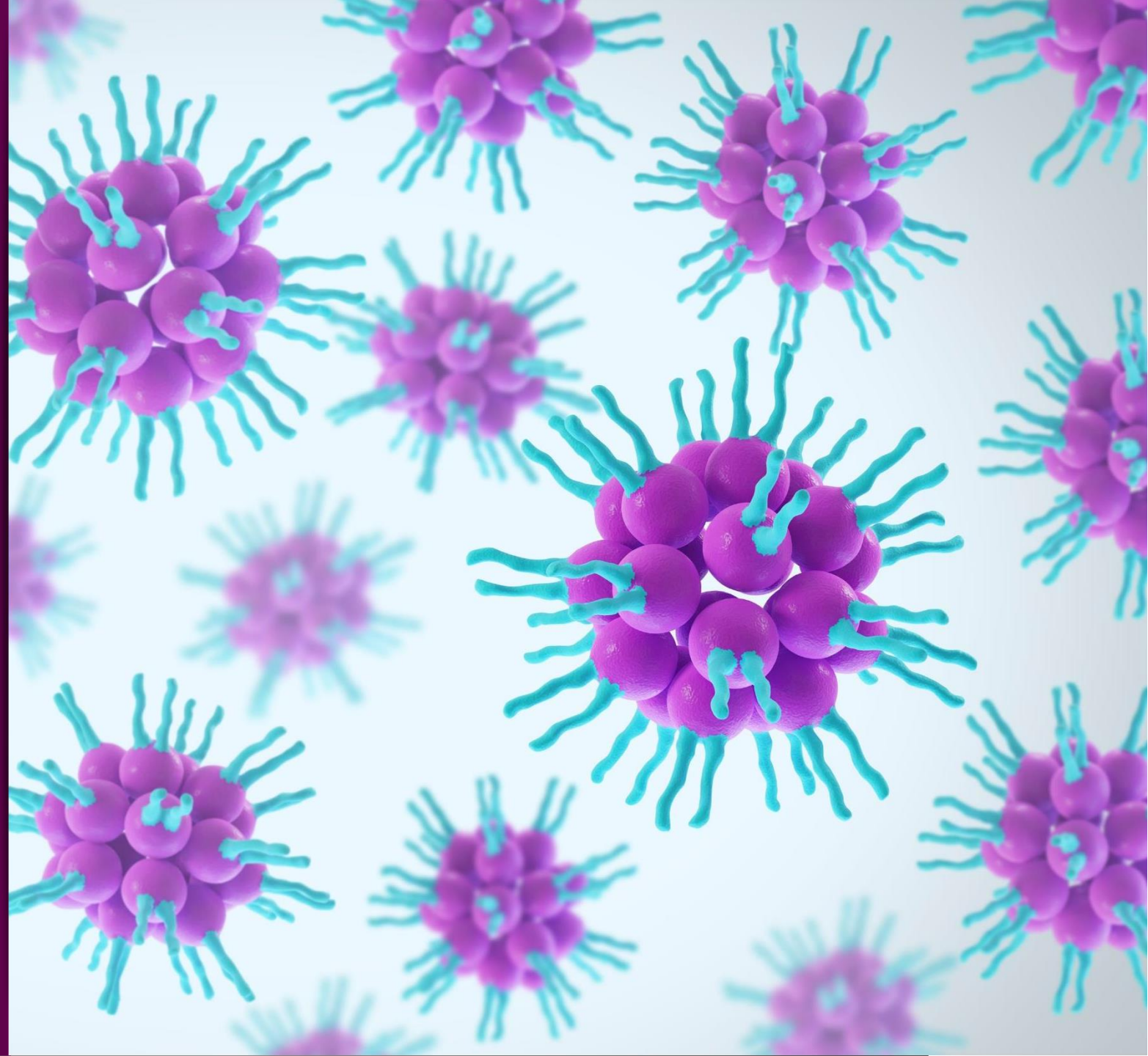

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Agenda

- Introduction – Fred Ors, CEO
- Patient population and safety – Dr. Gabriela Rosu, CMO
- Updated clinical results – Dr. Gabriela Rosu, CMO
- Conclusion – Fred Ors, CEO
- Q&A

Diffuse large B-cell lymphoma (DLBCL)

- DLBCL is an aggressive form of Non-Hodgkin Lymphoma (NHL) and the most common subtype accounting for ~35% of all newly diagnosed NHL cases
  - 27,000 new cases/year in the US, ~ 6500 cases will relapse or become refractory disease after 2nd line

- Current standard treatments
  - First line consists of chemotherapy plus a monoclonal antibody, rituximab (R-CHOP)
  - Secondary therapy based on “salvage” high dose chemotherapy and autologous stem cell transplant
  - 25-30% will eventually become relapse/refractory patients who are ineligible for transplant or for whom salvage chemotherapy and transplant have failed

- relapse/refractory DLBCL (r/r DLBCL)
  - If left untreated, r/r DLBCL has a life expectancy of 3 to 4 months
  - For majority of relapsed patients the only approved therapy is CAR-T cell therapy (beside salvage therapy)
  - Unmet medical need for a safe and effective treatment for patients not suitable for CAR-T cell therapy

Sources:
SEER; World Health Organization. Diffuse large B-cell lymphoma.(http://www.who.int/selection_medicines/committees/expert/20/applications/DiffuseLargeBCellLymphoma.pdf)

Survivin and PD-1/PD-L1 in DLBCL

Survivin

- Metanalysis of 17 DLBCL clinical studies (N=1352)
  - Average 62% patients had positive survivin expression (% higher in more advanced patients)
  - Survivin expression was strongly linked to inferior clinical outcome including more advanced clinical stage (III and IV), reduced complete remission (CR) and inferior overall survival (OS)

PD-1/PD-L1

- Targeting PD-1/PD-L1 patients with a checkpoint inhibitor as single agent has limited activity in r/r DLBCL
  - Nivolumab overall response rate was 11% (13/121) with a **3% complete response rate** (4/121)
- Multiple studies suggesting that tumor-specific PD-L1 is low in DLBCL, with expression primarily restricted to tumor-infiltrating cells

Sources:
Blood Advances 2019 3:531-540
Medicine 2015 Sep;94(36):e1432
J Clin Oncol. 2019 Feb 20;37(6):481-489

SPiReL Study Design

- SPiReL: DPX-Survivac with intermittent low dose cyclophosphamide administered with pembrolizumab in patients with persistent or recurrent/refractory diffuse large B-cell lymphoma
  - Investigator sponsored phase 2 non-randomized, multi-centre, open-label study
  - Two doses of 0.5ml of DPX-Survivac 21 days apart followed by up to six 0.1ml every two months with low dose metronomic oral cyclophosphamide (50 mg BID) and Pembrolizumab 200 mg administered every 3 weeks for up to one year or until disease progression
  - Primary Investigator: Neil Berinstein, MD, Affiliate Scientist, Sunnybrook Research Institute, Professor of Medicine/Immunology, University of Toronto
  - Expected to enroll 25 evaluable participants whose recurrent DLBCL expresses survivin

- Primary objective is Objective Response Rate (ORR)
- Secondary objectives include measuring tumor regression, and documenting the toxicity profile and durations of response
- Additional analyses to assess circulating antigen specific immune responses and changes in tumor-infiltrating T cell immune responses within the tumor microenvironment. Investigators also plan to assess potential biomarkers of immune and clinical response.

Patient population and Safety

- Persistent, recurrent/refractory DLBCL
  - Non-GCB and GCB subtype
  - Double hit or high-grade allowed

- Average of 2.9 prior DLBCL treatments

- Received between 1 and 6 prior lymphoma treatments, including patients with prior ASCT

- The treatment combination appears to be well-tolerated with only 2 serious adverse events related to treatment (low white blood count and low neutrophil count)

Update on clinical results

- 11 subjects enrolled (5 sites open)
- 6 subjects with evaluable scans at data cut-off*:
  - 4/6 tumor regressions
  - 2 complete radiologic responses, one is ongoing and completed one year treatment with a Complete Response (CR) that is still ongoing, the other one progressed after 6 month on the leg lesion from a rare form of DLBCL (primary cutaneous DLBCL-leg type)
  - 1 partial response (PR) ongoing at first CT Scan (78% tumor regression)
  - 2 SDs (including a 48% tumor regression) lasted 6 and 8 months
  - 1 with bulky disease progressed at first scan (PD)
- 3 subjects with first scans pending
- 2 subjects progressed while starting treatment and were not evaluable per protocol

- Disease Control Rate (DCR): 5/6 (83%)
- Objective Response Rate (ORR): 3/6 (50%)

- Complete radiologic responses correlating with highest level of survivin-specific T cells in the blood of tested subjects

* Data partially monitored

Other therapies approved in r/r DLBCL

- The FDA has approved two CAR T-cell therapies in 2017/2018
  - Axicabtagene ciloleucel (Yescarta, Kite) and Tisagenlecleucel (Kymriah, Novartis)
  - Accelerated approvals based on single arm phase 2 trials (80-100 patients)
  - About 1/3 of patients potentially cured
    - 40-50% complete response rates with 2/3 being durable (2 years of data so far)
  - Potential to cause severe side effects. Prescribing Information has a BOXED WARNING for the risks of CRS and neurologic toxicities
  - Other considerations: CAR T require previous administration of lymphodepleting chemotherapy, patients with rapid progression may not have the time to apheresis or CAR T-cell infusion

- On June 11, 2019, FDA approved polatuzumab vedotin (antibody drug conjugate) in combination with bendamustine (chemotherapy) and rituximab (antibody)
  - Significant improvement over bendamustine+rituximab
  - Phase 1b/2: 16 (40%) patients had CRs in the polatuzumab-vedotin arm as compared with 7 (18%) patients who received bendamustine-rituximab
  - median DOR was 10.3 months with polatuzumab-vedotin versus 4.1 months without

Conclusions

- r/r DLBCL is a hard-to-treat aggressive form of blood cancer where checkpoints inhibitors like Opdivo have shown limited activity
- Data so far looks promising showing the potential to be within the same range as other approved therapies with potential better safety profile
  - Tumor regressions, long lasting CR and PR
- If the level of activity and durable responses are confirmed in final dataset, we believe the combination will have the potential to offer a valuable new treatment option for r/r DLBCL patients

- Reinforces the idea that our new mechanism of action for targeted T cell therapy has the potential to be an alternative to other types of T cell-based therapies such as CAR Ts and TCRs

- First look at the potential of combining our targeted T cell therapy with a checkpoint inhibitor
  - Encouraging results for our other trials in combination with Keytruda in Lung, Bladder, Liver, MSI-H and Ovarian

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