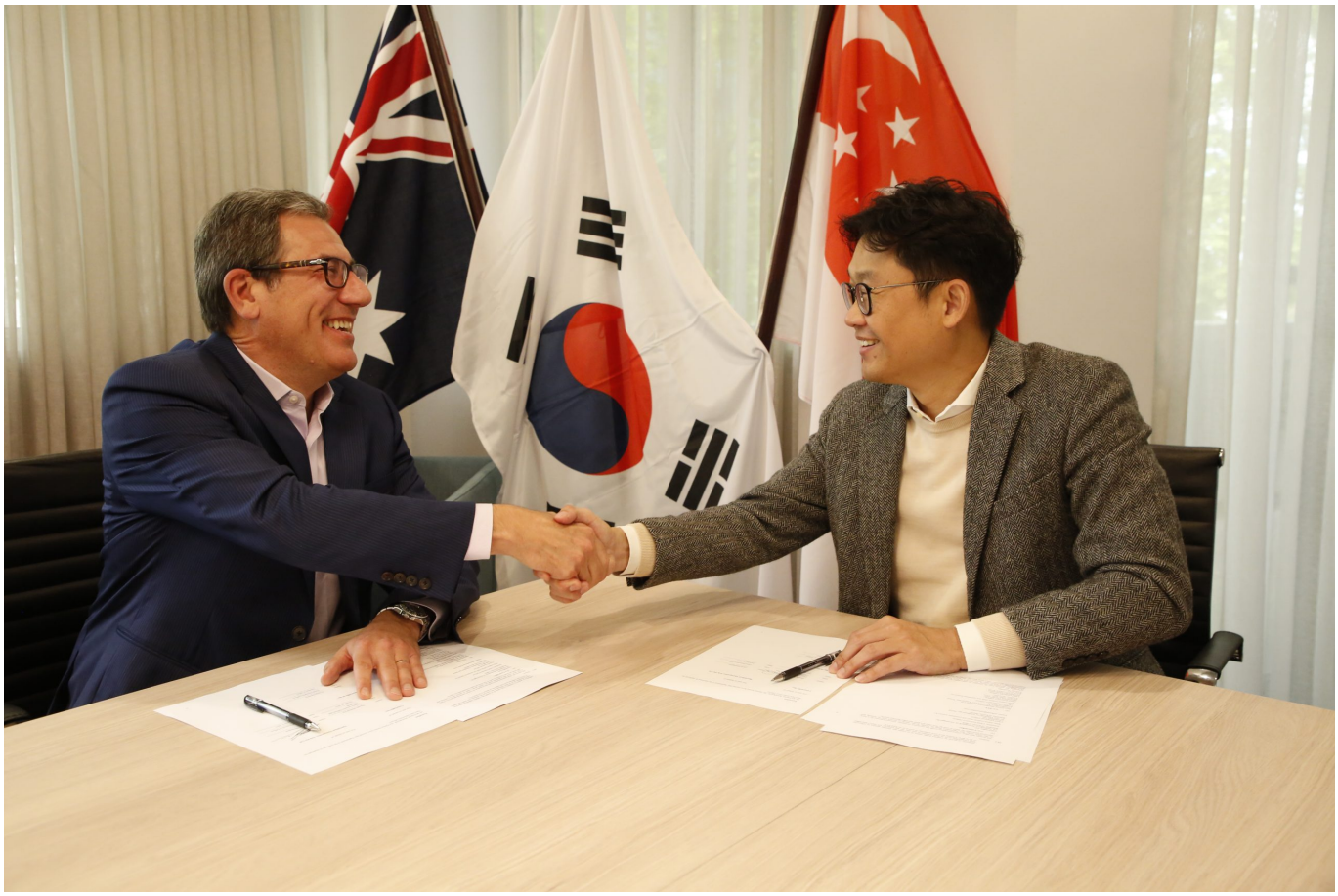
Specialised Therapeutics Signs Exclusive License Agreement with CanariaBio for New Ovarian Cancer Therapy

- First ovarian cancer therapy for ST oncology portfolio
- Phase 2 study demonstrated oregovomab in combination with chemotherapy improved progression free survival by ~30 months compared to chemotherapy alone[1]
- Phase 3 results expected in 2025
- Exclusive license for AU, NZ, Singapore, Malaysia, Brunei, Thailand and Vietnam

Singapore and Seoul, South Korea, 13 October 2023: Independent biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) has signed a license deal with Korea-based CanariaBio Inc., acquiring the exclusive license to a new monoclonal antibody therapy for patients with ovarian cancer in Australia, New Zealand and in select Southeast Asian countries.



The therapy, known as oregovomab, is currently in a pivotal phase III international clinical trial known as the FLORA-5 study.[2] This investigation is examining oregovomab in combination with chemotherapy agents carboplatin and paclitaxel for patients with advanced ovarian cancer.

Under the terms of the arrangement, ST will be responsible for all commercial, medical, regulatory and distribution activities for oregovomab in its key territories of Australia, New Zealand, Singapore, Thailand, Vietnam, Brunei and Malaysia. CanariaBio will be responsible for the manufacture and supply of oregovomab to ST.

Announcing the partnership, ST Chief Executive Officer Carlo Montagner said he was pleased CanariaBio had selected ST as a partner for this highly promising therapy.

“ST has a portfolio of anti-cancer therapies targeting multiple solid tumours with the exception of ovarian cancer, and now oregovomab becomes our first ovarian cancer agent,” Mr Montagner said.

“Despite great advances in recent years, there remains a high unmet need in all

our regions to treat this patient population. We look forward to working closely with our new partners at CanariaBio and pending the results of the pivotal Phase III registration study, making oregovomab available to eligible patients."

CanariaBio Chairman and CEO Michael Na said the company had selected ST for its regional expertise and strong track record commercialising oncology products. Carlo Montagner (Oct 11, 2023 12:11 GMT+11)

"Formalising this agreement is a pivotal moment for our program. This collaboration is more than just a deal – it's a shared commitment as we develop novel therapies to address unmet medical needs. At CanariaBio, we've always believed in the transformative power of partnerships, and teaming up with ST reinforces this belief." Oregovomab works by targeting and binding specifically to a surface protein known as CA-125 found on the surface of ovarian cancer cells, then activating the patient's own immune system to respond.[3]

In the Phase 2 study, the addition of oregovomab to chemotherapy yielded a median progression-free survival of 41.8 months compared with 12.2 months with standard chemotherapy alone (HR, 0.46, P=0.0027). The overall survival hazard ratio was 0.35.1 The Phase 3 FLORA-5 study is fully enrolled and ongoing. Final results are expected in 2025.

Ends.

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About Specialised Therapeutics

Founded in 2007, Specialised Therapeutics is the region's largest independent specialty pharmaceutical company, providing new therapies and technologies to patients in Australia, New Zealand and across Southeast Asia. Headquartered in Singapore, ST partners with global pharmaceutical, biotech and diagnostic companies to bring novel healthcare opportunities to patients who are impacted by a range of diseases. ST has built a strong track record of success, navigating complex regulatory, reimbursement and commercialisation environments in its diverse regions. The ST mission is to provide specialty therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, CNS, ophthalmology and supportive care, although it is not confined to these areas. Additional information: www.stbiopharma.com

About CanariaBio Inc. CanariaBio Inc. is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of innovative cancer biotherapeutics. CanariaBio's technology platform includes a portfolio of tumor antigen-specific monoclonal antibodies targeting CA-125, MUC1, PSA, and HER2/neu.

About Oregovomab

Oregovomab is a murine monoclonal antibody directed to the tumor-associated antigen CA-125 that stimulates a host cytotoxic immune response against tumor cells expressing CA-125, a biomarker commonly found in ovarian cancer (OC). In a randomized Phase 2 clinical trial, oregovomab demonstrated a significant improvement in progression-free and overall survival in advanced OC treatment when administered simultaneously with first-line chemotherapy. This promising schedule is currently being investigated in a Phase 3 trial.

About FLORA-5 Phase 3 Study

The Phase 3 clinical trial called FLORA-5/GOG-3035, is a double-blind, placebo-controlled, multicentre clinical study comparing the safety and efficacy of oregovomab versus placebo when administered in combination with specific cycles of a standard six-cycle chemotherapy regimen (paclitaxel and carboplatin)

for the treatment of newly diagnosed patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma, in conjunction with optimal debulking surgical resection. The primary and secondary endpoints, for both the adjuvant and neoadjuvant cohorts of this trial, are progression free survival and overall survival, respectively. The FLORA-5 trial is being conducted in collaboration with the Gynecologic Oncology Group Foundation in the US and IQVIA (a clinical research organization). Greater China area clinical trials are conducted in collaboration with OncoVent, a Shenzhen Hepalink Pharmaceuticals Group Company in China, which is also the commercialization license holder of oregovomab for China. Information on the clinical trial can be found on www.clinicaltrials.gov

References:

1. Brewer M, et al. Gynecol Oncol. 2020.156(3):523-529
2. ClinicalTrials.gov NCT04498117
3. www.FLORA-5.com. Last accessed October 2023.

New Therapy for Rare Gastrointestinal Stromal Tumours Approved in Singapore

- *Singapore's Health Sciences Authority (HSA) has approved QINLOCK® (ripretinib) for the treatment of patients with 4th line GIST*
- *QINLOCK significantly reduced the risk of disease progression or death by 85% and showed clinically meaningful overall survival in the INVICTUS Phase 3 Study[1,2]*

Singapore, 8 May 2023: Independent biopharmaceutical company Specialised Therapeutics Asia (ST) is pleased to announce that a new therapy to treat rare gastrointestinal stromal tumours (GIST) shown to improve survival has been approved for use in Singapore.

The therapy, QINLOCK (ripretinib) is now approved by the Health Sciences Authority (HSA) "***for the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib, sunitinib, and regorafenib***".

Singapore-based senior consultant in medical oncology Dr Richard Quek said QINLOCK represented a major treatment advancement for patients with advanced GIST.

"Since 2013, despite multiple attempts and studies, no therapy was shown to be effective for 4th line GIST patients whose cancers have progressed on existing treatment, until the discovery of QINLOCK," Dr Quek said.

In the pivotal INVICTUS study that led to QINLOCK's approval, QINLOCK was shown to significantly delay cancer progression.

"This approval in Singapore clearly provides an opportunity for us to improve the outcomes of our GIST patients who are refractory to the current existing treatment."

QINLOCK is an oral medication used to treat GIST in people who have received at least three prior treatments. It belongs to a drug class called tyrosine kinase inhibitors and works by blocking specific tumour proliferation pathways.[2]

A pivotal Phase 3 clinical trial of QINLOCK – the INVICTUS study – demonstrated that QINLOCK was able to significantly reduce the risk of disease progression by 85% (hazard ratio of 0.15, $p<0.0001$) with a median progression-free survival of 6.3 months in patients administered QINLOCK, compared to 1.0 month in the placebo arm.[1] QINLOCK was associated with clinically meaningful overall survival of 15.1 months vs 6.6 months and reduced the risk of death by 64% (hazard ratio

of 0.36). The objective response rate by Blinded Independent Central Review using modified Response Evaluation Criteria in Solid Tumors (RECIST) was 9.4% with QINLOCK vs 0.0% with placebo (p=0.0504).[1,3]

In addition, in a long-term follow up analysis of the INVICTUS trial, patients in the QINLOCK arm demonstrated a median overall survival of 18.2 months compared to 6.3 months in the placebo arm and reduced the risk of death by 59% (hazard ratio of 0.41).The objective response rate was 11.8% with QINLOCK vs 0.0% with placebo.[3]

ST Chief Executive Officer Carlo Montagner said the Singapore approval followed the recent approval of QINLOCK in New Zealand, as well as regulatory and reimbursement approval in Australia.

“Achieving these critical regulatory milestones is testament to the dedication of our regulatory teams to make QINLOCK available to all eligible patients in Singapore who are impacted by this rare gastrointestinal cancer.”

ST commercialises QINLOCK in Singapore under an exclusive distribution agreement from US based Deciphera Pharmaceuticals.

Further Inquiries can be directed to ST Senior Manager Communications and Corporate Affairs Emma Power on + 65 31589910 epower@stbiopharma.com

About GIST

Gastrointestinal stromal tumour (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST growth usually begins in the connective tissue in the wall of the affected organ and grows outwards. The common location of GIST is in the stomach (50 to 60%) and small intestines (30 to 40%) but can occur in any site in the digestive system. Other possible GIST sites are the oesophagus, rectum, and colon. GIST cases are rare and estimated to cause between 0.1% and 3% of GI cancer. The risk of GIST diagnosis increases with age, with GIST incidence peaking among people in their fifties and sixties.[4]

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRA mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.[5,6]

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients in Australia, New Zealand and across South-East Asia. ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Our mission is to provide therapies that would otherwise not be available to communities in our regions. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com

About the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomised, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK once daily (n=85) or placebo (n=44). The primary efficacy endpoint was progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median PFS in the study was

6.3 months in the QINLOCK arm compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, p<0.0001) compared to placebo.[1] Secondary endpoints included Objective Response Rate (ORR) as determined by independent radiologic review using modified RECIST and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo (p=0.0504), which was not statistically significant.[1] QINLOCK demonstrated a median OS of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).[1] In a long-term follow up of 19 months after the primary analysis, QINLOCK also demonstrated a median OS of 18.2 months compared to 6.3 months in the placebo arm and reduced the risk of death by 59% (hazard ratio of 0.41).[3] The most common (>2%) grade 3 or 4 treatment related adverse events in the QINLOCK group included lipase increase (5%), hypertension (4%), fatigue (2%), and hypophosphataemia (2%); and in the placebo group, anaemia (7%), fatigue (2%), diarrhoea (2%), decreased appetite (2%), dehydration (2%), hyperkalaemia (2%), acute kidney injury (2%), and pulmonary oedema (2%).[1,4]

References

1. Blay JY, Serrano C, Heinrich MC et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): A double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2020; 21:923–934.

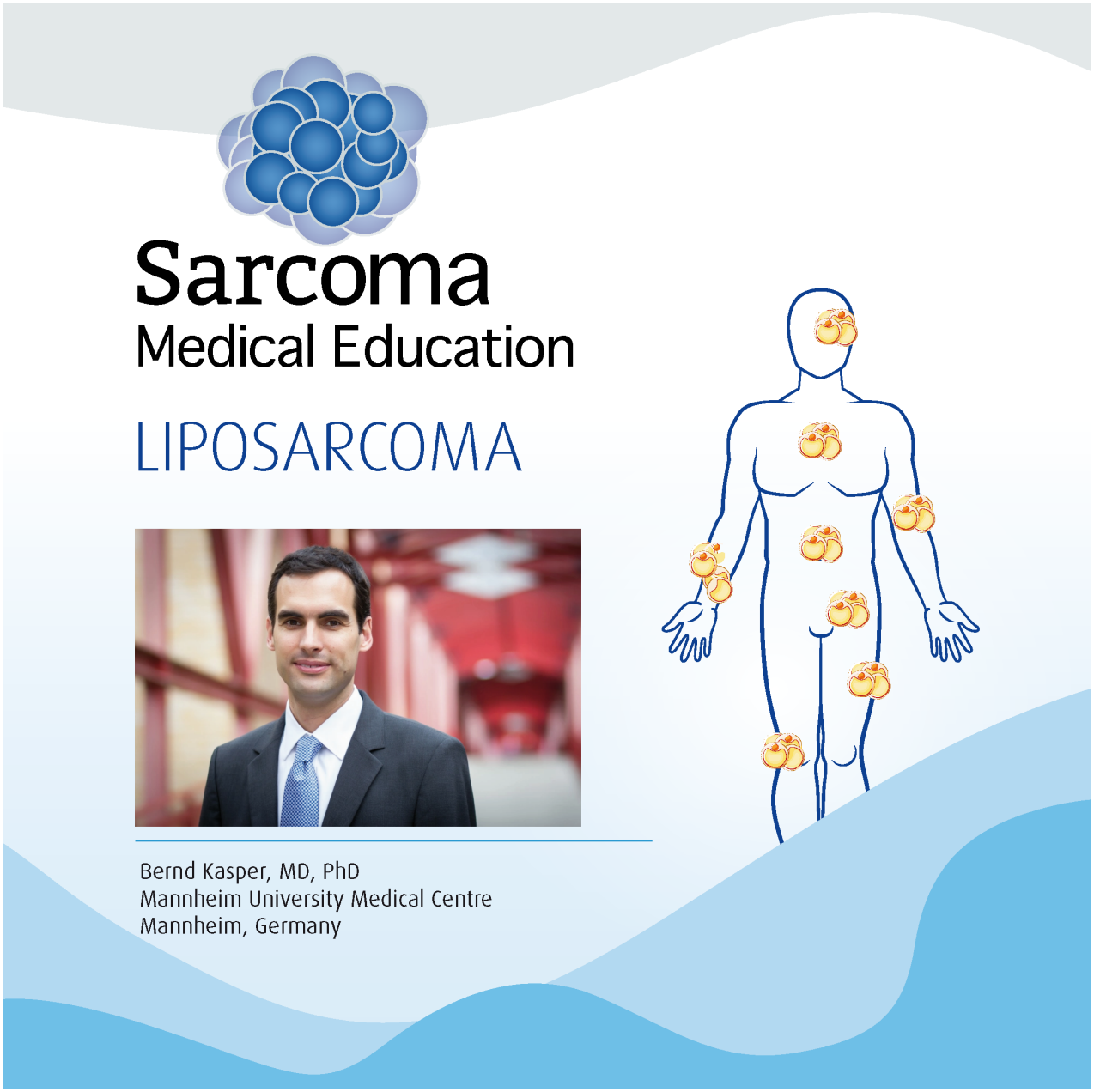
2. QINLOCK (ripretinib) HSA Approved Product Information, April 2023
3. von Mehren M, Heinrich M, George S, et al. Ripretinib as ≥4th-line treatment in patients with advanced gastrointestinal stromal tumour (GIST): Long-term update from the phase 3 INVICTUS study. Poster presented at: 2021 European Society for Medical Oncology Virtual Meeting; September 16-21, 2021.

1. GI Cancer Institute Australia https://gicancer.org.au/cancer/gastro-intestinal-stromal-tumour-gist/#cancer-explanation

5. Smith BD, Kaufman MD, Lu WP et al. Ripretinib (DCC-2618) is a switch control kinase inhibitor of a broad spectrum of oncogenic and drug-resistant KIT and PDGFRA variants. Cancer Cell 2019; 35(5):738–751.
6. Bauer S, Heinrich MC, George S et al. Clinical Activity of Ripretinib in Patients with Advanced Gastrointestinal Stromal Tumor Harboring Heterogeneous KIT/PDGFRA Mutations in the Phase III INVICTUS Study. Clin Cancer Res. 2021;27(23): 6333-6342.

Sarcoma Medical Education – Liposarcoma Podcast

Sarcoma Medical Education – Liposarcoma by Bernd Kasper, MD, PhD



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This audio is intended for healthcare professionals for informative purposes only. Click play above to hear Bernd Kasper MD, PhD provide an overview of Liposarcoma.

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Sarcoma Medical Education – Uterine Leiomyosarcoma (ULMS) Podcast

Sarcoma Medical Education – Uterine Leiomyosarcoma (ULMS) Podcast by Giovanni Grignani, M.D.

Sarcoma
Medical Education

UTERINE LEIOMYOSARCOMA (uLMS)

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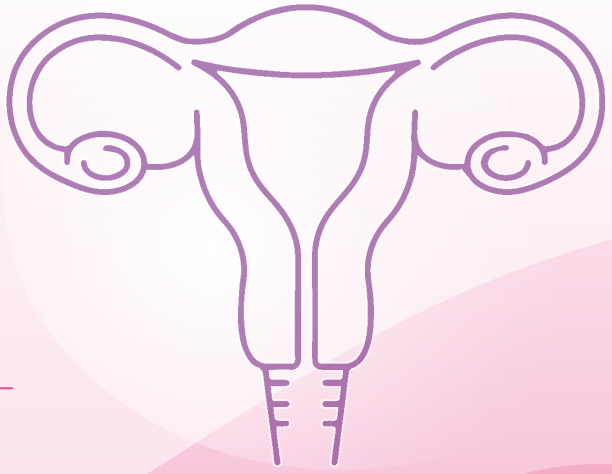

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Q&A Panel Discussion – New Therapy Options in Advanced Small Cell Lung Cancer (SCLC)

These videos are intended for healthcare professionals for informative purposes only. Click on the video above to watch the Q&A panel discussion with Dr Paul

Mitchell, Dr Santiago Ponce-Aix, Dr Amit Jain and Dr Tanujaa Rajasekaran.

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SCLC Webinar Chapters

Q1: Does the 3-year OS data from CASPIAN influence the long-term efficacy perception of IO + chemo in 1L ES-SCLC patients?

Q2 (Dr Tanujaa): Why is it that unlike the non-small cell lung cancer patients our small cell lung cancer patients don't seem to respond as well to immune checkpoint inhibitors? Any idea?

Q3: Why do you think Atlantis trial failed?

Q4: In your practice what do you use as second line treatment for the platinum refractory patients? Do you use a single agent lurbinectedin or do you do the combination of lurbinectedin plus Irinotecan?

Q5: Is lurbinectedin approved in Singapore?

Q6. Is the current trial with lurbinectedin plus atezolizumab (first line maintenance) enough for USA full approval of lurbinectedin in second line of SCLC? Or will it be necessary to launch a new phase 3 trial with lurbinectedin to get the full approval?

Q7: Thanks, Dr Santiago it's wonderful hearing your insights as you are in the thick of it and you're planning new trials? What are you going to put your money on if you want your phase III, 2nd line trial? What's your combination of choice there's so many ways to do this now? So, if you had to pick one, which one would it be?

Q8: You mentioned about PD-L1 in small cell lung cancer, do you routinely test for that in your patients?

Q9: Do you routinely re-biopsy your patients who progress on first line or second line therapy?

Q10: How important is maintenance immunotherapy in first line SCLC?

Q11 (Dr Tanujaa): For example, if you have an extensive stage small cell lung cancer patient and had just had etoposide plus carboplatin as first-line therapy and they progress without any immune checkpoint inhibitor or a similar situation where limited stage lung cancer had concurrent chemo RT and progress within three months and haven't seen immune checkpoint inhibitors and they are platinum refractory. So, what will be your choice for second line therapy? Would you consider using immune checkpoint inhibitors in the second line or would you still go back to your standard second line chemotherapy options?

Q12: Why temozolomide for your case study? And why not other chemotherapy agents?

Q13: What do you think of drugs to treat CNS metastasis in the future? What will be the brain penetration of the newer drugs?

Q14: Do you have any data on the CNS activity of lurbinectedin?

Q15: Do you often offer local therapy after response to etoposide platinum plus immune checkpoint inhibitors? What do you think about the role of local radiotherapy in this case?

Q16: What is the most promising biomarker in SCLC according to you?

Q17: Let's say if we were having this webinar five years down the road, do you think we will be still talking about overall survival being about what slightly more than a year or do you see things changing tremendously? What are your views?

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Dr Amit Jain – Treatment Landscape and Challenges in Treating SCLC

These videos are intended for healthcare professionals for informative purposes only. Click on the video above to watch Dr Amit Jain discuss the treatment landscape and challenges in treating SCLC.

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SCLC Webinar Chapters

Introduction – Dr Amit Jain

Paradigms in Treatment of Extensive SCLC

SCLC – A Challenging Disease

Chemotherapy in 1st and 2nd Line

Use of Immunotherapy in 1st Line

Use of Immunotherapy as Maintenance and in 2nd Line

NCCN Guidelines

Lurbinectedin – Key Points

Treatments on the Horizon

Case Study

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Dr Santiago Ponce-Aix – SCLC Post Progression Therapy Options

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SCLC Webinar Chapters

Introduction for Dr Ponce-Aix

New Standard of Care for ES-SCLC

Retreatment with Platinum as 2nd line (>90 days)

Immunotherapy in 2nd line

Biomarker Selection

Lurbinectedin Basket Trial Data

ATLANTIS Trial

RESILIENT Trial

Lurbinectedin plus Irinotecan

Lurbinectedin plus Atezolizumab

Summary

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Dr Paul Mitchell – Overview of the SCLC Treatment Landscape: the Australian Experience

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SCLC Webinar Chapters

Introduction: Dr Paul Mitchell

Background: Small Cell Lung Cancer

IMpower 133: Atezolizumab + Carboplatin + etoposide in 1L ES-SCLC

CASPIAN Trial: Durvalumab +Tremilimumab + etoposide in ES-SCLC

ECOG-ACRIN EA5161 – Cisplatin/carboplatin + etoposide + nivolumab in ES-SCLC

Keynote- 606. Pembrolizumab + etoposide +Cisplatin/Carboplatin in stage IV SCLC

Summary ES-SCLC: Key first-line IO trials

Checkmate 451 – Maintenance strategy of Immunotherapy

Biomarkers (PD-L1 AND TMB)

ES-SCLC: Adding Thoracic Radiotherapy and TROG Phase 2 study

Limited Stage small cell lung cancer (LS-SCLC)

Second line options and beyond

Summary of 1st line therapies in SCLC

Zepzelca Access Program Analysis (SCLC)

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New Therapy Options in Advanced Small Cell Lung Cancer (SCLC)

Webinar

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SCLC Webinar Chapters

Dr Paul Mitchell

2:31 to 3:03 **Introduction: Dr Paul Mitchell**

3:24 to 5:33 **Background: Small Cell Lung Cancer**

5.34 to 9.07 **IMpower 133: Atezolizumab + Carboplatin + etoposide in 1L ES-SCLC**

9:08 to 10:50 **CASPIAN Trial: Durvalumab +Tremilimumab +**

etoposide in ES-SCLC

10:51 to 11:25 **ECOG-ACRIN EA5161 – Cisplatin/carboplatin + etoposide + nivolumab in ES-SCLC**

11:26 to 12:20 **Keynote- 606. Pembrolizumab + etoposide +Cisplatin/Carboplatin in stage IV SCLC**

12:21 to 12:55 **Summary ES-SCLC: Key first-line IO trials**

12:56 to 13:25 **Checkmate 451 – Maintenance strategy of Immunotherapy**

13:26 to 13:55 **Biomarkers (PD-L1 AND TMB)**

13.56 to 15.27 **ES-SCLC: Adding Thoracic Radiotherapy and TROG Phase 2 study**

15:28 to 16:17 **Limited Stage small cell lung cancer (LS-SCLC)**

16:18 to 17:15 **Second line options and beyond**

17:16 to 18:19 **Summary of 1st line therapies in SCLC**

18:20 to 21:41: **Zepzelca Access Program Analysis (SCLC)**

Dr Santiago Ponce-Aix

22:05 to 23:04 **Introduction for Dr Ponce-Aix**

23:31 to 24:37 **New Standard of Care for ES-SCLC**

24.38 to 26.28: **Retreatment with Platinum as 2nd line (>90 days)**

26:29 to 29:29 **Immunotherapy in 2nd line**

29:30 to 34:26 **Biomarker Selection**

34:27 to 36:49 **Lurbinectedin Basket Trial Data**

36:50 to 37:23 **ATLANTIS Trial**

37:24 to 39:05 **RESILIENT Trial**

39:06 to 41:28 **Lurbinectedin plus Irinotecan**

41.29 to 44.33 **Lurbinectedin plus Atezolizumab**

44:34 to 45:32 **Summary**

Dr Amit Jain

46:00 to 46:34 **Introduction – Dr Amit Jain**

46:39 to 47:46 **Paradigms in Treatment of Extensive SCLC**

47:47 to 49:49 **SCLC – A Challenging Disease**

49:50 to 51:47 **Chemotherapy in 1st and 2nd Line**

51:48 to 52:33 **Use of Immunotherapy in 1st Line**

52:35 to 53:05 **Use of Immunotherapy as Maintenance and in 2nd Line**

53:07 to 54:01 **NCCN Guidelines**

54:02 to 55:30 **Lurbinectedin – Key Points**

55:31 to 57:14 **Treatments on the Horizon**

57:15 to 59:28 **Case Study**

Panel discussion

59:59 to 1:00:57 **Q1: Does the 3-year OS data from CASPIAN influence the long-term efficacy perception of IO + chemo in 1L ES-SCLC patients?**

1:00:58 to 1:06:53 **Q2 (Dr Tanujaa): Why is it that unlike the non-small**

cell lung cancer patients our small cell lung cancer patients don't seem to respond as well to immune checkpoint inhibitors? Any idea?

1:06:56 to 1:08:16 **Q3: Why do you think Atlantis trial failed?**

1:08:17 to 1:10:05 **Q4: In your practice what do you use as second line treatment for the platinum refractory patients? Do you use a single agent lurbinectedin or do you do the combination of lurbinectedin plus Irinotecan?**

1:10:06 to 1:11:06 **Q5: Is lurbinectedin approved in Singapore?**

1:11.07 to 1:12:17 **Q6. Is the current trial with lurbinectedin plus atezolizumab (first line maintenance) enough for USA full approval of lurbinectedin in second line of SCLC? Or will it be necessary to launch a new phase 3 trial with lurbinectedin to get the full approval?**

1:12:18 to 1:15:06 **Q7: Thanks, Dr Santiago it's wonderful hearing your insights as you are in the thick of it and you're planning new trials? What are you going to put your money on if you want your phase III, 2nd line trial? What's your combination of choice there's so many ways to do this now? So, if you had to pick one, which one would it be?**

1:15:07 to 1:15:56 **Q8: You mentioned about PD-L1 in small cell lung cancer, do you routinely test for that in your patients?**

1:15:58 to 1:16:39 **Q9: Do you routinely re-biopsy your patients who progress on first line or second line therapy?**

1:16:40 to 01:18:45 **Q10: How important is maintenance immunotherapy in first line SCLC?**

01:18:46 to 1:20:53 **Q11 (Dr Tanujaa): For example, if you have an extensive stage small cell lung cancer patient and had just had etoposide plus carboplatin as first-line therapy and they progress without any immune checkpoint inhibitor or a similar situation where limited stage lung cancer had concurrent chemo RT and progress within three months and haven't seen immune checkpoint inhibitors and they are platinum refractory. So, what will be your choice for second line therapy? Would**

you consider using immune checkpoint inhibitors in the second line or would you still go back to your standard second line chemotherapy options?

1:20:55 to 1:22:25 **Q12: Why temozolomide for your case study? And why not other chemotherapy agents?**

1:22:26 to 1:24:55 **Q13: What do you think of drugs to treat CNS metastasis in the future? What will be the brain penetration of the newer drugs?**

01:24:58 to 01:25:30 **Q14: Do you have any data on the CNS activity of lurbinectedin?**

01:25:31 to 1:27:10 **Q15: Do you often offer local therapy after response to etoposide platinum plus immune checkpoint inhibitors? What do you think about the role of local radiotherapy in this case?**

01:27:14 to 01:28:33 **Q16: What is the most promising biomarker in SCLC according to you?**

1:28:33 to 1:31:07 **Q17: Let's say if we were having this webinar five years down the road, do you think we will be still talking about overall survival being about what slightly more than a year or do you see things changing tremendously? What are your views?**

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