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EDITED TRANSCRIPT

DCPH.OQ - Q4 2019 Deciphera Pharmaceuticals Inc Earnings Call

EVENT DATE/TIME: MARCH 09, 2020 / 8:30PM GMT

CORPORATE PARTICIPANTS

Daniel C. Martin *Deciphera Pharmaceuticals, Inc. - Chief Commercial Officer*

Jennifer Robinson *Deciphera Pharmaceuticals, Inc. - VP of IR*

Matthew L. Sherman *Deciphera Pharmaceuticals, Inc. - Executive VP & Chief Medical Officer*

Steven L. Hoerter *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Thomas Patrick Kelly *Deciphera Pharmaceuticals, Inc. - Executive VP, CFO & Treasurer*

CONFERENCE CALL PARTICIPANTS

Andrew Scott Berens *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

Arlinda Anna Lee *Canaccord Genuity Corp., Research Division - Analyst*

Christopher Joseph Raymond *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Christopher N. Marai *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Eun Kyung Yang *Jefferies LLC, Research Division - MD & Senior Equity Research Analyst*

Jessica Macomber Fye *JP Morgan Chase & Co, Research Division - Analyst*

Michael Werner Schmidt *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

Peter Richard Lawson *Barclays Bank PLC, Research Division - Research Analyst*

Reni John Benjamin *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Robyn Kay Shelton Karnauskas *SunTrust Robinson Humphrey, Inc., Research Division - Research Analyst*

PRESENTATION

Operator

Good day, everyone, and welcome to the Deciphera Pharmaceuticals Fourth Quarter and Full Year 2019 Financial Results Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Jen Robinson, Vice President, Investor Relations. Jen?

Jennifer Robinson - *Deciphera Pharmaceuticals, Inc. - VP of IR*

Thank you, Michelle. Welcome, and thank you for joining us today to discuss Deciphera's fourth quarter and full year 2019 financial results. I'm Jen Robinson, Vice President, Investor Relations at Deciphera. With me this afternoon to discuss the financial results and provide a general corporate update are Steve Hoerter, President and Chief Executive Officer; Matt Sherman, Chief Medical Officer; Dan Martin, Chief Commercial Officer; and Tucker Kelly, Chief Financial Officer.

Before we begin, I would like to remind you that any statements we make on this call that are not historical facts are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements made during this conference call include the status of and our expected time lines for are preclinical and clinical studies, review of our NDA submission and potential commercial launch. Forward-looking statements made on this call involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we cannot assure you that our expectations will be achieved. Such risks and uncertainties include the execution

of clinical trials, the timing of study data, the actions of regulatory agencies and those set forth in our most recent annual report on Form 10-K as well as our other SEC filings. We assume no obligation to update or revise any forward-looking statements.

Following this call, a replay will be available on the company's website, www.deciphera.com.

With that, I will now turn the call over to Steve Hoerter, President and Chief Executive Officer of Deciphera. Steve?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Thank you, Jen. Good afternoon, everyone, and thank you for joining us on this call to discuss our fourth quarter and full year 2019 financial results as well as clinical and business updates.

2019 was a year of exceptional execution by the team here at Deciphera. Most significantly, we reported positive results from INVICTUS, our pivotal Phase III study with ripretinib in patients with advanced GIST whose previous therapies include at least imatinib, sunitinib and regorafenib. These results form to the basis of our first NDA submission, which was recently accepted by the FDA with priority review and assigned a PDUFA target action date of August 13 this year. The ripretinib NDA is being reviewed under the FDA's Real-Time Oncology Review, or RTOR pilot program. The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible.

In addition, with the ripretinib NDA, we are also participating in the FDA's Project Orbis Initiative. Under this program, we have received priority review for a new drug submission with Health Canada and a market authorization application with the Therapeutic Goods Administration in Australia for ripretinib in advanced GIST. We plan to submit a marketing authorization application to the European Medicines Agency in the second half of this year.

We're very proud of our execution on the ripretinib program in GIST where we took the compound from IND filing to NDA submission in just over 4 years. The team designed and executed a clinical and regulatory strategy that allowed us to move rapidly to multiple registration studies, generating compelling data sets that have resulted in our inclusion in a number of regulatory designations and programs, from breakthrough therapy designation to the Real-Time Oncology Review pilot program to Project Orbis. And we believe our team can direct these capabilities to the rest of our clinical and preclinical pipeline to continue to generate value beyond ripretinib.

Importantly, in 2019, we also made significant progress with our 2 other wholly-owned clinical stage product candidates, DCC-3014 and rebastinib, and we introduced our newest preclinical product candidate, DCC-3116. We remain focused on leveraging our proprietary research platform to build a deep pipeline of novel kinase switch control inhibitors to address unmet medical needs for patients with cancer.

Building off the tremendous work done in 2019, we look forward to a transformational year for Deciphera this year. We are well positioned for success as we seek to transition from an R&D organization to a commercial stage company based on the potential launch of our first approved products in the U.S. later this year. We believe 2020 will be an exciting year for our pipeline with significant milestones expected across our clinical and preclinical programs. As Matt will discuss in more detail, we expect to have important clinical updates with data on additional tenosynovial giant cell tumor patients with DCC-3014, data updates for our rebastinib development program and IND filing for DCC-3116, a potential first-in-class ULK inhibitor targeting mutant RAS cancers.

To review these programs in greater detail, I will now turn the call over to Matt Sherman, our Chief Medical Officer. Matt?

Matthew L. Sherman - *Deciphera Pharmaceuticals, Inc. - Executive VP & Chief Medical Officer*

Thank you, Steve. As Steve mentioned, we have a robust pipeline of novel kinase switch control inhibitors, all derived from our proprietary discovery research platform and all designed to address unmet medical needs and difficult-to-treat cancers.

First, I would like to review our progress with ripretinib, our investigational broad-spectrum KIT and PDGFR-alpha inhibitor. As we work towards the potential approval and launch for ripretinib in patients with advanced GIST whose previous therapies include at least imatinib, sunitinib and regorafenib, we continue to explore other possible uses of ripretinib, including in second-line GIST patients. INTRIGUE is our ongoing Phase III study of ripretinib in patients with second-line GIST compared to the current standard of care sunitinib. Both site activation, the end patient enrollment continue to go very well and we currently have 111 sites activated in 20 countries.

As we recently disclosed, due to an early trend of a higher-than-expected number of censored patients, we are planning to increase the total number of patients in this study to help achieve the prespecified number of events in a timely fashion. The anticipated increase does not change the total number of required events, the statistical powering of the study and our current guidance of achieving full enrollment in the second half of this year. We remain confident in the potential for ripretinib to become an important and effective therapy for patients with GIST after treatment with imatinib. The data we presented last fall from the second-line GIST cohort in our ongoing Phase I study continue to show highly encouraging clinical activity based on the median progression-free survival of 46 weeks or 10.7 months and a 19% confirmed objective response rate. As you will recall, published data from the centrally read pivotal study for sunitinib show the median PFS of 24.1 weeks or 5.6 months and a confirmed objective response rate of 6.8%. Outside of GIST, we expect to present data from at least one of the expansion cohorts of our ongoing Phase I study of ripretinib in the second half of 2020.

Beyond ripretinib, we are focused on rapidly developing DCC-3014, our highly selective inhibitor of CSF1R for patients with tenosynovial giant cell tumor, or TGCT. TGCT is a rare disease with an estimated annual incidence of the localized form of 13,000 and approximately 1,300 for the diffuse type of the disease in the U.S. Annual incidence rates may not provide a full picture since these patients typically present relatively early in adulthood and can live with the disease for a long time, indicating that the prevalent population may be substantially greater. The only approved systemic therapy for patients with TGCT is pexidartinib, a small molecule inhibitor of multiple kinases including CSF1R, which was approved in August of last year and is subject to our REMS program due to hepatotoxicity, which is believed to be off-target. We believe that DCC-3014 has the potential to fulfill the unmet medical need for an effective treatment with a more favorable safety profile for patients with TGCT.

Last year, we presented preliminary clinical proof-of-concept data in the initial three patients with diffuse-type TGCT at the Connective Tissue Oncology Society Annual Meeting. Encouragingly, all three patients showed preliminary antitumor activity as of the first scans. At their first tumor reassessment at cycle 3, day 1, tumor reductions from baseline were 48%, 25% and 24%, respectively. At the data cutoff date of September 10, 2019, one patient had a confirmed partial response, which was ongoing for 9 months with a tumor reduction from baseline of 84% as of cycle 10, day 1. Symptomatic improvement in mobility and reduced pain as reported by the investigator were also observed. DCC-3014 was generally well tolerated with no grade 3 or higher treatment-emergent adverse events observed in diffuse-type TGCT patients.

In 2020, we expect to select a Phase II dose and open a Phase II expansion portion of the study in TGCT patients. We are continuing to enroll TGCT patients in the ongoing dose escalation portion of the Phase I study and look forward to presenting additional data on these patients in the second half of this year.

Next in the pipeline is rebastinib, our potent and selective TIE2 inhibitor, which we're exploring in 2 clinical studies in combination with chemotherapy, 1 with paclitaxel and 1 with carboplatinum. In January, we announced that we have selected a Phase II dose of 100 milligrams twice daily of rebastinib in combination with carboplatinum and then activated part II of the study, where we are evaluating the combination in patients with breast cancer, ovarian cancer and mesothelioma. Last year, we presented preliminary data from the Phase Ib/II study of rebastinib in combination with paclitaxel. We saw encouraging preliminary activity with objective responses in patients who had been -- previously received treatment with paclitaxel across multiple solid tumor types. We are actively enrolling the expansion cohort part 2 of the study in patients with breast, ovarian and endometrial cancer. In the second half of this year, we expect to report data from both of the paclitaxel and carboplatinum studies.

Finally, our discovery research engine continues to generate new product candidates for novel targets, and we've disclosed last year that the next target we'll be pursuing will be ULK kinase for patients with mutant RAS cancers. The ULK kinase is the initiating factor in the autophagy pathway which is a cellular energy recycling pathway that has been shown to be upregulated in mutant RAS cancers and mediate resistance to inhibitors of a RAF kinase signaling pathway. DCC-3116 and is our potential first-in-class ULK kinase inhibitor that we intend to develop for the treatment of mutant RAS cancer, and we're working toward filing the IND for 3116 later this year.

Deciphera as a company founded on deep insights into kinase biology and focused on developing important new medicines for the treatment of cancer. We've demonstrated the ability to discover and develop novel drug candidates based on our proprietary research engine centered on kinase switch control inhibition, and I look forward to updating you on the progress with our clinical and preclinical programs throughout the year.

I will now turn the call over to Dan Martin, our Chief Commercial Officer, to discuss our commercial preparations for potential launch of ripretinib in the U.S. Dan?

Daniel C. Martin - *Deciphera Pharmaceuticals, Inc. - Chief Commercial Officer*

Thank you, Matt. We are tremendously excited about the potential for ripretinib to address critical unmet needs for patients battling advanced GIST. As many of you know, GIST is a rare cancer with significant unmet need for patients who develop resistance to first-line of imatinib. Current second- and third-line treatments confirm modest progression-free survival benefit and no overall survival benefit compared to placebo. Further, there are no currently approved treatment options for the vast majority of patients who progress on third-line therapy, except for the 5% to 6% who harbor a rare PDGFR-alpha exon 18 mutation.

Determining the precise number of patients who receive treatment for GIST after progressing on imatinib is challenging given that existing therapies are more widely used in non-GIST indications and GIST epidemiological studies have typically focused on patients with newly diagnosed GIST as opposed to those with metastatic disease. Analysis of U.S. claims data has helped to refine our understanding of the patient journey in advanced GIST. Based on these analysis, we estimate that in the U.S., there are approximately 2,000 incident patients eligible for second-line treatment. Second line is the patient population that we had always view as the primary long-term opportunity for ripretinib in the post-imatinib setting and is the focus of the Phase III INTRIGUE study. Beyond second line, we estimate a reduction in the incident treatment eligible population of approximately 20% to 30% in each subsequent line of therapy due to participation in clinical trials, treatment discontinuation or death.

In addition to these claims analysis, we've conducted extensive market research to better understand what GIST-treating physicians are looking for in a new therapy and to what extent they think ripretinib could address those needs. Irrespective of line of therapy, GIST treaters have consistently ranked overall and progression-free survival as well as safety and tolerability as their most valued markers of clinical benefit. And after reviewing blinded product profiles for ripretinib as well as other therapeutic options, GIST-treating physicians conveyed high interest in the ripretinib profile due to the efficacy and safety data from INVICTUS as well as the fact that INVICTUS was a Phase III placebo-controlled study, which they consider to be the gold standard, further enhancing their confidence in the data. Our preparations are on track for our first commercial launch, pending FDA approval of ripretinib. Under Matt's leadership, our medical affairs team is in place and our MSLs are engaging with sarcoma experts in scientific exchange.

On the commercial side, our marketing team has launched a disease education program to raise awareness of the unmet need in GIST and has defined our go-to-market strategies for launch. (inaudible) is focused on ensuring optimal patient access on approval of ripretinib, including building out our patient assistance program. As you know, these programs are important for any oncology drug, especially an oral oncology drug, often as a result of the patient affordability challenges that can arise due to the Medicare Part D benefit design.

Regarding the sales organization, we've identified who the top treaters of GIST are and where they practice. We've defined our sales force size and structure, we've built an incredibly seasoned sales leadership team and we've launched our recruiting of sales representatives. We've been extremely pleased with the deep and talented applicant pool, which includes candidates from virtually every leading oncology company in the industry and is composed of individuals with extensive oral oncology launch experience. We're tremendously excited about the commercial team and capabilities we're building and very grateful to have the opportunity, pending approval, to help bring ripretinib to patients this year.

I will now turn the call over to Tucker Kelly, our Chief Financial Officer, to review the financial results.

Thomas Patrick Kelly - *Deciphera Pharmaceuticals, Inc. - Executive VP, CFO & Treasurer*

Thanks, Dan. Let me take a minute to discuss a few highlights from our fourth quarter and full year 2019 financial results. We remain well capitalized to execute on the compelling opportunity we have with the potential launch of ripretinib and a strong clinical and research pipeline. We ended 2019 with cash, cash equivalents and marketable securities of approximately $580 million. And in February, we completed a follow-on public offering that raised approximately $188 million in net proceeds. Based on our current plans, we expect that our cash will be sufficient to fund operations and CapEx into the second half of 2022.

In the fourth quarter of 2019, our total operating expenses increased to approximately $70 million from $58 million in the prior quarter based on increased investments to support our potential commercial launch of ripretinib as well as increased clinical development activities across the pipeline. Research and development expenses were approximately $47 million and selling, general and administrative expenses were approximately $24 million for the fourth quarter of 2019. We expect our expenses to grow over the coming quarters as we build our commercial organization and expand our clinical development activities.

And with that, I'll now turn the call back over to Steve.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Thank you, Tucker. I'd like to take a moment to thank the entire team here at Deciphera for their dedication to our mission of developing important new medicines for the treatment of cancer. We're very proud of the progress we made in 2019 and are excited about the prospects for 2020 as we look to transition into a commercial stage company and aggressively develop our exciting clinical and research pipeline.

With that, Michelle, I'd like to open the call for questions. Operator, we'd like to go ahead and open the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from the line of Jessica Fye from JPMorgan.

Jessica Macomber Fye - *JP Morgan Chase & Co, Research Division - Analyst*

With the enrollment completion for INTRIGUE expected in the back half of this year, what's your latest estimate on when we'll see top line data for that trial?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Jess, it's Steve. Thanks for the question. So we have not changed our guidance in terms of time to completing enrollment, which is in the second half of this year. And when we reach full enrollment, our intent would then be to disclose what we anticipate as being the time for a potential readout of the study.

Jessica Macomber Fye - *JP Morgan Chase & Co, Research Division - Analyst*

Okay. Maybe I can get a second one. What will you be watching for when the avapritinib VOYAGER study reads out? Is it hazard ratio of safety profile? Absolute months of improvement over control? What are you most focused on in that data set?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Good question, Jess. I mean, we're interested really in the totality of the data. We -- based on our understanding, the company intends on reporting top line data. So depending on what level of detail they get into, we'll be interested in the total view of the data, the risk-benefit profile and the like and how that compares with the current label for avapritinib. So we look forward to seeing the data here in the coming quarter.

Operator

(Operator Instructions) And your next question comes from the line of Chris Raymond from Piper Sandler.

Christopher Joseph Raymond - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Just a question, I guess, on INTRIGUE. I know you had a disclosure about the censoring rate being a little higher than expected in the upside, and you talked about this in your prepared comments. But I guess, I'm wondering if you can give a little bit more sort of color or indication of your communication cadence going forward. So when you actually do decide to upsize it, will you announce that? And should we expect to see that perhaps on clintrials.gov (sic) [clinicaltrials.gov]? Or would you sort of announce that in some other fashion, if you will? And I'm just kind of curious as to how you intend to communicate any sort of changes that actually get enacted going forward.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Chris. Thanks for the question. I mean, first, let me just say that our confidence in INTRIGUE remains unchanged. So when we make the final decision on number of patients that we'll be adding to the study, we'll make a disclosure on that, probably both on clinicaltrials.gov as well as updating our investor deck just to make sure that the information is out there. And then as I mentioned earlier, once we reach full enrollment, our guidance remains the same for the second half. I will then provide at that time some additional guidance on when we expect the study to report out.

Christopher Joseph Raymond - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Great. Okay. And maybe -- I'm not sure if you're going to want to answer this, but just talking about your launch preparedness. You got a couple of different scenarios, I think, that you'll be launching ripretinib into. You either have a competitor with just a label for PDGFR-alpha exon 18 patients or one with a broader fourth-line label. I guess the question is, how different -- I would imagine you're planning for both scenarios, but how different are those plans?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Chris. Good question. Let me make a few comments on that, then I'll flip it over to Dan to add some more color. As we think about the profile of ripretinib, we view the data that we have to support the product, the basis for the NDA as supporting the drugs being best-in-class in this setting to treat this disease. It's not common that you see a drug in a pivotal study -- a randomized study generate a hazard ratio of 0.15. In our case, the hazard ratio for PFS is 0.15 or the overall survival for that matter of 0.36. So this is -- I think, signals a very compelling profile in terms of efficacy. And then we know from the tolerability profile of the drug, that the drug is generally well tolerated and INVICTUS was very consistent with the broad Phase I set of data that we've already published. So we have a high degree of confidence in terms of how physicians will view those data. Dan, I think, mentioned in his prepared remarks some of the research that we've done with physicians, with potential prescribers. And, Dan, maybe you want to add some additional color?

Daniel C. Martin - *Deciphera Pharmaceuticals, Inc. - Chief Commercial Officer*

Yes. Thanks, Steve. Chris, good question. So of course, it's great to have more options for patients. But when we think about how the treatment paradigm may shape up in the days to come, we really focus on what our market research has helped educate us about, which is what GIST-treating physicians say they're really looking for. And I mentioned in my prepared remarks, but it's these endpoints, progression-free survival and really unique in the space, overall survival relative to placebo. As Steve mentioned, in addition, a clean safety and tolerability profile. That's what they tell us they're looking for. And when we did the research to show blinded profiles across ripretinib as well as other treatment options in the space, what came back really consistently was their interest level in a product like ripretinib. In fact, in 1 study we did, about 97% of the respondents said they'd be interested in a product with ripretinib's profile for treatment of patients with GIST. So we really are focused on how we can best get ripretinib to patients as quickly as possible because we think it can have a real positive impact as they battle their disease.

Operator

(Operator Instructions) And your next question comes from the line of Eun Yang from Jefferies.

Eun Kyung Yang - *Jefferies LLC, Research Division - MD & Senior Equity Research Analyst*

So for second-line GIST, so when you look at Phase I study, you have shown more than 20 weeks of a PFS improvement compared to what sunitinib has shown in Phase III. But in the clinic, based on your conversation with oncologists, what would be the kind of a minimum PFS benefit that they would consider clinically meaningful compared to sunitinib?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Eun, it's Steve. Thanks for the question. So you're right. In that second-line cohort in the Phase I, what those data have shown based on our recent update from the end of last year is a 10.7-month progression-free survival for that cohort. Of course, that's a nonrandomized setting. But if you do the cost setting comparison that you just mentioned and look at the Sutent label, that does represent a really substantial difference relative to what Sutent offers. And I think Matt commented on this in his prepared remarks.

So in the context of INTRIGUE, we think that a clinically meaningful difference in progression-free survival would be in the range of 2 to 3 months. And we think, certainly, based on the data that we've generated in the Phase I study so far, we have a lot of optimism in terms of how we view the potential for ripretinib to offer benefits to patients in that setting.

Eun Kyung Yang - *Jefferies LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. And then one question on 3014 CSF1R inhibitor. So when you move into registration trial, do you think you'd the need to compare to pexidartinib in order to recruit patients faster?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks Eun for the question. So it's not clear to us yet whether -- what the design for that pivotal study would be. And as we've said, we'll provide some additional guidance on that toward the end of this year as we provide a data update from the Phase I. I think there are potentially a variety of different options. One could be a placebo-controlled study and another could be a head-to-head study. But we, of course, need to generate some more data, have some discussions with the regulators and then determine what our pivotal study strategy is going to be. And as I said, we'll have some additional information on that, we think, at the end of this year.

Operator

And your next question comes from the line of Michael Schmidt from Guggenheim.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

I just wanted to follow-up on the INTRIGUE trial disclosure. We've gotten a fair amount of questions on, sort of -- maybe you could help us understand, again, sort of what's been driving the higher-than-expected rate of discontinuations, I suppose, and what your confidence level is that there is no imbalance in those dropouts in either of the arms.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Michael, it's Steve. Thanks for the question. As I noted earlier, our confidence in INTRIGUE is unchanged. I noted that our guidance remains the same in terms of enrollment. And I think it's also important to remember that there's been no change in the number of events required to reaching the study or the powering of the study. So this is really about enabling a readout in a timely fashion for the study. In terms of censoring seen in the study, this is a phenomenon in any event-driven study in oncology where you see censoring. So it's not something that's surprising to us that we see this dynamic, and we have confidence that by adding a number of subjects to the study that we can ensure a timely readout for INTRIGUE. So we look forward to, of course, generating the data. And as I noted, when we reach full enrollment, we'll then provide some additional disclosure on potential time to read out for the study.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

Okay. Great. And then regarding the update from the Phase I study of ripretinib in other cancer types that you've guided to in the second half of this year. I guess, should we think about this predominantly as an update from the Systemic Mastocytosis arm or potentially from some of the other cohorts that you've been enrolling? And I guess, what type of data would you like to see there in order to justify potential further next steps and additional trials in any of these indications?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Michael. So as you noted, we have a number of expansion cohorts in the ongoing Phase I, including a cohort in mastocytosis. We have a cohort in KIT-driven melanoma. We have a GBM cohort. So a number of cohorts where we're investigating the potential for ripretinib to play a role in other tumor types. So as you noted, our guidance is to provide an update from at least one of those cohorts within the year. And our hope is that mastocytosis could be one of those cohorts and potentially a lot of further data as well. And this is, of course, dependent upon getting patients enrolled and generating data.

So it's really premature for me to comment on what the bar would be in any of these cohorts, such warrant further study. I think we need to see the data mature, understand the data, of course, present the data, and then at that time, I think we'd be in a position to offer some additional color on where we might go from there.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

Understood. And then you did provide some updated information on the identified or treated patient population in GIST in the U.S. How should we think about the potential market opportunity ex U.S. and maybe more specifically in Europe for GIST?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Let me -- good question, Michael. Let me start off with an answer to that, and then I'll go ask Dan to offer some additional color if he has any. So in this disease, we wouldn't expect that the incident population of GIST is any different in the U.S. versus any other geography around the world. So I think the best way to generate an estimate for GIST in Europe is really to look at it on a population basis relative to the U.S. And so based on that, we would expect to see a not only larger number of patients in Europe relative to the U.S. just based on population differences. But Dan, I don't know if you have any additional color you'd offer on that?

Daniel C. Martin - *Deciphera Pharmaceuticals, Inc. - Chief Commercial Officer*

Yes. Sure. Just a little bit. So when you extend the incident rate that Steve was mentioning to our European and Japanese population, whereas in the U.S., we think there's probably 4,000 to 6,000 incident patients with GIST, newly diagnosed GIST as per the American Cancer Society, we think in Europe and Japan together, that would bring you to approximately 8,000 new patients -- incident new patients in those parts of the world.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

And when you think about second through fourth line, would that be a similar, I guess, haircut, so to speak, to get to those numbers ex U.S.?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Well we haven't done the primary research in those territories yet, Michael, to provide further guidance. But we would assume that it would be substantially similar in terms of what you'd see in the treatment paradigm as patients receive clinical (inaudible) of therapy and then progress and need to receive treatment with the next one.

Operator

And your next question comes from the line of Robyn Karnauskas from SunTrust.

Robyn Kay Shelton Karnauskas - *SunTrust Robinson Humphrey, Inc., Research Division - Research Analyst*

Just a couple of follow-ups. Maybe first, on the NCCN guidelines. Avapritinib got on there pretty quickly. Maybe give your thoughts on any hurdles you think about getting on the guidelines should your -- once you're approved? And then second, how is your early access program going? And then third, I know you feel like you're not surprised that these -- that you may have to upsize the trial because of the censoring that you're seeing. But why weren't those assumptions included in your original protocol? Can you just help us understand, like, maybe some differences between your original assumptions and maybe what you're seeing in the blinded data.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Robyn, it's Steve. Thanks for the tripartite question. Let me try and knock these off one by one. So in terms of the NCCN guidelines, we think it's very encouraging that the NCCN chose to act so quickly to update the treatment guidelines in the compendium post the approval of avapritinib. And I think that is reflective in part of the unmet need, generally speaking in GIST and how physicians are excited about the potential for new treatment options for their patients given that unmet need. So our expectation would be that the panel moves quickly upon a potential approval of ripretinib in the U.S., to evaluate our data and then make a determination of how to reflect that in the NCCN guidelines.

So I think there's -- the second part of your question, I think, was related to the Expanded Access Program that we've launched. And maybe I can provide just a brief update on the EAP. So we're very pleased with the pace of sites opening and patients enrolling on the EAP. I can offer that we've seen patients enroll in a variety of different jurisdictions in the U.S., in Europe and in a variety of different other geographies beyond the U.S. and

Europe. And again, our view of the number of subjects that we now have on the EAP is that this is, again, just reflective of the general unmet medical need in this population. So we're pleased to see that patients have the ability to access ripretinib in that context.

So then I think the third part, Robyn, had to do with INTRIGUE, and I think your question was why is it that we find ourselves adding subjects to the study. And I think there's kind of an easy way to think about this. Generally, with event-driven studies in oncology, as I noted, you have this phenomenon where patients are censored. So when you set out, when you initiate a study, I think there are certain set of assumptions in terms of how many subjects might be censored and therefore, what is your overall [NB] in the population. And it's probably not entirely common that companies come to this realization in the course of a study's conduct early enough to be able to actually add subjects to the study. So oftentimes, what you'll see companies do is simply announce that there's a delay in the report out of a study as they're waiting for the number of events to accumulate.

So in our case, we made a certain assumption when the study -- when the protocol was written. It turns out, based on some early indications from INTRIGUE that, that set of assumptions may have been a little bit off of the mark. And so that's the reason we've taken this approach to just ensure we get to the requisite number of events in a timely fashion.

Operator

And your next question comes from the line of Ren Benjamin from JMP Securities.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Could you talk a little bit about how many patients might be added to the INTRIGUE study? Are we talking about a handful, tens, hundreds? And maybe what is the gating factor that remains before you implement such a change? And kind of how long does it take once you've decided on the change to actually get the trial sites to implement this?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Brent, thanks for the question. So we haven't yet disclosed what that number is. We're still working through the amendment. And there's -- as you probably know, there's a process one has to go through to get the amendment written, to get it reviewed appropriately, get it out to sites. And so as soon as we're on the back end of that process, we'll then update our disclosures, as I mentioned earlier.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Okay. And then one of the things that we noticed, at least with the Orbis Initiative is, I guess, a couple of additional countries have come on board. If we read it right, Singapore and potentially Switzerland. Is -- does the application with ripretinib kind of automatically get filed to those countries? Or is that something that you need to apply for separately?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Ren, I think that's right. So the FDA's intent, at least based on what we've seen based on interviews that have been given by Dr. Pazdur, FDA's intent, I think, is to try to broaden this program over time. I think I maybe wrote the same article that you did about Singapore and Switzerland potentially being included in future. But in our case, the 2 countries that are within scope are the ones that I mentioned, so Canada and Australia, where we've now received priority review. And so we don't have any expectation that the number of countries is going to increase from those two. So you can expect it would be just Canada and Australia that would be part of this project Orbis for the ripretinib application.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Got it. And then just one final question is, have you already had discussions with the EMA as you were preparing for this filing in the second half? Or is -- are you waiting on anything in particular before having the discussions?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. We're working towards, as I noted, a filing in the second half of the year. And so we haven't talked about specific interactions with specific regulators. We're just working toward getting that filing in, and that will be the next disclosure that you see from us related to the MAA is the disclosure related to the filing in the second half.

Operator

And your next question comes from the line of Peter Lawson from Barclays.

Peter Richard Lawson - *Barclays Bank PLC, Research Division - Research Analyst*

Steve, just wondering if you could -- do you have a good handle -- as we think about INTRIGUE, do you have a good handle on the censoring events? Or is that still kind of playing out? Is that still evolving?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Peter, for the question. I think we have a very good sense of what we see in the early data, and that was the reason that we took the decision that we did to add a number of patients to the study. But we don't have any expectation that, that trend is going to change over time. It's still early, so I suppose that, with the addition of more subjects, that we might see fewer censoring events. Kind of difficult to predict, but it's not anything that's concerning to us. We have a pretty straightforward remedy for those, and that is to add a number of subjects to the study. So we're working on that.

Peter Richard Lawson - *Barclays Bank PLC, Research Division - Research Analyst*

Would there be any changes to the enrollment criteria for those new subjects? Or that stays the same, locked in?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

No. I'd say it's absolutely the same. Yes. So there aren't any other changes to the study. This is just about enrolling subjects to get to the requisite number of events in a timely fashion. No other changes to the study.

Peter Richard Lawson - *Barclays Bank PLC, Research Division - Research Analyst*

And just on -- how should we think about pricing, discounting, any expectations around net? Just metrics that we should be thinking about?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. So let me make a couple of remarks, and then I'll turn it over to Dan just to comment on that. So as we look at the pricing landscape, of course, we are out talking to payers right now, sharing with them the product profile for ripretinib, trying to get an understanding of how they view value.

Certainly, we're doing the same with physicians and sharing blinded product profile with them and understanding how they view the data. And that will eventually guide a pricing decision for us. And, Dan, I don't know if you want to offer any more color there?

Daniel C. Martin - *Deciphera Pharmaceuticals, Inc. - Chief Commercial Officer*

Sure. Yes. A couple of points. Peter, thank you for the question. So from a research perspective, we have, of course, been engaged with payers to understand their view of GIST and the unmet need. And we've been really pleased to see in the research that payers actually really do appreciate the degree of unmet need in GIST. You don't always see that in this kind of research. And so we are really encouraged to see that. They also, when responding to these blinded product profiles, really seem to have a positive view of the ripretinib profile and what that could mean for patients. So we're confident that payers ultimately will appreciate the value that ripretinib can bring to their patients. And beyond that, it's a little premature for us to comment on price. As it relates -- you mentioned discounts. While we wouldn't comment on gross-to-net per se, one thing that we have tried to underscore is the importance of patient assistance programs, these free drug programs in the space, any oral oncology drug. These programs are important, just given the patient affordability challenges that can arise as a result of the Medicare Part D benefit design. So that's something that you want to keep in mind as you're thinking about your models.

Operator

And your next question comes from the line of Christopher Marai from Nomura.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

First, just with respect to ripretinib and future potential studies. Maybe elaborate on when you might start or if you're thinking of starting earlier line setting trials. In particular, some physician checks suggested combinations within that might be interesting to try. I was curious if you've initiated or when you might initiate some trials in that regard. And then I have a follow-up.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Sure, Chris. Thanks for the question. It's Steve, so I'll take that one. So yes, we're certainly thinking through other places in just, for example, where we think ripretinib might be able to offer benefit to patients. And I think you named some of the possibilities. Certainly, there's a lot of investigator enthusiasm for the INVICTUS data and for the potential for ripretinib in this disease, and that could include combinations with other therapies. Certainly, the tolerability profile for ripretinib based on the INVICTUS data suggests that the drug might be a good combination partner. And I think there are other settings in the disease where we could generate meaningful data and potentially demonstrate that the drug can offer benefit to patients. So we intend to actively pursue those now that we have the INVICTUS data behind us and determine next steps in GIST specifically.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

When might we hear from you on the initiation of those studies? And when might they initiate?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

So we haven't -- I don't have specific guidance for you, Chris, on that. It's a little early for us to talk about planning for any additional studies. So at the right time, we'll certainly provide an update on our thinking there and on potential study initiation.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Will it be contingent upon the second-line data in your mind? Or do -- in terms of setting up those studies and starting them?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. I think from our point of view, based on the strength of the INVICTUS data, it's very clear that we have a very active drug in this disease. So I wouldn't see any need for us to wait for any additional clinical data to accrue to guide us to look at other strategies with ripretinib in GIST. I mean, as you know, in addition to INVICTUS, of course, we have the 178 patient experience from the Phase I. So we generated a lot of data with ripretinib in GIST, and I think we have the basis of information that we need to consider additional clinical steps in the disease.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Okay. And if we could just shift then to 3014 for a second. You guided to providing some Phase II dose selection updates and some data updates in the second half of the year. How many patients' worth of data might we see there? And then secondarily, it occurred to me that this trial has -- it looks like been running since 2017, early 2017. So I was just wondering what's been the delay in accruing patient data here, correct me if I'm wrong, about the study start time? But anyway, details on both those would be great.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Chris. Thanks for the question. So we've reported for the first time the Phase I at the triple meeting. And this was in a solid tumor patient population. So as you might recall, it wasn't until, I think, early last year that the company disclosed a move into tenosynovial giant cell tumor. So the way to think about it is we've made that declaration of that disclosure in early last year, then started to get sites open that had these patients to enroll. And that was -- the result then was the data we presented in the initial 3 patients at the Connective Tissue Oncology Society Conference in Tokyo in November, the one that Matt referenced in his prepared remarks. So that's been kind of the history on the study. So we're actively opening additional sites, frankly. We have, over time, opened additional sites focusing on tenosynovial giant cell tumor, actively enrolling subjects with TGCT in the Phase I. And while I can't provide guidance now specifically to a number of patients that we might report on in the second half, we expect to have a number of additional patients enrolled on the study from the additional sites that we've opened. So we think we'll have a good number of patients. And again, as Matt mentioned in his prepared remarks, the intent here is to get to a recommended Phase II dose, open an expansion cohort and then based on the data, make a determination about next clinical steps for the drug in TGCT. This is, again, a disease that we know is driven by genetic translocation that results in overproduction of the ligand for the receptors of the biology. We think it's very straightforward. And we also know that 3014 is a highly selective inhibitor for this target, so we think it's very well suited for us to move relatively briskly with 3014 in this disease to a potential future registration.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Great. That's helpful. And then I guess, just to follow-up on some of the clarity you provided. The data you'll share in the second half won't be sufficient in your mind to progress into pivotal trials just yet. So I assume -- you said you'll be opening the expansion cohorts, we'll need to see some data from the expansion cohorts. How much longer might we have to wait for that data? And then would that data be comparable in your mind to some data we have for pexidartinib currently to help you make your decisions? And is that the right way to think about it?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, Chris. That's exactly the right question to ask, I think. And it's just premature for me to comment at this time on when we might be ready because it depends on data and as data comes in and data matures, and that will then determine when we're ready to launch and do a potential pivotal study with 3014 in this disease. So just difficult for me to forecast that from where we are today.

Operator

And your next question comes from the line of Andrew Berens.

Andrew Scott Berens - *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

Congrats on all the progress. A couple of questions on where we might see some data presented, assuming that there are going to be any medical conferences in the near future. Are we still planning -- you may have said this in the prepared comments, but I missed it. Are we still planning to see the Systemic Mastocytosis data this year? And I do have a follow-up on INVICTUS, too.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Sure, Andy. Thanks for the question. It's Steve. So yes, what we said and guided to since the beginning of the year is that we would expect to have data from one or more expansion cohorts from the Phase I with ripretinib, and that would include Systemic Mastocytosis. So our hope, of course, is that there are medical conferences during the course of the year, and that would enable us to speak with experts and, of course, get data published. So that's our focus.

Andrew Scott Berens - *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

Okay. And then in regards to INVICTUS. It's my recollection there was an extension phase for patients that progressed, I believe on either arm, were able to remain -- to enter the extension phase and get double the dose of ripretinib. I don't believe we've seen those data presented anywhere. So when are we going to see the patients that had more than the normal -- the 150 QD. And then also, how should we think about those patients potentially on the label?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Good question. So you're right. In the INVICTUS study, patients who started off on the ripretinib arm upon central PD had the opportunity to dose escalate to 150 BID. And actually, similarly, in the Phase I study, patients in the Phase I also had the opportunity to dose escalate to 150 BID. So that's an analysis that we intend on publishing. I can't guide you specifically when we might have that analysis ready for publication, but it certainly is we think, going to be an interesting set of data. So that's something that the team is working on in terms of analysis and publication plan for those data.

So second part -- sorry, Andy, was there a second part to that question? On the label, I think was the other part.

Andrew Scott Berens - *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

Yes. Just -- yes. Would those appear on the label potentially?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes, it's not -- it's too early for me to comment on that. Of course, as you know, the FDA is going to be the decision-maker in terms of what appears in the label. I think a base case assumption would be that it's going to be based on the 150 QD dose, but we'll have to see how that discussion goes and what the final label ends up looking like with the potential approval.

Operator

And your last question comes from the line of Arlinda Lee from Canaccord.

Arlinda Anna Lee - *Canaccord Genuity Corp., Research Division - Analyst*

I just wanted to clarify on the Phase I update for ripretinib. Is that data only going to be for non-GIST indications? Or might we see any additional GIST data there? And is that data going to be sufficient to decide on a go-to expansion phase?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Arlinda, it's Steve. Thanks for the question. So that's right. So what we've guided to is that we'd have some data from at least one of the expansion cohorts during the course of this year, in the second half of the year. And so it's too early for me to comment on where those data may or may not lead us. So we have to look at the totality of the data. And once those data are mature, and we present them in the second half, and I think at that time, at the time of data presentation, we'd be in a position to then provide some additional color on where we might go with that.

Arlinda Anna Lee - *Canaccord Genuity Corp., Research Division - Analyst*

And then similarly for the scope of the CSF1R inhibitor data at year-end. Is that going to be sufficient to decide on mix -- help decide on an expansion?

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. So Chris, I think, had the same question a couple of minutes ago. And it will depend on the totality of the data that we have. So I think it's premature for us to comment on what we might have at year-end and whether that's going to be sufficient for us to decide on the next clinical step. I can just offer that Matt and his team broadly, whether it be the clinical operations team or the development team, are very actively working on the balance of our clinical stage portfolio, getting the requisite sites open, getting patients put on study. So we're looking forward to having additional data, more mature data in the second half that we can share with investors and with the clinical community to guide the next potential steps with each of these programs.

Operator

And this does conclude the Q&A portion. I would now like to hand the call back over to Steve Hoerter.

Steven L. Hoerter - *Deciphera Pharmaceuticals, Inc. - President, CEO & Director*

Yes. Thanks, everyone, for joining us on the call this afternoon. Thanks for your continued interest and support of us here at Deciphera. I wish you all a wonderful evening. Thank you very much.

Operator

And ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.
