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Seagen Inc. (SGEN)

Q2 2021 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good day and welcome to the Seagen Second Quarter 2021 Financial Results Conference Call. All participants will be in listen-only mode. [Operator Instructions] After today's presentation, there will be an opportunity to ask questions. [Operator Instructions] Please note this event is being recorded.

I would now like to turn the conference over to Ms. Peggy Pinkston, Senior Vice President of Investor Relations. Please go ahead.

Peggy Pinkston

Senior Vice President-Investor Relations, Seagen Inc.

Thank you, operator, and good afternoon, everyone. I'd like to welcome all of you to Seagen's second quarter 2021 financial results conference call. This afternoon, we issued a press release with our results. And that press release and supporting slides are available on our website in the Investors section, Events & Presentations page. Speakers on today's call will be Clay Siegall, President and Chief Executive Officer; Todd Simpson, Chief Financial Officer; Chip Romp, Executive Vice President, Commercial US; and Roger Dansey, Chief Medical Officer.

Following our prepared remarks, we'll open the line for questions. We aim to keep this call to one hour, and so I ask that you limit yourself to one question to give everyone an opportunity to participate in Q&A during our call today.

Today's conference call will include forward-looking statements regarding future or anticipated events and results, including the company's 2021 financial outlook, anticipated product sales, revenues, costs, and expenses, and potential clinical and regulatory milestones, including data readouts, regulatory submissions, and approvals. Actual results or developments may differ materially from those projected or implied in these forward-looking statements.

Factors that may cause such a difference include the difficulty in forecasting sales, revenues and expenses, impacts related to the COVID-19 pandemic, and the uncertainty associated with the pharmaceutical development and regulatory approval process.

More information about the risks and uncertainties faced by Seagen is contained under the caption Risk Factors included in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the Securities and Exchange Commission and the company's subsequent reports filed with the SEC.

And now, I'll turn the call over to Clay.

Clay B. Siegall

Chairman, President & Chief Executive Officer, Seagen Inc.

Thank you, Peg, and good afternoon, everyone. This was an exceptional quarter for our business in terms of commercial performance as well as regulatory and clinical progress. We're pleased to report the highest-ever net product sales across each of our approved medicines as well as the highest sequential quarter-over-quarter dollar growth in product sales in our history.

These results reflect strong commercial execution across PADCEV, TUKYSA, and ADCETRIS. Our financial strength is driven by product sales as well as royalties and multiple strategic collaborations. We ended the quarter with $2.5 billion in cash and investments and have no debt. This positions us to expand our programs, advance our research and development, and continue investing in our business.

We remain focused on maximizing the opportunity and value of our approved drugs and developing additional transformative cancer therapies for patients around the world. We look forward to sharing key business regulatory, commercial and development updates on the call today. We are focused on three strategic priorities that empower our ability to drive innovation, growth, and substantial benefit for our stakeholders, including employees, oncologists, our communities, shareholders and most notably, cancer patients.

Our first strategic priority is to maximize the global potential of our three approved medicines through robust clinical development and exceptional commercial execution. The first product I would like to highlight is PADCEV, a first-in-class ADC that has quickly become standard of care in previously treated metastatic urothelial cancer. Earlier this month, FDA granted PADCEV regular approval in the US based on data from the Phase 3 EV-301 trial which demonstrated an overall survival advantage for patients treated with PADCEV versus chemotherapy. Full approval is important for the commercial team as inclusion of the OS data allows for promotion of PADCEV demonstrated clinical benefit.

PADCEV was also granted a second indication making it the first and only FDA-approved therapy for urothelial cancer patients who are cisplatin-ineligible and have previously received one or more therapies. As a meaningful proportion of bladder cancer patients cannot tolerate cisplatin-based chemotherapy, there is an urgent need for more treatment options such as PADCEV. In addition to supporting regular approval in the US, the EV-301 data supports global regulatory submissions, which we and our partner, Astellas, continue to move forward.

Another key product is TUKYSA, a best-in-class HER2 tyrosine kinase inhibitor, which has become an important standard of care in the US for the treatment of second and later line HER2-positive breast cancer patients with and without brain metastasis. TUKYSA is now approved in 36 countries and in addition to the US has launched in Germany, France, Switzerland and Austria.

We are actively engaging with country-specific authorities to gain reimbursement and broader access for TUKYSA outside the US. We're pleased by early uptake, healthcare provider feedback and the fact that TUKYSA has already been included in key treatment guidelines.

TUKYSA's broad clinical development program includes evaluation in HER2-positive breast cancer as well as colorectal and gastric cancers and in other HER2 amplified or mutant tumors. We expect our strategic commercial collaboration with Merck to further accelerate TUKYSA's global reach in regions outside of the US, Canada and Europe.

The third product I'll highlight is ADCETRIS, which is the established foundation of care in multiple CD30-expressing lymphomas. ADCETRIS is a remarkable product that is commercially available in 76 countries and serves as the bedrock of our core business, enabling us to continue investing in our pipeline and other products.

A decade after approval, ADCETRIS just reported its highest ever quarterly sales, which serves as further evidence of the significant benefit it offers to patients. We are committed to maximizing ADCETRIS' reach and continuing to advance a comprehensive clinical development program in Hodgkin lymphoma, diffuse large B-cell lymphoma and solid tumors. In addition, our partner, Takeda, is pursuing approvals for frontline Hodgkin lymphoma and peripheral T-cell lymphoma in its territories.

Our second strategic priority is to advance late stage programs toward securing approvals for new products. Tisotumab vedotin or TV is currently under priority review by FDA seeking accelerated approval for recurrent or metastatic cervical cancer with a PDUFA action date of October 10. TV is positioned to be our fourth commercial product as we look to expand our portfolio further and together with our partner, Genmab, we are currently on track with launch preparations. This is an important development in the treatment of cervical cancer, which in the recurrent or metastatic setting, has a significant unmet medical need.

Our third strategic priority is to expand our deep and diverse early stage pipeline through continued innovation, encompassing antibody drug conjugates, immuno-oncology agents, R&D investments, corporate development, and strategic partnerships.

In closing, I'd like to recognize our employees and partners around the world who despite challenging conditions over the past 17 months have worked tirelessly to progress our programs and build our business. We have now begun the process of appropriately and safely returning our US-based workforce to the office in a phased approach.

Next, I'll turn the call over to Todd who will provide an overview of our financial results. Then Chip will discuss our commercial performance. After that, Roger will provide an update on clinical development activities and our pipeline. Todd?

Todd E. Simpson

Chief Financial Officer, Seagen Inc.

Great. Thanks, Clay, and thanks to everyone for joining us on the call this afternoon. Our financial results reflect significant advancements made across the business. Today, I'll summarize our financial results for the second quarter and year-to-date, which are in line with our expectations for the full year. Total revenues were $388 million in the second quarter and $720 million for the year-to-date in 2021.

Products sales from our three oncology franchises totaled $347 million in the second quarter, representing 15% sequential quarterly growth and 44% growth over the second quarter of 2020. This reflects revenues across our diverse commercial portfolio which now has international reach.

Royalty revenues were $36 million in the second quarter and $64 million for the year-to-date in 2021. Growth over 2020 reflects increasing sales of ADCETRIS by Takeda as well as royalties on sales of Polivy by Roche and Blenrep by GSK.

As expected, collaboration revenues were modest at $5 million in the second quarter and $7 million for the year-to-date in 2021. Costs of sales increased to $78 million in the second quarter and $142 million for the first half of 2021. This included product costs of sales and royalties for each of our three brands, the PADCEV gross profit share to Astellas which was $39 million in the second quarter and $71 million for the year-to-date, as well as non-cash amortization of acquired technology costs for TUKYSA.

R&D expenses were $235 million in the second quarter and $465 million for the first half of 2021. These are increases over 2020 and reflect increased investment across our early and late-stage pipeline. SG&A expenses were $165 million in the second quarter and $325 million for the first half of 2021. These are increases over 2020, reflecting investments to support European TUKYSA launches and our global expansion efforts.

Lastly, we are maintaining our 2021 financial guidance, and we're pleased with our performance in the first half of the year. We have significant financial strength, which allows us to continue investing in our pipeline and business.

Now, I'll turn the call over to Chip for an overview of our commercial performance.

Charles Romp

Executive Vice President-Commercial U.S., Seagen Inc.

Thank you, Todd. Performance across the commercial portfolio was strong in Q2 and we believe we are emerging from the pandemic with positive momentum. We are well positioned to drive continued growth with the recent PADCEV label expansion, additional country launches for TUKYSA, and the potential approval of TV. We are seeing meaningful increase in the number of in-person sales calls by our field team, and our commercial infrastructure and capabilities are in place to maximize future product launches.

ADCETRIS delivered a record quarter, a noteworthy accomplishment for a 10-year-old brand. ADCETRIS sales were $182 million, a 9% increase over Q2 2020 and a 12% increase in volume over last quarter. Our field sales force is returning towards normal call activity levels, with mostly face-to-face interactions. We are now actively promoting the landmark five-year ECHELON-1 progression-free survival data in frontline Hodgkin lymphoma, as featured in The Lancet Hematology publication. This is meaningful data to physicians and patients and solidifies the ADCETRIS regimen as the best option for frontline Stage III or IV Hodgkin lymphoma patients.

Moving on to PADCEV, second quarter sales were $82 million, a 44% increase over the second quarter of 2020 and an 18% increase over the last quarter. We are pleased with the conversion to a full approval for PADCEV and a new indication for cisplatin-ineligible metastatic urothelial cancer patients who previously received one or more lines of therapy.

Our ability to now promote this new indication should drive incremental uptake, representing a meaningful but modest opportunity. As we've discussed in past quarters, the metastatic urothelial cancer setting continues to evolve, and we are confident that PADCEV is well positioned to remain the standard of care.

Transitioning to TUKYSA, second quarter sales were $83 million, an increase of 18% over last quarter. Our US launch has been very successful, and we continue to see high levels of utilization in patients with and without brain mets. In patients with brain mets, TUKYSA is the most utilized product in second and later lines for HER2-positive breast cancer.

In Europe, early uptake has been very encouraging, notably with recent launches in France and Germany. The strength of evidence including demonstrated overall survival benefit from the HER2CLIMB trial, along with favorable clinical guidelines, gives us confidence as we execute our reimbursement strategy in Europe.

And finally, we are pleased that the TV BLA received priority review, and if approved, this would be an important new drug for women with previously treated metastatic cervical cancer. The team will be ready ahead of the October 10 PDUFA date with a dedicated sales force in place. We are starting the second half of the year with great momentum across our portfolio of first-in-class or best-in-class products, and look forward to potentially adding another important medicine soon to our proven commercial model.

Now, I'll turn the call over to Roger to talk about our robust development activities. Roger?

Roger D. Dansey

Chief Medical Officer, Seagen Inc.

Thank you, Chip, and good afternoon everyone. I'm happy to share recent clinical development updates for our approved medicines and our pipeline. I'll start with PADCEV. The FDA originally granted PADCEV accelerated approval for the treatment of patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy.

Continued approval was contingent upon confirmation of the clinical benefits in the EV-301 pivotal trial. The FDA has now granted PADCEV regular approval based on the trial's success which demonstrated improved survival among patients who received PADCEV compared to those who received chemotherapy.

Further, the PADCEV US prescribing information now includes a new indication for the treatment of metastatic urothelial cancer patients who are ineligible for cisplatin and have previously received one or more prior lines of therapy. The new indication was also granted regular approval and is based on Cohort 2 of the EV-201 trial.

These results were recently published in Lancet Oncology and were updated with additional follow-up in a presentation at ASCO. 51% of patients achieved a confirmed objective response with a median duration of response of 13.8 months. These data are clinically meaningful in the setting of high unmet need where patients are older and are suffering from multiple comorbidities commonly including poor kidney function. We are pleased with the broad nature of the second indication, which does not specifically require prior PD-1 or PD-L1 treatment.

Additionally, the new label has been updated with important safety information, which further informs physicians on how to safely use PADCEV. The clinically compelling PADCEV data have enabled substantial regulatory progress outside of the United States with marketing applications currently under review in the EU, Australia, Canada, Japan, Brazil, Switzerland, and Singapore.

I'll turn now to first-line metastatic urothelial cancer. At ASCO, we presented updated durability and other long-term outcomes from Cohort A of the EV-103 trial evaluating PADCEV plus KEYTRUDA in cisplatin-ineligible patients. The data showed a continued objective response rate of 73% and median duration of response extending to 25.6 months. Encouragingly, median PFS was 12.3 months and median OS was 26.1 months.

The safety profile of this combination was generally consistent with previous findings. We are using the same regimen in Cohort K, which is intended to support accelerated approval, and we expect to complete enrollment of this cohort by the end of the year. In addition, we continue to enroll patients into the Phase 3 EV-302 global trial, which includes both cisplatin-eligible and ineligible patients, evaluating PADCEV plus KEYTRUDA compared to platinum-containing chemotherapy regimen. Our broad PADCEV development program also includes two Phase 3 trials in patients with muscle invasive disease. Both trials [indiscernible] (00:18:25) in combination with KEYTRUDA.

The KEYNOTE-B15 or EV-304 trial is enrolling cisplatin-eligible patients and KEYNOTE-905 or EV-303 trial is enrolling cisplatin-ineligible patients. Additionally, in the next few months, we expect to initiate a dose-finding trial of single agent PADCEV in non-muscle invasive bladder cancer. PADCEV will be administered intravesically in BCG non-responsive patients. NECTIN4 is highly expressed in non-muscle invasive bladder cancer and there is promising preclinical data to support the potential opportunity for PADCEV to be active in this setting.

We are also evaluating PADCEV in a basket trial of high NECTIN4 expressing solid tumors, including lung, breast, head and neck, gastric and esophageal cancer, and we await initial data to inform our next steps.

Turning now to TUKYSA. At ASCO, we presented long-term data from the HER2CLIMB trial. The primary analysis upon which TUKYSA was approved was conducted with 14 months of follow up. This presentation extended the time of follow up to 29.6 months. The updated median overall survival increased to 24.7 months for the TUKYSA arm with benefit maintained across all pre-specified patient subgroups. There has also been a recent update to the NCCN treatment guidelines for patients with CNS involvement. TUKYSA plus trastuzumab and capecitabine is now the only regimen in the setting with a Category 1 level of evidence.

In earlier stages of breast cancer, we are evaluating TUKYSA plus Kadcyla versus Kadcyla alone in first- and second-line metastatic patients in the HER2CLIMB-02 trial. We and Merck intend for this trial to support global approvals including in China. In high-risk adjuvant breast cancer enrollment continues in the randomized CompassHER2 RD trial evaluating TUKYSA plus Kadcyla versus Kadcyla alone which has been run by the Alliance Cooperative Group.

In GI cancers, we remain on track to complete enrollment in the MOUNTAINEER trial by the end of 2021. This trial is intended to support an accelerated approval in the United States for patients with advanced HER2-positive colorectal cancer. Also, we are advancing TUKYSA in several studies including in combination with oxaliplatin-based chemotherapy in first-line GI cancers, in a basket trial for solid tumors of HER2 alterations that include mutations and in combination within HER2 for HER2-positive breast cancer.

Moving on now to ADCETRIS, we are pleased that the ECHELON-1 five-year manuscript was published in Lancet Haematology during the second quarter. As we have discussed, results demonstrated robust and durable remission in patients with newly diagnosed advanced Hodgkin lymphoma who received ADCETRIS in combination with AVD.

Importantly, we also saw fewer second malignancies and more pregnancies in patients on the ADCETRIS arm of the trial. We continue to execute our ADCETRIS clinical development program that includes ECHELON-3, our Phase 3 trial in relapse diffuse large B-cell lymphoma, which compares ADCETRIS plus Revlimid and Rituxan versus Revlimid and Rituxan. In frontline advanced as well as early stage Hodgkin lymphoma, we are evaluating ADCETRIS in combination with nivolumab, Adriamycin and dacarbazine. And in solid tumors, we are evaluating ADCETRIS as an immunomodulatory agent in combination with KEYTRUDA.

I'll turn now to TV, which we are developing in collaboration with Genmab. The BLA currently under review is seeking accelerated approval of TV for the treatment of women with previously treated recurrent or metastatic cervical cancer. The BLA is supported by data from the innovaTV 204 trial which was recently published in Lancet Oncology. In addition, we are enrolling the innovaTV 301 global Phase 3 trial in a similar population that is intended to serve as the confirmatory trial in the United States and to support global regulatory applications.

We believe TV could make a meaningful difference for women with cervical cancer where there is such a high unmet need. Our next goal is to bring TV into earlier lines of metastatic or recurrent cervical cancer. And for that purpose, we are conducting the innovaTV 205 trial in first or second line. In this trial, we are evaluating TV in combination with chemotherapy or KEYTRUDA, and we expect to report data at a medical meeting before the end of the year.

Turning now to ladiratuzumab vedotin, we are working with our partner Merck focusing on optimizing dosing schedule as monotherapy and in combination with KEYTRUDA in breast cancer. We plan to present data from LV later this year.

Next, I'd like to highlight the breadth and depth of our early stage pipeline. We are advancing seven programs in Phase 1 clinical trial across a range of solid tumors and hematologic malignancies. These include the ADC's SGN-CD228A, SGN-B6A, and SGN-STNV. And we expect to submit INDs for at least two more ADC programs this year.

In addition, we have four effective function enhanced antibodies utilizing our SEA technology, including SEA-CD40, SEA-CD70, SEA-BCMA, and TIGIT. With regard to SEA-CD40, earlier this year, we completed enrollment in a clinical trial evaluating it as part of a combination regimen for the treatment of pancreatic cancer. We expect to report clinical data from the trial sometime either later this year or early next year as the data mature. We are also planning to initiate a basket trial to evaluate SEA-CD40 and other solid tumors.

In closing, we have achieved many important milestones and have made significant headway across our pipeline in the first half of 2021. We look forward to providing you with further updates on future calls.

And now, I will turn the call back over to Clay.

Clay B. Siegall

Chairman, President & Chief Executive Officer, Seagen Inc.

Thank you, Roger. I'm proud of the remarkable progress we have made in growing and evolving our business and technology enabling us to develop exceptional oncology therapies. Today, we have a deep and diverse pipeline, a multiproduct commercial portfolio, and additional potential approvals on the horizon. Strategic partnerships, our expanded global infrastructure, and substantial financial power fuel our ability to advance our portfolio including our early and mid-stage pipeline.

Our robust clinical development program and proven commercial engine demonstrate our ability to compete in the marketplace. And we are poised to maximize new assets in future launches. With our solid foundation, we are operating from a position of strength and our confident in our ability to continue delivering cutting-edge innovation and transformative medicines for cancer patients worldwide.

Operator, please open the line for Q&A.

QUESTION AND ANSWER SECTION

Operator: We will now begin the question-and-answer session. [Operator Instructions] At this time, we will pause momentarily to assemble our roster. Our first question comes from Andrew Berens with SVB Leerink. Please go ahead.

Andrew Berens
Analyst, SVB Leerink LLC

Q

Hi. Congrats on the strong execution, guys, this quarter. I know you've given some guidance about the addressable markets by line of therapy for PADCEV in the past. So I was wondering if you could tell us how much you think the label expansion to the second line increases the addressable market now, and how saturated do you think PADCEV is in the third line.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Thank you for the questions and the comments, Andy. We're really pleased with the broad label that we got for PADCEV. There was – the EV-301 study confirmed the existing label and then the Cohort 2, as we called it, gave us a new population of patients that were cisplatin ineligible. We believe that some of these patients were likely getting un-promoted use of the drug in that setting. It's very hard to know how many but it's certainly – we don't think it was zero. So, we'll continue to monitor the impact of this new indication on the commercial uptake of this. But we feel really great about the new labels.

Andrew Berens
Analyst, SVB Leerink LLC

Q

Okay. How saturated do you think it was in the third-line setting that was originally approved then?

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

I think we're – we got to standard of care pretty quickly there. And docs really embraced using it. And I don't think we were 100% saturated. It's hard to give guidance on it for what's happening. It's also – it feels like we're coming out of COVID a little bit although we have the new variants, who knows. And – so, it's really hard to give exacting guidance. But I think we have room to continue moving upstream with that. But it's a great drug and doctors are embracing it.

Andrew Berens
Analyst, SVB Leerink LLC

Q

Okay. Thanks for the color, Clay. I appreciate it.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Sure. Chip, would you like to give a little color on this?

Charles Romp
Executive Vice President-Commercial U.S., Seagen Inc.

A

Yeah. [ph] Clay (00:28:49), absolutely. I think it's just important to note that this is a dynamic market. And with the advancements in treatment with regard to maintenance, we are seeing more and more patients become eligible for PADCEV earlier in their treatment journey than they would have in the past.

Operator: Your next question comes from Salveen Richter with Goldman Sachs. Please go ahead.

Salveen Richter
Analyst, Goldman Sachs & Co. LLC

Q

Good afternoon. Congrats on the nice quarter. Could you comment on the trajectory of your products in the second half given there is suggestion of negative growth for ADCETRIS and TUKYSA per your guidance? And then what drove the inflection for ADCETRIS this quarter?

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Okay. Well, thanks very much for the questions on everything. We're not trying to provide down guidance on anything. It's just hard to really know exactly what will happen as we either get out of COVID or not. And so we just wanted to be prudent with our guidance and we watch things very close on this. Todd, do you want to give a little bit of color on what we're thinking about in terms of financials and guidance?

Todd E. Simpson
Chief Financial Officer, Seagen Inc.

A

Sure. So, thanks for the questions, Salveen. First, I'll start off by saying we don't try to give quarterly guidance. We give annual guidance. And the reason for that is quarters fluctuate. We just came out of a very strong quarter, which we're delighted about. Q2 typically is a strong order for us, especially compared to Q1. And when you annualize first half of the year and compare that to our guidance, we think our guidance is appropriate, which is why we've maintained it. But there's a lot going on and we're really pleased with what we're seeing and the year is off to a great start. It's terrific to get our field teams for the most part back into the field, which is where they can do their best work.

And there are a lot of things that we're tracking. For example, with ADCETRIS, we've now – we're now promoting to the five-year data. We're looking at return of patients in the clinic out of the pandemic. But it's frankly a little too early to tell exactly what's going on. For PADCEV, we're looking forward to now promoting to the Cohort 2 label, which as you heard on the call is incremental because we're probably getting some of those patients before.

And then with TUKYSA, we're delighted to now complement the US launch with now launches starting in Europe, most notably in France and Germany. So, again, we're really pleased with how the year has gotten off to a start and feel like we're in a good position going into the second half.

Salveen Richter
Analyst, Goldman Sachs & Co. LLC

Q

Great. Thank you.

Operator: Our next question comes from Kennen Mackay with RBC Capital Markets. Please go ahead.

Kennen Mackay
Analyst, RBC Capital Markets LLC

Q

Hey, thanks for taking the question and congrats to the team on the really terrific quarter here. This is awesome to see after the seasonal weakness in Q1 and COVID impacts there.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.
A

Sure.

Kennen Mackay
Analyst, RBC Capital Markets LLC
Q

Maybe on the commercial side of things for Clay or for Chip. Can you maybe talk to US trends versus ex US, I mean European trends, and perhaps how that Q2 outperformance related to easing of COVID-19 restrictions, and any commentary you can give on early signs of how that's continuing into Q3? And I'd love to hear any commentary you can give around US versus European growth, especially if it relates to the geographic expansion for TUKYSA.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.
A

Sure. Kennen, thanks for the comments and the questions. Chip, can you try to talk a little bit about US trends and what you're seeing with all three brands and as it relates to COVID-19, and we'll start there and then we'll get into the US versus European.

Charles Romp
Executive Vice President-Commercial U.S., Seagen Inc.
A

[ph] No (00:32:42). Absolutely, Clay. So as far as ADCETRIS goes, I think this is an opportunity to show how the five-year data is resonating with physicians. Five years is an important and meaningful endpoint for physicians. This shows the durable aspect of the original trial that we did on ADCETRIS. And I think in addition to that we have some publications that have put out in June in The Lancet Hematology, which represent this dataset.

I think we're getting traction with that now on ADCETRIS. I think as far as PADCEV goes, I spoke earlier about the dynamic nature of the market. What we're seeing is as the market continues to change, more maintenance therapies being used and PADCEV is being used in earlier lines as a result of that. We are excited to have the new label to where we can promote for cisplatin-ineligible patients and we think we will get transaction from that.

And then with regard to TUKYSA, TUKYSA has demonstrated an overall survival benefit in HER2CLIMB trial. This really resonates with physicians. It's helped us to continue to gain share in patients with and without brain mets.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.
A

And concerning the European question of the US [indiscernible] (00:33:49) European, we're really excited with going into Europe. We have broad approval throughout all of Europe. But we only have a few countries that we have reimbursement to-date. So, most of our sales are coming from the US because [ph] there's only (00:34:07) a few countries in there. But we expect over time to get all those countries reimbursement. It just takes a little longer to get reimbursement. In Europe, there's no issue. No problem. This is all what we expected and you've seen before with other products. And so things are going well there. But it's really hard to give you a definitive answer on the ex-US trends with TUKYSA since we're pretty early in the game there.

Kennen Mackay
Analyst, RBC Capital Markets LLC

Q

Yeah. Totally get it. Maybe just a follow-up Clay or perhaps for Roger. The potential for PADCEV to move into pre-muscle invasive bladder cancer with intravesicular dosing is super interesting given the potential to transform that market and maybe even alleviate the reliance on cystectomy. And you have that linker that maybe uniquely enables you to perform that intravesicular delivery.

Can you maybe talk a little bit about how you're thinking about going forward potentially into that market there? I know it's early but I'd love to understand at least whether you're thinking about combinations either BCG or checkpoints or simply planning to evaluate that monotherapy activity before making any decisions? Thank you and congrats again.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Great question, Kennen. Really good question. Yes, we're very interested and, Roger, can you take this and see the best way to address it?

Roger D. Dansey
Chief Medical Officer, Seagen Inc.

A

Yeah. Thanks, Clay, and thanks for the great question. I think we've got strong preclinical evidence to move forward, the value proposition of giving something like PADCEV into the bladder because the main body of people who treat patients with superficial bladder cancer is urology and urologists, that's their bread and butter. So it's a really good sort of it's a good match for the disease state because we expect the systemic exposure of PADCEV to be very limited. So, safety profile could be quite promising. And as I said in my prepared remarks, NECTIN4 is expressed in non-muscle invasive bladder cancer.

And I think, Kennen, all of the things that you've raised, like, where could we go with this and what populations could we address. I think those are all at least theoretically on the table. But we have to start at square one, which is let's take the people who have failed BCG and see if we can reverse their disease state. So that is our starting point. We need to prove that PADCEV can, in fact, have impact on those late sort of non-muscle invasive bladder patients.

And once we've got that and we can determine what its profile looks like, then I think the development in non-muscle invasive bladder cancer can go as far as we like. As you know, pembrolizumab is approved. There are some other agents that are approved. The goal is to clear the disease. And so, depending on the efficacy profile, adding another agent would be a reasonable thing to do.

Operator: Our next question comes from Geoff Meacham with Bank of America. Please go ahead.

Q

Hey, guys. It's [indiscernible] (00:37:27) for Geoff. Thanks for the questions. Just a couple on the commercial launch for TV. Basically I just want to get some more color on what needs to be done and what exactly has been done to prep for that and maybe how the emerging variants kind of play into your thoughts and what that launch might look like in the US? Any learnings you can take from the [ph] – being on (00:37:51) the mid-pandemic TUKYSA launch over to TV would be helpful as well. Thanks.

Clay B. Siegall

Chairman, President & Chief Executive Officer, Seagen Inc.

A

Sure. Look, we're really excited about potentially getting a fourth product. I say potentially because it's not approved yet by FDA but we're – we submitted those file. We're working hard with them to try and get this thing on the market to help patients. The PDUFA date is I think October 10. And we're working hard towards that. There's a lot of work to do behind the scenes that nobody knows that companies do when they're trying to launch product.

Chip, can you talk a little about the commercial, what we're seeing and whether you think there's anything going on with the COVID variants? But in general, can you talk a little bit about how we're thinking about this launch?

Charles Romp

Executive Vice President-Commercial U.S., Seagen Inc.

A

Yeah. Absolutely, Clay. So the teams have been working for over a year now getting the right structure and the right roles in place associated with this. We have a fully staffed and dedicated sales force which is going to work in co-promotion with Genmab in the US. So we've got a corporate partner that we're looking forward to partnering when the product becomes approved. In addition to that, this is an important kind of unmet medical need. Metastatic cervical cancer is a devastating disease. And I think there's going to be an opportunity for improvement, potentially an outcome with a product like this.

As far as the COVID commentary goes, we – most of our field sales force is now out making face-to-face calls or most of our calls I should say are face to face. We're continuing to monitor what happens if it's an unforeseen future with regard to these variants. But what we do have is a model which a full virtual launch behind us. We can leverage that experience should things in the future change. And we will do that. But our plans right now are really to build upon the successful launches that we've had, leveraging the right parts of that infrastructure when necessary.

Q

Thank you.

Operator: Our next question comes from Michael Schmidt with Guggenheim. Please go ahead.

Michael Schmidt

Analyst, Guggenheim Securities LLC

Q

Hey, guys. Thanks for taking my questions and congrats on the quarter as well from me. I had a couple of pipeline questions. Maybe first on the list [indiscernible] (00:40:11) data that we saw that title for the upcoming ESMO presentation, Roger on the weekly dosing schedule. Just wondering what are you looking for in this data and how it will guide next development steps in breast cancer.

And then on the SEA-CD40 antibody, pancreatic cancer is obviously a huge potential market opportunity but it also has been difficult in terms of drug development historically. What do you need to see in this single arm study to really – that really gives you confidence in this combination to potentially succeed in a future Phase 3 trial? Thanks so much.

Roger D. Dansey
Chief Medical Officer, Seagen Inc.
A

Clay.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.
A

Go ahead.

[indiscernible] (00:40:53)

Roger D. Dansey
Chief Medical Officer, Seagen Inc.
A

Yeah. Thanks. Thanks for the question. So, LV is, as we have said a few times now, we are continuing to work on optimizing dosing schedule. And the first piece of data that we have – that we will be sharing will come up at ESMO. And we're still working – we're working with our partners. It's an active agent. Of that, there is no doubt, both as monotherapy and in combination. And we are trying to find the sweet spot of what is the right dose and what is the right scheduling. So that's our plan with LV and you'll see some data coming up at ESMO.

With regard to SEA-CD40, it's a great question. Just from a science – firstly, we have a well-defined SEA-CD40 agonist. We understand the dosing as a monotherapy. We have some activity as a monotherapy, so that part is clear. With regard to the scientific concept of combining a SEA-CD40 agonist together with chemotherapy and the PD-1 inhibitor that's exciting and that doesn't necessarily have to limit itself to pancreatic cancer. And that's why we're indicating that we're interested in pursuing a basket trial in tumors that may in fact be more immune manipulable and something like pancreatic cancer.

With regard to what data do we need to see, as you pointed out, pancreatic cancer has been a very difficult disease to develop drugs in. And people have been misled with small numbers and focusing on sort of early endpoints to find out in large trials that one doesn't show any improvement over standard of care. So I think we're interested without going into the details of what exactly we would like to see. We are interested in all endpoints which will include what is the response rate look like on the frontend, how much disease control can we get that will be measured by PFS. And most importantly, what is the survival curve looks like. And I think all three of those elements need to be part of our evaluation once we have the data.

Michael Schmidt
Analyst, Guggenheim Securities LLC
Q

Great. Thanks so much, Roger.

Operator: Our next question comes from Cory Kasimov with JPMorgan. Please go ahead.

Cory Kasimov
Analyst, JPMorgan Securities LLC
Q

Hey good afternoon, guys. Thanks for taking the question. I wanted to follow up on the SEA-CD40 program. And I guess, first of all, what determines whether we'll see that SEA-CD40 data later this year versus early next? Is it getting kind of that early look at those survival curves as you were just talking about, Roger? And when we do see the data, I believe like with pancreatic, the expansion cohorts go up to 75 patients per indication. But are all the pancreatic patients on the same combination or there are variety of combinations being evaluated? Thank you.

Roger D. Dansey
Chief Medical Officer, Seagen Inc.

A

Yeah. Thanks. Thanks for the question. With regard to the last piece, that we have focused the same combination. So it's the standard chemotherapy plus pembrolizumab plus our SEA-CD40. So, the triplet in that component is in fact the same. With regard to timing, you're exactly right. We need enough maturity on all the endpoints in order for us to make our best estimate as to whether this is worthwhile taking into a pivotal trial or we need to do more work.

And so, in terms of the timing of when that data will be available, it sits on the cusp of the year. And so it's very hard for us to predict will we be able to share the information in 2020 or will it go into – sorry, not 2020. I'm a year behind, 2021, or will it be in 2022. But we're monitoring very closely. And as soon as we believe we have mature enough data, we'll get it out in the public domain.

Cory Kasimov
Analyst, JPMorgan Securities LLC

Q

Okay. Thank you.

Operator: Our next question comes from Gena Wang with Barclays. Please go ahead.

Gena Wang
Analyst, Barclays Capital, Inc.

Q

Thank you for taking my questions. So, I have one question regarding the Daiichi litigation. I know the arbitration decision should be anytime now. Just wondering how will you share the decision with us and how the decision impact the next steps and also the other ongoing litigation?

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

So, thanks very much for the question on our litigation. I'd like to say first of all that over our history of 24 years, we are not a litigious company. We have only taken action that's appropriate to defend our IP, our contractual rights. So this is not something I hope you'll see from us on a routine basis. Now the arbitration hearing was conducted in June and we expect a decision sometime later this year from the arbitrator. And the things are proceeding according to the schedule that was set by the arbitrator. So right now, we think everything is proceeding in an expected standard way and nothing is unusual from what we've seen but – and we're going forward there.

We will provide updates as soon as we have them and when we're permitted to in the process. So we're not going to hold something just for ourselves as soon as we can do stuff. But I want you to know that we feel very confident in our position and we feel like it's very important to defend our legal rights and protect the innovation that we work on so hard and deliver for patients. And so that's really where it is.

And you asked a question on what's the next step. Well, it depends on what comes out of the arbitration. So it's hard really to predict the next step but we feel very good about our case. You asked also, I'm sorry, about the other litigation. There's also a patent infringement lawsuit that that's not going to court for some time next year. So that's a little different. That's not in front of an arbitrator. That's actually in a court. And so, that's ongoing as well and we feel good about that one as well.

Gena Wang
Analyst, Barclays Capital, Inc.

Q

Great. Thank you.

Operator: Our next question comes from Zhiqiang Shu with Berenberg. Please go ahead.

Zhiqiang Shu
Analyst, Berenberg Capital Markets LLC

Q

Great. Thanks very much for taking my questions and congrats again on the great quarter. I have two questions. One is related to ADCETRIS. So, obviously, it's a strong quarter [ph] after a few (00:48:00) second quarter. I was wondering this growth, is it a reflection of the pandemic is behind us or is it a result of the five-year data that compelled the physician to prescribe the drug? That's the first question on ADCETRIS.

And the second question is related to your TIGIT antibody. I think you shared some very interesting preclinical data last year at your R&D Day. I was wondering do you plan to share more data on this program. And in light of the new developments in the field, how is your thinking around this asset evolving? Thanks very much.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Sure. Let's start with the ADCETRIS question. Yes, indeed, we had a strong quarter. We're really excited. I think there might be something about [indiscernible] (00:49:02) although we continue to monitor that. And then – wow. I'm sorry.

Peggy Pinkston
Senior Vice President-Investor Relations, Seagen Inc.

A

God bless you.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

[indiscernible] (00:49:15). And then there's the five-year data that Chip referred to. So I think, Chip, you may want to comment, give more color. I think it's a little bit of both, not just one or the other. Chip, what are you thinking?

Charles Romp
Executive Vice President-Commercial U.S., Seagen Inc.

A

So, I would agree with you, but I can speak to the five-year data with regard to feedback from our physicians and customers. They have found this data to be compelling.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

All right. You asked a question about TIGIT. So TIGIT, we have a differentiated TIGIT. And Roger's development team is developing it. And I think they plan to put out data at appropriate time. Roger, do you want to provide any color on that?

Roger D. Dansey
Chief Medical Officer, Seagen Inc.

A

Yeah. Sure. And it's a great question. I think we – certainly, pre-clinically we see our TIGIT is a best-in-class. I mean we absolutely understand that this is a competitive environment. And so, we're working hard on coming up with a development plan that will have the opportunity or give our TIGIT the opportunity to showcase itself and move as quickly as possible if it's appropriate into pivotal trial.

So, what I [ph] can (00:50:33) say is that the TIGIT development team is excited by the opportunity. We're enrolling well. We're working on things like defining dosing schedule, which is what one does in a Phase 1 trial, and thinking very carefully about where we would like to expand our evaluation including obviously in combination. So, no details to disclose but lots of thought is going on into that program.

Zhiqiang Shu
Analyst, Berenberg Capital Markets LLC

Q

Great. Thanks very much.

Operator: Our next question comes from Jay Olson with Oppenheimer. Please go ahead.

Jay Olson
Analyst, Oppenheimer & Co., Inc.

Q

Oh hey, congrats on the quarter and thank you for taking the questions. Can you talk about what lines of therapy you're seeing in the US and Europe for TUKYSA? And if there's any spontaneous un-promoted use in first line? And then, can you also talk about any impact you might be seeing from Trodelvy to PADCEV in bladder cancer and any feedback that you're getting from doctors related to the efficacy and safety profiles, or how these two compare in clinical practice? Thank you.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Sure. On the TUKYSA front, Chip, can you address like where it's used in lines and then I'll come back to the second question?

Charles Romp
Executive Vice President-Commercial U.S., Seagen Inc.

A

Yeah. Sure. What I can tell you is that we are seeing continued utilization and growth in share across all lines of therapy in the label second line and beyond, in both patients with and without brain metastasis. It's also important that TUKYSA is now the most utilized product in second line and later for HER2-positive metastatic breast cancer patients with brain mets. So it's broad – it's broad growth.

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

Sure. As far as your second question, Trodelvy is not approved in bladder cancer at this point. So, you're asking sort of ahead of time what it is, and we have some fantastic data and survival data. We're not expecting much impact from Trodelvy. I think that largely would be used after PADCEV. I think PADCEV has such premier data. We're focused on also frontline and getting that. But even in the setting where we are with survival data, you'd be hard pressed for a doc to use that ahead of another product. But I'm glad the Trodelvy existed. I hope they get approval and could be there for patients that need it, PADCEV doesn't – it doesn't cure every patient and other therapies are needed. So it's fine.

Jay Olson
Analyst, Oppenheimer & Co., Inc.

Q

Great. Thanks again for taking the question.

Operator: [Operator Instructions] Our next question comes from Andy Hsieh with William Blair. Please go ahead.

Andy T. Hsieh
Analyst, William Blair & Co. LLC

Q

Great. Yeah. Thanks for taking my question. I'm really glad to see the commercial inflection across the three key products this quarter. Clay, in your prepared remarks you mentioned this phrase which I found very interesting. You said ADCs and immuno-oncology. So, I'm just curious if you're hinting that we could expect modalities beyond the sugar-engineered antibodies or traditional kind of antibody linker payload construct of ADCs in your development pipeline?

Clay B. Siegall
Chairman, President & Chief Executive Officer, Seagen Inc.

A

So first of all, our SEA products, we refer to as our immuno-oncology products. We also do a lot of immuno-oncology work in combination with our ADCs as you know from all the work we've done with KEYTRUDA, OPDIVO and many others actually. It does – it's not limited just to those two. So, we do take into account immuno-oncology. We're always looking at other ways to append things to antibodies. And you can be guaranteed that in our lab we are looking at some very interesting approaches, things that we won't be talking about on a conference call now but can come out in not too distant future. So we have some exciting things that are in the horizon. So, buckle up and stay tuned.

Andy T. Hsieh
Analyst, William Blair & Co. LLC

Q

Great. Thank you.

Operator: This concludes our question-and-answer session. I would like to turn the conference back over to management for any closing remarks.

Peggy Pinkston
Senior Vice President-Investor Relations, Seagen Inc.

Okay. Thank you, operator, and thanks everybody so much for joining us this afternoon. Have a good evening.

Operator: The conference is now concluded. Thank you for attending today's presentation. You may now disconnect.