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Presentation

Operator

Welcome to the Immunovia teleconference regarding autoimmune strategy. For the first part of this call, all participants will be in listen-only mode, so there is no need to mute your individual lines, and afterwards there will be a question and answer session. Just to remind you, this conference call is being recorded. I'll now hand the floor to our first speaker, Mats Grahn, CEO. Please begin.

Mats Grahn

Thank you. And welcome to this telephone conference on the autoimmune strategy. This is a very important step for Immunovia moving forward utilising the power of IMMray™ platform in a different field than cancer as well. So today with me, I have also Laura Chirica, our Chief Commercial Officer. Laura has a strong background from the autoimmune field as she was previously head of sales and marketing for a company called Euro Diagnostica that actually introduced today's golden standard in the rheumatoid arthritis diagnostics called anti-CCP. She has worked quite a number of years in the autoimmune field and will cover some of the main aspects today.

The agenda, we will talk about, I will give a short overview of the autoimmune field. And then Laura will take us through the clinical need in some detail in the rheumatoid arthritis field. We will comment on the studies that have been performed up-to-date and the next steps now in our chosen strategy. I will talk shortly about the general commercialisation options that we have at hand, and we will talk about, at the end, communication moving forward and summary of course. So these are the areas that we plan to cover today. And we'll of course finish with the question and answer session.

So the autoimmune field is very interesting. It's a large field where the autoimmune diseases are in a state, in which the immune system or the body attack their own body in different ways. There are very many different autoimmune diseases in various areas such as the CMS, the brain, the nerve system, can attack the heart, skin, kidneys, pancreas, etc, etc. So, it's a lot of harm under different diseases. And all these diseases and states have a very strong impact on healthcare costs in society. Actually, much larger than oncology to almost twice as big costs in the healthcare systems.

The whole autoimmune field as compared to all other fields is somewhat more conservative, but it does start to adopt new technologies such as multiplex modern diagnostics. So, it's a good time to move in with a new technology that can solve problems that haven't been solved before. Our focus in this large field will be in the area of rheumatic autoimmune diseases, most important diseases in this area are, for example, rheumatoid arthritis and SLE that we touched on before and several others. But only rheumatoid arthritis and SLE is today a market of US$3.4 billion in terms of sales of diagnostics and that is tests and solutions that actually do not solve some of the major clinical needs, that is required to move into much more efficient patient management and for the payer side, care in the autoimmune field of rheumatoid arthritis and SLE.

So, to enter such a market, there is a need to start with a game-changer as an entry point. And to enable an efficient and smooth penetration on the market, it's crucial if you can find a way into ongoing healthcare reforms, which is the case for rheumatoid arthritis, as you'll hear about today. There is a healthcare reform going on both in Europe and US and starting in also other parts of the world, where the healthcare systems are changing the ways of working in order to do early diagnosis of RA patients that are at risk of developing RA. And the reason for that, which we'll come back to in the next part of this call, is because RA unlike many of the other diseases, actually has treatments that if you apply them early can retard or delay the onset of serious symptoms and thereby save people from getting out of work and several severe pains.

So, this is a slight overview, a short overview of the autoimmune field, with a focus that we will now put on rheumatoid arthritis that Laura will take you through when it comes to the current clinical needs and future clinical needs that we will focus on.

Laura Chirica

Yes. Thank you, everybody for joining us today. I am Laura Chirica. And I am very happy to have the opportunity to take you through, as Mats just introduced, to the major clinical unmet needs in rheumatoid arthritis. To better understand the clinical needs in rheumatoid arthritis, I will give firstly a short background of this disease. I will then describe the current clinical practice and its shortcomings. And lastly, I will focus on, what Mats just mentioned, the most recent healthcare recommendations and definitions that address the detection of all the RA in patients having a risk of developing the disease.

If we start with just a quick background of the disease to put it into a context. Rheumatoid arthritis, as we all know, is a very devastating, the most common chronical autoimmune diseases that destroys tissues and deforms joints. In US and Europe, it's estimated approximately seven million people are affected by this terrible disease. As Mats mentioned, and very important to remember, fortunately new treatments that resolves in retardation and even remission of RA are becoming more and more available but it's very important to remember, for these treatments to be effective better, earlier diagnostics are urgently required.

And this is taking us to the next topic that I would like to explain in a few words, the current clinical practice in the diagnosis of rheumatoid arthritis. And also, I will touch upon its limitations. Today, the diagnosis of rheumatoid arthritis, and you will hear me time and again and probably Mats as well, saying RA, because it's easier. So, if we want to say rheumatoid arthritis, we actually say RA. So, the diagnosis of RA is made by rheumatologists, specialist clinicians in patients having clear symptoms and what is called today established RA. The diagnosis is decided based on a combination between the guidelines from 2010 from American Congress on Rheumatology and European League Against Rheumatism together.

These guidelines define clear criteria that score the systems together with the results on serological testing. As Mats also mentioned earlier, the golden standard for RA diagnosis since more than one decade, is a test that measures antibodies against a certain peptide as you will also be able to hear in different presentations called anti-cyclic citrullinated peptide, also known as anti-CCP. These antibodies are measured at advanced stages of the disease, thereby the test is used to diagnose established RA. There are also several other similar tests. These are based on the same or similar structure of the test. They are on the market called ACPA, also known, as anti-citrullinated protein antibody measuring the same autoantibodies.

Anti-CCP tests are having a good specificity of 96%, which is the main reason they have become a golden standard but they have a much lower sensitivity of 68% to 75%. Another test that is used is called rheumatoid factor. It's using the RA diagnosis but it has actually a much lower performance of specificities in the range of 80%, 85% and sensitivities much lower between 65% and 80%. The shortcomings of anti-CCP testing and anti-rheumatoid factor, also known anti-RF, results in a critical clinical unmet need today. The rheumatologists need the test for the 25% to 30% patients who are having clear symptoms and established RA but they are testing negative to the current standards.

So, remember keep this in mind, because now as I told you, I will end this part that describes RA and its clinical needs by discussing about the recent healthcare systems the recommendations and also the definitions that are ongoing starting from the work in Europe, then moving also in US and in other parts of the world, has been picked up and they relate to the detection and the preselection of the patients at risk of developing RA as early as possible in the primary care to be referred to a specialist for confirmation and implementation of treatment as early as possible.

And to move on to this extremely important clinical unmet need, I will just stop a minute to go to why is RA such a major healthcare issue. There are several factors that contribute to make RA a major healthcare issue, issue that has to be solved. As Mats mentioned in the beginning, RA strikes early and in the most active years between the ages of 40 and 60. Within 10 years after onset, 50% of the patients have to leave full-time employment. RA is not just a debilitating disease. If untreated, it's proven to short-term life expectancy by six to 10 years.

And lastly but definitely not least, RA contributes to very high cost to the society. In US, there are recent reports of US$19-$20 billion annually as a total economic burden from RA current management of patients.

In conclusion, the preselection of patients at risk of developing RA is extremely important for the successful treatment. But today, there are no available tests that can detect early RA. In the earlier stages of RA, autoantibodies are not yet fully developed now at present in certain patients which result in 80% of the patients testing negative with the current anti-CCP anti-RF assays.

So I just want to make a quick recap. In established RA patients, 25% to 30% are having CCP negative RA, which represents an immediate clinical unmet need in all the RA, so we are moving earlier in the development of the disease in the clinical pathways. In the patients at risk of developing RA, as many as 80% of the patients are testing negative to anti-CCP and anti-RF. This is an even larger clinical need because it results in a window of treatment opportunity much earlier in the early RA stages when the treatment is proven to be most efficient.

Mats Grahn

Right. And all these opportunities tying together with the movement in the healthcare sector, that makes it a good window to work in the coming years to introducing it. It's a great opportunity for the company to move into this area. Strategically we are basing this decision to focus on the management of RA with a test for early detection of the difficult-to-diagnose patients. In the studies that have been performed up to now, we first did a study, you may remember, on differential diagnosis, where we showed that we could differentiate SLE from rheumatoid arthritis with 96% accuracy, and we also later on also showed that we could differentiate RA from a mixture of SLE and the other autoimmune major diseases.

This is a good proof that it's possible to pick out RA from a mixture of patients with symptoms that are RA like. So that was a first test that gave us the confidence to move forward into the autoimmune area in general. And particularly since doing testing of RA patients, the patients that come to rheumatologist or to primary care, do have some signs and symptoms. They do have pain, and they maybe have RA but it may also be other diseases, so that's why the differential results were very important for this step.

Secondly, recently released results where we showed that we differentiate RA patients with those who test negative for both current golden standard test that Laura referred to, as well as the ones that test positive and vice versa versus healthy. That was the study we have released in August. And that was a very important step that shows up that they have a very good starting point for the development of the test for early RA going forward, and for the difficult-to-diagnose ones, which is basically the same test. The key thing is to find the double negative and the ones that also test positive of course.

So, these great results from the studies done this fall and ultimately gave us now the foundation to build the development towards a commercial test of early RA patients to differentiate them from other diseases or other symptoms from the real RA ones.

So, the next step will be to do a study that represents exactly the clinical situation that the test will be used in, namely to pick out the RA patients up from the ones that have RA symptoms but it is not RA and not even an autoimmune disease. There are other rheumatoid diseases or diseases they give the same symptoms. And these are the ones that come to the rheumatologist and this is why patients come to primary care as well. And that's what now we'll show in a study that we can find RA patients among these ones and that will provide them the needed test.

So once that study has been done, that's a discovery study, which is the immediate next step here. Then we move into the standard development for regulatory approvals and accreditations and so forth. Just to remind you, these steps are the first ones, it is a signature test development and a fine-tuning study, a fairly large one that is already documented, put into the files that go into accreditation, followed by a smaller verification study with a locked signature on known samples, and then finally a validation study with a blinded sample, also a small study. These three steps are the ones that will follow after the study now of the RA versus patients with RA symptoms but that is not RA. And that's the development part moving forward in the development of the commercial product for early RA.

So, given that we have of course a fantastic opportunity to utilise all the infrastructure we have built up during the development of the pancreatic test and that goes not only for the development structure, so development tools, the development processes, the documentation and quality improvement systems and so forth, which makes it smoother to work from the development process but also for the commercial and delivery options.

And in general, for our coming pipeline products after the first test, we have a number of advantages in the commercialization. First of all, we will have the Immunovia IMMray Dx Labs, the reference labs running, and so a new test is straight forward to introduce from a technical point of view. I mean, they do look exactly the same. It's the same chip but different antibodies on the chip of course. And there is exactly the same procedure how to run them, so you don't need to train the operators or anything in the laboratory. So that infrastructure is very, very strong for the test coming off the pancreatic test that will be the first on the market of course.

We do have production and logistics running for the second test production. It's also the same for any test on the platform. Of course, we will have different antibodies, but everything else is exactly the same. And also, sales operations is an important piece on the commercial organisation early. The systems to do billing to the payers, which is a rather complex. That needs to be put in place once and can be reused of course for all the tests. Same with CRM, customer relationship management systems and so forth. So, the whole infrastructure also in the sales and commercialisation and marketing side can be used. However, a new test will of course require investments in sales force and marketing, although everything else can be reused. And to do that, there are several options that are open to us. We can of course invest in our own sales force, or one can complement with hiring sales for certain areas. That's one option.

Plus there is also an opportunity since this is a different market and opportunity to work with partners also in different geographies. Partners can be large reference labs systems such as Quest, LabCorp and others, or specialised reference labs that have their own sales force and maybe extremely interested in partnering with us. Even pharma has shown interest in this as you have seen on the market maybe with Pfizer working together with Exact Sciences.

So, there are many options, and we will of course evaluate the best way forward once we move forward in the development process of this one. That needs to be decided about a year before the actual launch and so forth.

So there also great opportunities for various commercial strategies moving forward, and we will not have anything installed at this stage but there are many, many interesting possibilities moving forward. And we have advantages of the built-up infrastructure that we have set during the pancreatic introduction that is ongoing.

So, before I summarise I will also give the word to Laura to discuss very importantly about the communication that we've put in place right now and moving forward for the autoimmunity progress.

Laura Chirica

Yes, thank you. Well, I would just like to add to the commercial options is the fact that what we have seen in different geographies and different countries, have different ways of working with the RA clinical pathways. They are really very different. Even though they follow the same guidelines, they have differences. So that is also going to influence the way we are going to handle the commercialisation in the different geographies with these different models that Mats hast just presented.

So yes, now communication, and we know that you are very interested to receive a lot of news and interesting information from us, so we are working hard on that. And we are now having information about the RA strategy and the programme that it is going to be available on our website by the end of this telephone conference sometime this afternoon, it takes a bit of time for the publication but we are just on our way to release it.

We have had a press release just summarising main points of what we are discussing now. We are also going to provide a transcript of the whole call within 24 hours. That is going to be available on our web page, so you can actually go through everything that we have been discussing. And we are going to provide you updates on the study that we have been describing and also the next steps in the development process as we are moving forward and we have them available.

Mats Grahn

Okay. So, let's summarise. First of all, one of the major drivers for us choosing RA is that there is an ongoing healthcare reform with recommendations from guideline committees for early diagnostics of patients at risk of developing RA and this is a three million test opportunity per year. It's a fantastic opportunity moving forward as the healthcare system moves in that direction. That's point one.

Point two is that there is also an immediate need of a diagnostic test for these difficult-to-diagnose advanced RA patients, who actually test negative for both current standards. And that is an immediate need for rheumatologist specialist. This is about 0.5 million test opportunity in the Europe and US.

And thirdly, there is a crucial need for this test. There is nothing solving this problem today and the current gold standard is particularly bad in early diagnostics, and we have very promising data to build this on. So, these three points are the reasons why we strategically focus on RA moving forward. And then generally the fourth point for the rheumatic autoimmunity field is that it is a very large area with additional unmet needs going forward a little bit longer term. There are several opportunities for additional products, particularly in monitoring patients for a disease activity and treatment response and so forth. So rheumatic autoimmunity field is extremely interesting and we have – we believe the best entry point that we could think about.

All right, so with that, I would like to conclude and open up for questions.

Q&A

Operator

Thank you. If you wish to ask a question, please dial 01 on your telephone keypads now to enter the queue. Once your name is announced, you can ask your question. If you find it's answered before it's your turn to speak, you can dial 02 to cancel. So once again that's 01 to ask a question or 02 if you need to cancel. There'll be a brief pause now whilst we register your questions.

And our first question comes from Juan Zerate of Edison. Please go ahead. Your line is open.

Juan Zerate

Hello, good afternoon. So my question is, I mean, you mentioned you're going to focus on RA. In the past, you've also mentioned the potential of IMMray in other autoimmune and inflammatory diseases like Lupus, Sjögren's Syndrome and Systemic Vasculitis. So could you tell us what's your plans on those indications please?

Laura Chirica

Yes, hi. Thank you for your question. Yes, we have been releasing earlier results from this initial discovery study, in which we have been looking at differential diagnostics between SLE being Systemic Lupus Erythematosus, compared to a number of the main autoimmune diseases and they are represented by RA, Sjögren's Syndrome, and Vasculitis. And the results that we have been reporting, they were promising and very good. And in there we actually also looked at the behaviour of RA versus other autoimmune diseases with very good results.

What we have done during this time, we have been working in very close relation with large number of key opinion leaders and rheumatologists in this field. And in these discussions, we have identified their major clinical unmet needs. And as we have been presenting here early RA and the CCP-negative RA established disease is one of the major main, most important needs. And when it comes to SLE, yes, the differential diagnosis is interesting but the major need that relates to monitoring of treatment and prediction of flares. And for that, we would need to have a much larger discovery study with many samples per patient to be able to identify and monitor the flares and the treatment and this would be required to confirm the initial findings.

We have some preliminary studies published, very preliminary though, in 2016 that show that the platform could measure high and low activity. But for taking the test further and for even confirming this, we would need to run much larger studies in the next steps.

Juan Zerate
Okay, thanks. And just my last question. Could you remind me of the timelines of the RA study?

Mats Grahn
The timeline of the RA studies. Yes, we are right now in the process of designing the study together with the key opinion leaders and getting the right samples. And we anticipate that we will be able to release results during next year, 2019. And then if everything goes properly moving forward, we have a 2021, but that will of course be subject to the development results of the first one, it may go faster.

Juan Zerate
All right, good. Thank you very much. That's all.

Operator
Thank you. Our next question comes from Hans Quiding, a private investor. Please go ahead. Your line is open.

Hans Quiding
Yes, thank you. Hello. I think it was very interesting and very promising concerning RA. And if I understood now the development of the RA test, you talked about three steps. And I understood or I believe you were talking as they were sequential. My question is, would it be possible to do step one and step two in parallel because of your good results so far? Yeah, that's my question. Step one and step two in parallel.

Mats Grahn
Okay. Yeah, that would be great if it will be possible. But when you develop a test like this, the output of the first study is the input to the second one. So you don't know how to run the second one before you have done the first one. So, they have to be sequential. And this is true for all diagnostic developments in all companies.

Hans Quiding
Okay, I understood. I thought they were a little different – okay. I have another question. Are you also looking at other autoimmune diseases? Could you say anything about that? I mean, Celiac for example or any other fields that you're interested in?

Mats Grahn
You're absolutely right that the whole autoimmune field is huge. There are many, many diseases that are potentially interesting in the area. You mentioned Psoriasis, definitely you have of course type 1 Diabetes is another one. You have MS and you have many, many other ones.

Laura Chirica
Such as Immuno Neurology diseases that are increasing in incidence lately.

Mats Grahn
But we have our knowledge now and great results within rheumatic autoimmune disease, and with this are also driven by the – as I mentioned, the healthcare reforms and we need to focus. And that's why we are focused on a very large area of rheumatic autoimmune diseases. But in general, you're right, the whole autoimmune area is almost even outside the very large area we are focusing on. So but we'll stick to early discoveries and so forth within the area we are focusing on right now. Yes, there are other diseases, SLE, there is vasculitis and other ones as well. So we're sticking to that for the time being. But we are fully aware and we're also reminded by our Key Opinion Leaders that this technology may have applications far beyond what we are focusing on currently.

Hans Quiding
Okay. Thank you, very much, and good luck.

Mats Grahn
Thank you.

Laura Chirica
Thank you.

Operator
Thank you. And our next question comes from Hanna Norrlid of BioStock. Please go ahead. Your line is open.

Hanna Norrlid
Hi. Thank you. Good afternoon. You repeatedly talked about the changes in treatment guidelines regarding early diagnosis in RA. And as I understand, this is the first to both Europe and the US. I was wondering could you elaborate a little bit on what these changes entail and what they imply for Immunovia?

Laura Chirica
Yes, thank you for your question. Well, so this healthcare reform that we are referring to, it started from the definitions coming from 'European League Against Rheumatism', and they have been actually implemented by 2016. After that they have been discussed with a number of different specialists for the implementation in the different countries. These are not yet guidelines- they are recommendations. And they have started their implementation, in The Netherlands being the first, then Germany, then Sweden, Scotland, UK, France and now begin to be introduced in Italy, Spain. And then just less than a year later they have been discussed by American Congress of Rheumatology in the US and are being now into kind of a proposal stage, so they are going to start the implementation during this and next year.

So what it means in fact is that the whole healthcare system is going to look for the patients at risk of developing RA and preselecting them and finding them, identifying them at the early stage of the disease, which is at the primary care. So we are then moving both the disease and the clinical pathways into primary care for the preselection and then the primary care physician will be able to send the patient on to specialist clinics to the rheumatologist who is going to confirm and implement the treatment because as we all know it is extremely big difference in the efficiency of the treatment if it is implemented at the earlier stages of the disease.

Mats Grahn
Yes. If you remember when you are pushing it towards or into primary care, the importance of having a selection test, so you don't send enormous amounts of people to the specialist, is crucial. And the current test, I want to remind you is negative for 80%. It says that 80% of the ones with RA actually don't have it, so the test doesn't work to be moved out in primary care, so that piece is missing in this whole healthcare definitions and recommendations. That's the piece we want to see if we can add to this reform and actually enable it.

Laura Chirica
Yes, and the reform is actually the healthcare definitions that are very clear on how to identify the symptoms and the different early signs and symptoms and to somehow be able to preselect these patients based on their symptoms. But originally that is of course not enough because as Mats mentioned, it would create a very, very large flow of patients at risk that would be moved into rheumatologist that are already extremely busy. So the need for biomarkers and blood-based biomarkers is repeated absolutely at every meeting and workshops. Recently it was in July at EULAR meetings.

Hanna Norrlid
So you want to use your test in primary care? Do you see any specific challenges in implementing it in primary care?

Mats Grahn
Yes, it's a little bit of problem to implement in primary care. That's why when you go for such strategy, it has to be tied to a healthcare reform that's driven by healthcare systems. Companies are not trying to change healthcare practices or systems, but you should tie onto reforms that are ongoing. That's why we selected this one, one of the main reasons. Secondly, remember we mentioned also that there is an immediate need already now with the specialists because even at the specialists the gold standard test negative in 25% to 30% of the cases who actually have RA. So that's the short-term introduction of a test. You have a group that you can address immediately in the current situation at the same time as this reform is happening right now actually. So that's important to understand.

Hanna Norrlid
Okay, great. Thank you.

Operator
Thank you. And our next question comes from the line of Lars Hevreng of Vator. Please go ahead. Your line is open.

Lars Hevreng
Thank you. Can you please say anything about your comment in the release, the last sentence in particular, the global market for testing. It's growing strongly. I guess it has something to do with the – what you mentioned about the reforms, etc. But if you could say anything about the current value or that testing market today you say it's estimated to be €2.5 billion by 2024. But how is – what's the size today and of course the main drivers behind that anticipation of market growth. That's one question. The other question is, you mentioned briefly about the expected timelines here. I'm talking about rheumatoid arthritis and early detection for disease. Could you say anything about, I guess, that's dependent upon your discussion with opinion leaders. But anything about the size of the trial, I mean, anticipate the enrolment etc you're mentioning in 2020 or 2021. What was that? Was that for completion of that study or something else?

And also, now the question is about the – you mentioned potential partnering particularly if it comes to lab chains. When, during this process, would they typically be interested to partner with the core diagnostic company? I guess they would like to have some saying about the design of the studies etc. When in this process do you think they will be involved in partnering discussions?

Mats Grahn
All right, so there are many questions I'd say in fact. Let's start with the first one in terms of the market. Well, the US$3.5 billion RA and SLE in total is the current sales of the current single market test has that's used in this area. And they do not address this clinical needs at all. But the effect, the healthcare effects or healthcare economy effects of introducing a test for early detection of rheumatoid arthritis specifically would be very, very large. So the value of that is very high, so we anticipate that the growth in this area would be strongly enhanced with these years due to these opportunities given that very, very high cost of treatment over a very long period of time. So that's something about that.

When I said 2021, that's our rough estimate for a start– mainly as a LDT. And given the question about when does external partners get interested? That depends on the size a little bit. Specialised reference labs that focus entirely on this area are interested in the much earlier stage, even to some extent, participate in the later development stages and so forth in general terms.

Laura Chirica
Once we have a proof of principle.

Mats Grahn
Yes, when we have proof of principles, which is the first study basically. And then it's a different question when it's most optimal for us from a value point of view. We of course want to retain as much value as possible for our shareholders. Large players wait longer. They want to see product being used commercially most often. And in the first stages – that's why we have a great setup being able to do that with our own reference labs in Boston and now in Lund as well.

Not many small companies have that opportunity. And that's an investment that you do once to setup and then reused – since we have this platform we can reuse it for different tests for the introduction phase and that makes the test very attractive, if you want to attract the larger players definitely. So I would say for smaller players, you can do it a bit earlier after proof of principle, which is the first or maybe second study, and the larger players its after commercial introduction. Did I miss some of your questions?

Lars Hevreng
Okay. That's helpful. Do you have any ongoing retrospective studies in RA and anytime that would – from now on whether you primarily see, would only see, retrospective studies the discussion about this – in prospective studies I mean. Is that what you will see going forward?

Mats Grahn
Yes, as I said, we expect to have results during 2019 on that one if it's most important and largest the ones we talk about here.

Lars Hevreng
Sorry, Mats. I missed that.

Mats Grahn
Yes, we expect the first retrospective study where we define the signature for differentiating or optimise the current one for the differentiation of two RA patients versus patients with RA-like symptoms but with other diseases not even autoimmune sometimes. That is the key one and that's the one we are about to run now after designing it together with our key opinion leaders. So that one we anticipate to have results from during 2019. We can be more precise when we have finalised the agreements of samples supply. But 2019 definitely we should have a result of that one.

Lars Hevreng
Okay. And do you know anything about the magnitude of such trials?

Mats Grahn
For such trials, you mean how many samples or –

Lars Hevreng
Yes.

Mats Grahn
Maybe it's hard to say but it's up to 1,000, so it's in the range – it's pretty large. Yes, it is. It's in a range of the studies we did for the validation study for example of the pancreas test that was published right now with 1,000 patients.

Lars Hevreng
Okay.

Mats Grahn
It just helps in mostly running time and analysis time but most of the time I presume it's the sample supply process with the full clinical records. The advantage in autoimmunity is of course that the main centres have a rather high flow of patients and you have many, many more patients than you have if you compare to pancreas cancer. So the autoimmune area has an advantage compared to cancer in that sense patients don't die first of all. And secondly, there is a much higher flow of patients through the main healthcare centres focusing on this, which is great.

Lars Hevreng
So we will learn about this retrospective study, which is being fairly big but we will hear about this study during sometimes during next year and that's in advance of the prospective trials even getting started?

Mats Grahn
Yes, definitely. That's the key big, big milestone is this development.

Lars Hevreng
Well, okay. Thank you.

Operator
Thank you. And our next question comes from the line of Mikael Peterson[?] of Crayley. Please go ahead. Your line is open.

Mikael Peterson
Yes, hi. This is Mikael Peterson from Crayley. So based on last question earlier, the market as we see it today is US$3.5 billion you said. And how do you build that up? What's the – how many test is that, and what's the price per test? And also secondly, if you were to get your first incremental revenue from this in 2021, does the – sort of the infrastructure you're mentioning, does that include some sort of sales force or do you sell that this future test in a different way, which means that the structure of the company is going to be a little bit different? Those are the two questions. Thank you.

Mats Grahn
Okay, Mikael, thanks for the question. The US$3.4 billion is sold for today of the current test on the market for SLE and RA.

Laura Chirica
By all the players.

Mats Grahn
By all the players. So that's you get a picture of the market as it is today. But of course, this does not solve the problems moving forward. So we estimate that the market for this particular application, this test of RA difficult-to-diagnose and the early ones,

which is the same test, is between three to four million test cases per year total in US and Europe. That's our estimate. So there is total market of three to four million tests per year for this particular RA test. That's the volume. Then the price per test is of course a crucial testing. In autoimmunity test prices in generally lower than in cancer. So one has to take that into account. And the volume is higher, penetration may also be faster in this area, where you solve a problem that is crucial for the healthcare to move forward.

But we are conducting healthcare economy studies to get a more precise estimate of the cost of the price. And that of course is the challenge. But if you want to be conservative at least, say, half the price of the pancreas test, around 300 but that may change upwards once we do the healthcare study. But US$300 per test is something that one could think about at this stage. I want to say that we will do health economy studies and it may change but that's something to look for.

And then last question about the sales structure. We can use the current structure with additional sales because it's a different market, sales people for the introduction and establishment for penetration, one has to work very likely with partners that have established sales forces in the field and geography, may choose or will actually choose a different strategy per geography in this field.

Mikael Peterson
Okay. So US$500 million to US$600 million, that's sort of three to four million test times 150 or something like that. And yeah, this was per year exactly, yeah. And if the three to four million, which you think has potential to grow quickly over the coming years I think?

Mats Grahn
Yes. We think that's the need. If you look upon how many people are diagnosed with RA, but also how many are coming today to the centres and are having RA like symptoms and are investigated and that's significant multiple of the ones that actually have RA. Now all of these ones of course need a test, so that's why it becomes quite a substantial amount.

Laura Chirica
So why we call them the 'patients at risk'.

Mats Grahn
The patients at risk, yeah. So they include not only the ones that actually get RA diagnosed, but also the ones that have RA-like symptoms and another disease, so other problem. And that's why it's a little bit hard to talk to key opinion leaders driving large centres and they have slightly varying factors but it's three, five, seven times more than the actual ones that have RA that come. And when you move it out to primary care, it's going to be even more that do not actually have RA but still –

Mikael Peterson
Which in my ear it sounds like you should partner with somebody like Exact Sciences and Pfizer to get it out. You have to give away more but you get it out much, much quicker than you can do on your own?

Mats Grahn
It's a question when it comes to the large penetration following the healthcare reforms, that's correct. Also you need to prove to get you need to prove that it works and that's why it's great to have our own organisation to do the introduction to the specialists and so forth.

Mikael Peterson
And finally, obviously these numbers we are talking now is not included in the financial targets you communicated a couple of months ago?

Mats Grahn
They are preliminary, we need to do the next step, so after we have the results, but of course they also dependent on the better results you have the higher penetration rate you get. And so after this very important study we're almost starting, I think we should be able to give some guidelines.

Mikael Peterson
Thank you very much.

Operator
Thank you. Once again, if there are any further questions, please dial 01 on your telephone keypads now to join the queue.

And we have one further question coming through that's a follow-up from Lars Hevreng of Vator. Please go ahead. Your line is open.

Lars Hevreng

Yes, thank you. Just if you could give some indication on again on the timelines here. Should we expect similar regular process? I mean, you discussed it a bit with the sequential approach. But should we see – I mean, the potential for preapproval sales, let's say, in advance of the final prospective trials. So we could see sales in when you have this retrospective studies and finished and complete by 2021 or is this much longer processes than that?

Mats Grahn

Well, we anticipate to start to sales directly after introducing the LDT in US particularly. Then the CE mark here In Europe. So that's great starting selling there. And then of course some time before that we can start prospective study to collect data for reimbursement, which of course increases penetration rates.

Laura Chirica

And inclusion in guidelines.

Mats Grahn

And inclusion in guidelines, yes. So in that sense it's the same process. The difference is of course that we have our own infrastructure for the systems and so forth up and running fully, we have now developed them in parallel as you know with the first test here. So with the process internally will be much smoother but the steps from the market side is – well that's the market, that's how it is in diagnostic world.

Laura Chirica

That's the regulatory process.

Mats Grahn

That's the regulatory process, yes.

Lars Hevreng

Okay, thank you.

Operator

Thank you. Once again if there are any final questions, please dial 01. Okay, there seem to be no further questions, so I'll hand back to our speakers for the closing comments.

Mats Grahn

All right, thanks for listening. This is truly an exciting moment for the company. We are moving from a one product company into a platform in the extremely interesting area of autoimmunity and more precisely in the rheumatoid arthritis area. Using the healthcare reform ongoing for early detection of rheumatoid arthritis in patients at risk of developing RA. It is a three million test opportunity over that one. We also have the more fast penetration need where the specialist that need an immediate solution for the difficult-to-diagnose patients that test negative for the current standards, which is at least half a million opportunity test area.

And there is no tool working yet in the market and that's what we have very promising data to deliver. So truly an enthusiastic and important step for the company taking forward this project. So thanks for listening and I hope this gave you some more flesh to the bone when it comes to how we go about it in the autoimmunity field. Thanks for listening.

Laura Chirica

Thank you.