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PRESENTATION

Operator

Welcome to the Immunovia investor presentation. (Operator Instructions)

Today, I'm pleased to present the CEO, Patrik Dahlen. Please begin.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Thank you. Good morning, everyone, and thank you very much for joining this webcast.

If we move on to the forward-looking statements, I do encourage you to read and understand our forward-looking statements.

If we then move on to the next slide, for those of you who are new to me, my name is Patrik Dahlen, and I'm new in the role of CEO for the company. I joined as the new CEO just a month ago. I'm really excited to be here at the helm of Immunovia. We're in a very important phase of the company, and we are on a very last home stretch of making Immunovia's blood test IMMray PanCan-d available to patients on the U.S. market.

If we could turn the page, today's discussion will really follow from the unfortunate media coverage that has been over the last couple of days, starting with an article by Dagens Industri, and we wanted to take this opportunity to add some clarity to the picture. Obviously, at the end of the Webinar, there will be room for you to ask questions, and I do encourage you to ask as many questions as you'd like. The topics that I will address today are the following.

I'd like to talk about the huge unmet medical need and what solutions we are providing and what markets we're addressing, so that it becomes clear how we have calculated the addressable market size, et cetera. Second, I would like to shed some light on the data from the commercial test model study that was released in September and the verification study that was released in October. We're aware that we have perhaps not been so clear in our communication, and we want to take this Webinar today to once again go through the data that was released and hope to clarify any questions that you might have. And last, I will take you through what the process look from now until the first tests are available for the U.S. patients in quarter 1 2021.

With that said, I will now move to the next slide. As all of you probably know by now, for these patients, early diagnosis is key. If pancreatic cancer is detected in stage I and II, the tumor is still resectable and the 5-year survival rate can be increased from a mere 5% to over 50% survival rate. The very tragic truth is that with today's standard of care, the vast majority of the patients are diagnosed too late, i.e., they are diagnosed in stage III and IV. And this means that it's difficult to operate on the patient. The cancer is not resectable. And on average, you have 5 months' time left to live. And our task as a company is to launch tests that enables early detection of pancreatic cancer such that we can improve the standard of care for detection of pancreatic cancer and thus, help save lives.

If I could have the next slide. Our IMMray PanCan-d test, it's not a test for screening of the general population. I think it's very important to emphasize that we have never intended the test to be used for the general population and broad-based screening for pancreatic cancer. Instead, it is intended to be used for 3 very specific risk groups.

The first risk group that I'd like to talk about is the familial or the hereditary patient group. This is a group of individuals where there is a family history of pancreatic cancer and where genetic traits have been detected. This risk group should be monitored twice a year with a test like IMMray PanCan-d, which enables early detection of even stage I and II pancreatic cancers. The clinical unmet need here is huge, and our data to date show a strong diagnostic performance of our test. We believe and are convinced that we have a unique test with an ideal performance criterion for early detection of patients in this risk group.

The second risk group I would like to talk about is the one with early and concerning symptoms. Here, our test is meant to be a complement and improve current standard of care. Standard of care today, including different imaging methods and a biomarker CA19-9. For this risk group, our test is intended to be used also as a rule-out test, providing clinically more relevant information than CA19-9 data alone. We believe our test can be used to help further improve the standard of care and improve the decision making and make it faster in a diagnostic sense. In this rule-out context, the negative predictive value is very important. And we have released data that show our IMMray PanCan-d has a high negative predictive value of 99.3% in a clinical cohort like this group. I should emphasize that we do not propose that the IMMray PanCan-d would replace the need for other confirmatory diagnostic methods, including imaging techniques like scanning.

Third risk group we will address in the future are those patients, who have recently been diagnosed with type 2 diabetes and are over 50 years old. Here, we are proposing the IMMray PanCan-d test when, in the future, it has been validated on larger prospective studies like PanDIA, which is an ongoing study, that it can be used for diagnostic purposes for the detection of early-stage pancreatic cancer. Our data so far is encouraging, and we hope to be able to publish more data in the future based on the PanDIA study that we are conducting.

And again, before moving to the next slide, I just, again, would like to emphasize that the test is targeting these patient risk groups and is not intended as a general population screening tool.

If I could have the next slide. One of the questions that have arisen from the article is how we calculated our initial addressable market and specifically, there were questions around the diabetes patients. The facts and the assumptions for the first 2 risk groups are clear and evident. So I will not address those today because it's very easy to follow the assumptions that we made, the math that we made and the approach that we have taken. However, I would like to take a few moments to discuss the diabetics group. As the diabetes type 2 patients that are newly diagnosed and are over 50 years of age have a 10x higher risk of developing pancreatic cancer within the first to the third year after diagnosis. There is a high demand driven from the medical community to be able to early detect pancreatic cancers in these patients. And as we all know, the issues around diabetes is increasing year for year in the western world. Obviously, it's a huge market, and it will take time to penetrate it. We are clear about that. However, we see support in the medical community that this is a growing unmet medical need, and we have several clinicians who support our thinking. This is also evidenced by the mere fact that we have had a strong support to engage patients in our prospective study, PanDIA. Here, we have collected since 2018, more than 6,000 samples from patients with new-onset diabetes type 2 and are over 50 years of age. We are working side-by-side with different types of experts in the field in order to closely identify and address the medical needs with our prospective study.

As a general observation on the market size estimates that we have given, I would like to state that we have so far only focused on the U.S. and the European markets, and we have not begun to include Asia as part of our estimated addressable market. But it's a well-known fact that in several Asian countries like China, Korea, Japan, pancreatic cancer is an even bigger challenge than in Europe and the U.S.

With that, I'd like to move to the next slide, please. We have presented before on the Commercial Test Model Study and the results from thereof. I just want to briefly go through again and describe what we did. All in all, we had 1,113 serum samples, we had 315 PDACs or pancreatic cancer patients, samples in stage I through IV. We had 310 healthy controls and 488 symptomatic controls. We ran an 8-plex biomarker signature on the IMMray PanCan-d in combination with the biomarker CA19-9. And we applied the data from this analysis into our bioinformatics systems. The data that we were able to present is very impressive. We have accuracies that exceed 90% in all our cases. So all pancreatic cancers could be separated from all controls with an accuracy of 94%. All pancreatic cancer cases from symptomatic controls could be separated with an accuracy of 93%.

Maybe more impressively also pancreatic cancer cases, stage I and II could be separated from controls with an accuracy as high as 95%. Very impressive data, showing the ability of the test to detect very early stage pancreatic cancer in patients.

And if we could move to the next slide. In terms of the verification study, again, I'd like to repeat some of the data that we have released before. This verification study was run as the same way as the commercial study and we have used the same software that was locked, the same production processes and QC methods. We had 81 cancer cases, stage I and II; we had 114 stage II and IV; 212 healthy; and 112 symptomatic controls. In terms of accuracy, the pancreatic cancer cases could be separated from healthy controls with an accuracy of 94% and the pancreatic cases from all controls could be separated with an accuracy of 91%. We have elected to give some more detail on specificity, sensitivity and negative predictive value in some of these cohorts and the ability for us, the specificity in detecting early stage I and II pancreatic cancers from healthy controls, the specificity is 99%, the sensitivity is 78% and negative predictive value is 99.3%. In terms of differentiating all controls or early stage I and II pancreatic cancer patients from all controls, symptomatics and healthy, we do that with an accuracy of 91%. There, the specificity is 93%, the sensitivity is 78% and the negative predictive value is 99.3%. So very encouraging data that we think are very significant and really provide strong evidence of the utility of the test going forward.

All in all, the verification study confirms to rule out paradigm for the -- with a very high negative predictive value of 99.3%, which is a very outstanding number. Furthermore, on this call, I'd like to state that the positive predictive value for IMMray PanCan-d from the verification is 78% for a rule-in in pancreatic cancer. And interestingly enough, just as a comparison, the positive predictive value for a PSA test for prostate cancer, for instance, is about 30%. So we think we have, with the verification study performed extremely well, and we're very encouraged about the data that we have obtained.

With that, I would like to move on to the next slide, please, and this is more about the road to market and the timelines going ahead. So where are we right now? We are awaiting the data from the validation study and that will be available in Q1. Then we will move on for the clear certification of our lab in Boston. With that, we will then be ready for sales start in late Q1 2021. The first sales wave will be for private persons that pay out of pocket. And in the meantime, we will continue with our efforts to proceed with reimbursement process and market expansion studies. It's very important to emphasize that the reimbursement process is run by prospective studies and by providing forward-looking data in terms of -- in our dialogues with the authorities. In my experience, reimbursement discussions will take roughly 1.5 years. So we put a 12 to 18 months estimate on -- from Q1 2021 forward until we can start roughly with reimbursed sales. But again, it's very important to emphasize that parallel with these efforts our prospective study programs are ongoing, and we will continue to work on the prospective study analysis. And these are obviously important steps as we move towards reimbursement.

If I could get the next slide, please. We have a very extensive cooperation with a large number of key opinion leaders in the U.S. and Europe. We have more than top 30 key opinion leaders that are engaged in pancreatic cancer and that we cooperate with in the U.S. and Europe. They have been a part of our several clinical studies. All key opinion leaders that are on this slide are also principal investigators leading clinical studies at their clinics. This, of course, underlines the huge medical need for a blood test for pancreatic cancer as a complement to the diagnostic methods used today. The crucial difference we can deliver in this early diagnosis and in the case of symptomatic cases, accelerated diagnosis.

If I could have the next slide. So in summary, the key takeaway message is today is that Immunovia is addressing a large unmet medical need for early diagnosis of pancreatic cancer. The IMMray PanCan-d has the potential to complement today's diagnostic methods. We have generated great clinical data and the test performance to date, and there is more data to come in 2021. We are particularly proud that we have been able to show that early detection of pancreatic cancer stage I and II in so-called healthy populations is possible. We have the U.S. organization in place and ready for launch in Q1. And we are expecting revenues from 2021 forward.

With that, I would like again to thank you for listening in. And I also would like to reiterate that the main reason we are here at Immunovia is, of course, for the sake of pancreatic cancer patients. This is the basic motivation of all of us here at Immunovia, and we're very proud of the work that we have done to date.

Now I would like to open up the call for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from the line of Viktor Sundberg of ABG Sundal Collier.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Yes. So maybe just on some of the numbers you presented with regards to specificity and sensitivity. You quote here a negative predictive value of 0.993, and that is, of course, based on a specificity and in prevalence in some population. So what is that based on in terms of prevalence and specificity?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So the specificities are what I mentioned and what we have released, obviously. For us, what's important is obviously the negative predictive value and the fact that it's high. And this is in the context of symptomatics, that is -- I'm assuming that's where your question is kind of focused on. For us, what's important is obviously, that we have a high negative predictive value because this is the very basis by which the test can be used for rule-out purposes, and this will then enable clinicians to make faster decisions and move the patients onwards in the work up in the workflow. So this is the very -- let's call it, the sort of reason why we think the test is better, and it's significantly better than the standard of care today, which is largely speaking, based on CA19-9 alone, cutoff based analysis to either propose an increased risk for pancreatic cancer or not.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

But just to be clear, is the specificity coming from healthy controls, all controls? And also the prevalence, is that based on the prevalence in the population? And what prevalence do we have in, in the asymptomatic individuals coming into a gastro clinic?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Yes. So the NPV that I closed -- that I cited of 99.3% is from the clinical cohort, i.e., the symptomatics. So it is in that cohort. And the same with the PPV that I mentioned comes from that. And there, the prevalence is 3%.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Exactly. And how do you define a rule-out test? If you say that PanCan-d is not intended to replace imaging and further diagnostic tests. Per definition, isn't that not a rule-out test? I mean you have to use it with other diagnostic modalities to so to speak, in a combination with all the other tests, then you could potentially rule out the disease or say rule-in the disease. Could you just comment on that maybe?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So yes, a brief comment. I think from the very beginning, I think we, at least, from our point of view, have been very clear that we did not intend in the group of symptomatics to replace imaging or scanning. It is not something that we have communicated and it's not the intention. So some of the comments from the Dagens Industri article, for instance, in that sense, are really irrelevant because it's never been our intention to replace imaging as a final diagnostic method for the symptomatics.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Yes. Fully agree. And yes, as we are thinking, we are thinking of this, as you said, in combination with other diagnostic modalities to work in that setting. But in terms of pricing them, for example, CA19-9 is used here, as you said, and I guess the value that clinicians see here is that it is a scale and high values can tell you something and very low values can tell you something as well. And your test is binary in that sense. What supports in terms of pricing that should be priced maybe 80 to 100x the price of CA19-9 in this setting? Or can you speak a bit more about the pricing strategy that you see here?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So in general terms, if I start just with generic terms about the pricing strategy, it's clearly and obviously, based on the fact that there are different types of tests and for different cancer types in the marketplace that are used in the same context as our test will be used going forward and that are priced significantly higher. And of course, the other part of the equation is the sort of clinical utility. And I think without a doubt, in general terms, the price that we have proposed, which, again, is $600 per test, is a test price based on the market conditions and other tests' price versus the clinical utility that we bring. In terms of the symptomatics, specifically, there, our test brings significantly higher value than CA19-9 alone. And this is, of course, for maybe not you and I, Viktor, to discuss so much, but more for us and the clinicians to discuss as we continue to provide more data to the market. And based on the feedback that we have -- we have feedback from key opinion leaders that clearly indicate that this is a valuable test to accelerate the diagnosis and make earlier diagnosis.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Yes. And in terms of -- you also talked about the positive predictive value here for the first time. And I mean the positive predictive value that you are quoting are coming from the verification study, but maybe the prevalence in that cohort of samples is a bit overexaggerated compared to the prevalence maybe that you see in the population. Maybe there, a prevalence of 1% would be more appropriate and then your positive predictive value would be a low single-digit number. I mean could you just comment on that of your thinking about using a positive predictive value from a sample study and applying that, so to speak, generally among the PDAC patients?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So the cohorts that we have studies are, of course, a reflection of the type of patients that are in the gastro centers and the like. And the positive predictive value that we state here is obviously based on the prevalence in the cohort that we have studied. And that's, to the best of my knowledge, the only way we can express the positive predictive value.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

But it would be very low, I guess, in the real settings, so to speak, in a gastro clinic or in a diabetes group or whatever you would apply the test?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So what I have referred to here is a clinical cohort that comes from symptomatics from these types of clinics. And the prevalence that we have chosen to calculate the PPV, or the positive predictive value, is based on the prevalence of PDACs in that setting. So that is how we have derived at this number.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. So please stop me if I have a lot of questions here, maybe other people are waiting in the queue. But just to touch on maybe the nuance of diabetes population, I mean that's a big population. It's 1.5 million people in the U.S. And a test with your performance, as it looks now at a verification

study, would send maybe hundreds of thousands of people as being false positive to additional screening, perhaps biopsies. And in worst case, people could also get pancreatectomy that carry a high mortality, and that's something that the U.S. Preventative Task Force is, of course, very concerned about in general with screening of PDAC. And -- could you just comment -- I mean for all tests, I guess, that have been introduced in a new cancer, mortality outcome-based studies have been the norm for USPCTF (sic) [USPSTF] to accept that and include that in guidelines. Why do you think that PDAC would be a free pass, for example, in this population?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

I don't remember that I would have said a free pass or someone else would have said a free passing. In fact, what I said is that we have some early data. We think it's encouraging data. The sample sizes that we have included so far in the verification study are small. So it's too early to draw absolutely conclusive conclusions from that. We are conducting, to the best of my knowledge, one of the largest studies ever done on new-onset diabetics over 50 years of age. We have more than 6,000 samples so far collected. And we will test these when we have a validated test that we will have, as you know, at the end of quarter 1 2021. So I think from that point of view, we are discussing a little bit sort of a ahead of time, if I put it that way, Viktor. I think it's best always in these type of situations to conduct the clinical studies, report the full data and then discuss where we go. So I think, at least from my point of view, I think we are positioning this clearly as a future potential. And we think there is a big, big unmet need since the patients will display such a high increased risk.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

But that mortality outcome-based study could be a possibility. You don't to rule that out, so to speak?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

I think what's most important for us is, of course, to do the -- conduct the prospective study, get the data from that and then move on from there. So that's how we view it. We -- as in many of these studies that we are conducting, the number of positive cases that you can collect in a relatively short period of time is still relatively small, as you know. And therefore, we need to be cautious about making too forward-looking statements with regards to whether we need to run a mortality-based study or not.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And just a final question. Do you still reiterate your plan to present the interim data for the PanFAM study here in the first half of 2021? And what kind of data could we expect there?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Yes. So as you know, I'm new here, and we are going through and evaluating a communication plan. And we will, of course, as soon as we have the validation study done and we have a validated test, then we will move ahead with PanFAM, PanDIA and the other tests where we have -- studies where we have collected samples.

Operator

Our next question comes from the line of Alex Cogut of Kempen.

Alexandru Cogut - *Kempen & Co. N.V., Research Division - Analyst*

I just would like to hear a little bit more about your guidance regarding reimbursement discussions. I believe you mentioned you expect it to take 12 to 18 months from the sales day launch. Could you talk a little bit more about kind of the steps that you need to take in order to get that reimbursement in the U.S.?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Yes. So it's basically about collecting a dossier where you have, based on prospective studies, you have clinical data. You present the clinical data and the payers and the HMOs will be evaluating the data. And based on that, they will do their health economics calculations and determine not only reimbursement but also reimbursement rates, et cetera, and also for the breadth of availability of reimbursement. So this is a fairly standard process. What's a little bit unique, of course, in the U.S. is that they require U.S. samples. So this is obviously something that we are taking into account.

Alexandru Cogut - *Kempen & Co. N.V., Research Division - Analyst*

Got it. And I believe for the sort of the lead indications, if I may, for asymptomatic and patients at higher risk, you don't have -- you don't require any changes in USPSTF guidelines. Is that correct?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

We are -- right. We don't know for sure, but we are, of course, due to our long-time relationships with the key opinion leaders, many of our key opinion leaders that we work more closely with are themselves, guideline authors, and obviously, we work very closely with them. And as the data unfolds and we move forward, we will be able to be a bit more specific about this. But it's obviously something we've been extremely focused on for 5, 6 years already, understanding what are the guidelines and how do we fit into the guidelines and how do we possibly improve the guidelines with the tests that we come. So it's -- we have a very, very close relationship with the key opinion leaders.

Operator

(Operator Instructions) And we have a question from the line of Sven Nordenstam of Dagens Industri.

Sven Nordenstam

I would like to return to the question of false positives, and I'd be curious to hear if you had any discussion with clinics and so on with -- about how that flow of patients will be handled. Because it looks like your tests in a clinical setting with a prevalence of 3% and specificity of say, what, 85%, bearing in mind that symptomatics drag down the average, that the rate of false positives to true positives would be at least 5x. So I mean since this is a very serious condition, you -- some number of false positives is acceptable, but what is the -- what are the discussions there? What do your key opinion leaders say about the -- and how high rates can be accepted?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So we have, obviously, set the specifications for the performance of our tests according to very close discussions with our key opinion leaders. And we have -- are following that. And with the data that we have put out from the verification study, we have had discussions with key opinion leaders about the utility and the way the test would be used in these 3 different risk groups. And the feedback that we have is that we have seen it exactly correctly, i.e., that for the hereditary group, this is very, very unique and fantastic performance that the test provides and that we can detect with very high sensitivity and high specificity, early stages stage I and stage II pancreatic cancers.

In the symptomatics group, which, I guess, is the one that you are mostly interested in, there, again, as I have -- think -- said multiple times today, the intention is not to replace scanning as it seemed at least a few of the opinion leaders that have been quoted in your article, I would have assumed that, that was what we were intending to do, which has never been the case. We are again following the guidelines of our clinicians and input from our key opinion leaders and our test is intended to provide a deeper and better understanding of the status of the patient than CA19-9 alone can do. And that is what it's doing. And I think I'll leave it at that.

Sven Nordenstam

Okay. That's very clear. I would also like to return to the question of negative predictive value and positive predictive value. If you -- I don't -- I just don't get the numbers here. The positive predictive value and the negative predictive value that you have provided, they think cannot be there at the same time. It's a mathematical impossibility, in fact, generally with the prevalence of 3% at specificity around 90%, sensitivity of 80%, you cannot have an NPV of 0.993 and the PPV of 70%. In fact, PPV could be around 20%. So are you -- what numbers are you referring to when you're talking about the PPV of 78%?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So it is, again, Sven, as I just explained already earlier that the positive predictive value for IMMray PanCan-d that comes from the verification study is 78% for rule-in in pancreatic cancers in the group of the symptomatics. And it's based on the clinical cohort that we were examining, which is the cohort of symptomatics collected from clinics like gastro centers, where the relevant prevalence of PDACs is what we have taken into account. So there is -- it's a perfect reflection of the actual situation in the clinics in terms of the samples that we get in for our studies. And we are just reflecting the prevalence, and the cohorts are what we get in. So -- and then we do the data and then now we report the data. There's nothing statistically impossible about what we report.

Sven Nordenstam

Okay. Right. Maybe we can figure that out at a later stage, as that may be a little bit technical for the telephone conference. Okay.

Operator

And we have no further questions on the telephone lines at this time. Please go ahead, speaker.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Okay. Thank you very much. I'm Laura Chirica, and I'm in charge of the commercialization here at Immunovia. And today, I am also participating to this call together with Patrik, and I am receiving your questions. So I'm going to go through and read them one by one, and we are going to give answers to, hopefully, all of you. And I will start with in the order you have sent them to me.

The first one is, can you mention something about the critique from Dagens Industri involving 1 person that is also involved in PharmaCyte conflict of interest. And then you are referring to our collaborator, Matthias Löhr.

The other question is will Immunovia be more aggressive in the media from now on to bring forward the positive aspects of your company?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

That is a very broad question. I think, first of all, whilst we feel that it has been important for us to react on the article and articles that have been published recently and this is, in fact, the very basis for this call. In general terms, I would say that we as a company and I as a person at least, don't

want to meet critique with more critique, if I put it that way. I'm a much more a believer of general sharing of information and discussing of information and then we kind of take it from there. In terms of communication going forward, we're definitely looking at a new communication plan and a new way to communicate with the market. This is not a reaction to the last few days' articles. This is only because I am new at the helm of Immunovia and I feel a need for a more forward-looking communication strategy for the company. And this is why we will be a little bit more forward-looking as we move forward in terms of our communication.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

And I forgot to say that this question came from [Frederik Alcrist]. And because this question is repeatedly coming from some other people, I will just add because I have been working with Matthias Löhr for a very long time and extremely productive and good collaboration. So I just want to confirm Patrik's comment, and I just want to say that we are looking forward to a great collaboration.

Then I will move to the next one, which is from [Michael Gröning] from Danske Bank.

Can the IMMray first detect pancreatic cancer in an earlier stage than using imaging scanners?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

You can answer very shortly on that. But I think in general terms, the patients that come in, that are symptomatic, have been sick for a while and they have developed more and more symptoms. These are often vague and wide symptoms and therefore the disease continues to develop. If they do have a pancreatic cancer, they can have a whole host of other disorders that are causing these vague and concerning symptoms. So in that sense, the role of our test in that group of people is, again, as we have said a few times earlier today, it's really to enhance the current standard of practice and make a better test than what's currently available. But in the end, the ultimate detection or diagnosis will be made with the scanner.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Okay. Then we are moving to the next question, that we have, comes from [Yunus Pashan]. And he is asking which are the risks that are connected to the process that is leading to the reimbursement in late 2023.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So we have started in good time to collect samples for -- to be used for the reimbursement process in terms of collecting prospective samples. So we are in that sense started early, which is great. The next step that needs to be taken is obviously with the validation study and putting in place the validated test. From there on, it's obviously about making sure that we have enough prevalence, so that the data that we collect is and the data that we will be presenting to the authorities is such that it gives meaningful medical data. And what I mean with that is that the prevalence of incidences needs to be high enough, so that we can with the statistical significance present data that shows the useful of the test. So this is obviously one of the areas that we are very focused on, and this is why we feel we are in a good position right now because we -- as I said, we have started to collect the samples very early.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

We got the feedback that there was no sound.

Operator

I can confirm that we can hear sound from yourselves. Please continue.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Okay. Perfect. We continue.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

We continue. Okay. We move to the next question, which comes from Andreas Barry -- Berryman, and he's asking, there are 3 categories that are the target group for the test. How large in comparison is the number of pancreas cases that come from -- pancreas cancer, of course, that come from outside of those 3 categories.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

That is a question that's very hard for me to respond to, as I'm, again, quite new to the company. So that is something that I will have to revert to later on.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Okay. Then we take the next one from Victor Danielson. Which subgroup in the verification study did the positive predictive value of 78% refer to? Would you be able to provide the positive predictive value for all subgroups, please?

And now we actually received from outside that the connection broke and it wasn't possible to follow.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So Jerry, it seems that we have lost the outside, I don't know. You seem to be hearing us quite well.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

But the people outside are complaining.

Operator

Yes, I can confirm we still have sound in the audio teleconference. I'm checking with my colleagues to see if sound can still be heard via the webcast.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

They are writing they are leaving the call because they cannot hear.

Operator

Okay. I can confirm we do still have sound in the teleconference, and we still have a number of lines dialed in.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Okay.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Okay. Yes. So it was about the positive predictive value for all subgroups. That was the question.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Yes. Yes. And I think what we'll do on that is obviously -- we'll come back with publication around that or a release around that, so that we properly share all of the information as widely as possible. So that's probably the best way to release that data is to go out with it.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Yes. We get the question, [Lum Ba] says, why have you not included any projections from Asia?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

This is because we have been extremely focused on Europe and the U.S. And as you can see from the clinics and the key opinion leaders that we work with, we are exclusively focused on the U.S. and Europe. And in order to really include and do proper calculations on the Asian situation, we would, first of all, need to start broader collaborations in Asia. We have a few key opinion leaders there but not a lot. And it would really require us to broaden out. And this, we will -- we think it's -- the pancreatic cancer is a significant challenge in the Asian population, particularly in China, Korea and Japan, as I have mentioned. And we will definitely -- once we're well grounded in the U.S. and Europe, we will definitely move on and start addressing that. And when we do that, we will also do the same calculations as we have done for Europe and the U.S. and provide sort of an outlook of potential market size in this region.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

And the next question comes from Michael Loughman. Can you give us an update on the pipeline? Where are you with RA and lung? And when can we expect to hear more about this big project?

Patrik Dahlen - *Immunovia AB (publ) - CEO*

So at this stage, there's really no update that I can give you. We will return to that in the New Year 2021. The situation is still the same for RA and for lung cancer that we had when we last discussed with the market in context of the quarter 3 interim report.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Yes. And we are moving on to the question, and we should actually answer that because we've had the connection broken. So I got the question, will you be publishing today's webcast on your website, so that they can follow the part that was broken?

Oscar Peterson was asking, and the answer is yes.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Yes.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Okay. I'm just looking through and we got actually a comment that the connection broke during the answer to -- it was through -- to Danske Bank. But anyhow we are going to have this in recorded.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

I think that's it then if...

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

This is what we have had.

Patrik Dahlen - *Immunovia AB (publ) - CEO*

Thank you. Thank you so much, Laura, and thank you, everyone, for calling in. I do apologize if the webcast stopped giving audio at some point in time. Obviously, this discussion has been recorded anyway. So it will be available for you to listen to in its entirety. Again, I really would like to thank you all for your contribution and for your interest. Thank you for your interest in Immunovia. Again, as I said a few times before, we are extremely excited here at Immunovia to be a company in the forefront for providing early diagnostic means for pancreatic cancer and doing that with a simple and easy-to-use blood test. So for us, we're really, really excited about the future. And again, thank you very much for participating. Thank you.

Laura Chirica - *Immunovia AB (publ) - Chief Commercial Officer*

Thank you. Bye.
