0:0:0.0 --> 0:0:6.210
Peter Traber
You efficacy and point and we're highly statistically significant, which of course is the first thing.

0:0:6.780 --> 0:0:37.30
Peter Traber
Uh, the response rate in the high dose group was 56% in dissolved, one which was done primarily in the US and 47% in dissolve too. Or you know approximately, you know, if you mean those, it's probably 51%, but 56% is very close to the same endpoint that we did in our compare trial, which was 54%. So this really.

0:0:37.90 --> 0:0:42.80
Peter Traber
Kind of met the expectations that we had for the efficacy.

0:0:44.840 --> 0:0:45.120
cfaba92d-c131-4088-a604-c6a55575e65a
Sorry.

0:0:43.140 --> 0:1:13.150
Peter Traber
We found very importantly that the response rate for patients greater than 50 years old was 65% in the US and 48% in the global studies, and this was the largest demographic group of nearly 70% of patients in the studies. It's a very prominent patient group that one sees in practice. It's a it was a predetermined then point that the FDA.

0:1:13.230 --> 0:1:28.210
Peter Traber
Wanted us to take a look at and so both we and the FDA feel that this is a a very important patient population and we were correct gratified to see that the response rate was even higher in this subset.

0:1:29.450 --> 0:1:50.590
Peter Traber
The third bullet point there is also very important, and that is that the majority of those that entered the six month extension phase, as you may recall after the six month primary endpoint in the US study, we had a six month extension that was blinded and that was.

0:1:51.50 --> 0:2:17.780
Peter Traber
Ohh was requested by the FDA because they feel they've patients will likely stay on this drug longer if it's being successful. And so they wanted to look at both safety and efficacy and what was really very gratifying about this is that of those that entered the six month extension phase, 75% remained responders at 12 months.

0:2:19.40 --> 0:2:49.820
Peter Traber
And they had no new safety signals, no infusion reactions over that second six months. So it is really a very clean and they continue to respond. Now, you may say, well, why not? Why didn't all of them respond? Well, various things happen for patients to drop out. For instance, one subject died in a

unfortunately in a motor vehicle accident. Other patients had adverse events that were unrelated to the drug. So people drop out of the study for various reasons.

0:2:50.330 --> 0:2:57.330
Peter Traber
And so therefore we looked at those patients that got the 12th dose in the 12th month.

0:2:58.0 --> 0:3:15.490
Peter Traber
Of those, 100% responded to the drug treatment. So this tells you that if you get through month six, you can you have a very high likelihood of not having any any adverse events and continuing to take the drug through a full year.

0:3:16.810 --> 0:3:29.460
Peter Traber
The next bullet point here was infusion reaction incidence. This was is the most important adverse event. I would remind you that in the.

0:3:30.570 --> 0:3:38.510
Peter Traber
In the recent PEGLOTICASE only trial there, infusion infusion reaction incidence was 30%.

0:3:39.470 --> 0:3:45.100
Peter Traber
Of the infusion reaction incidence in the high dose group was 3.4%.

0:3:45.820 --> 0:4:4.850
Peter Traber
Being very favorable to pegloticase plus methotrexate and that was something when I said exceeded our expectations. This was one of those points where we were hoping for a very good low infusion reaction rate, but we were quite pleased with this.

0:4:6.360 --> 0:4:12.410
Peter Traber
Uh, the next bullet point was a bit of a a a surprise and a pleasant one at that.

0:4:13.190 --> 0:4:21.820
Peter Traber
So in in clinical trials of gout, where you have a rapid reduction in serum urate levels.

0:4:22.540 --> 0:4:53.430
Peter Traber
Virtually all of them have an increase in gout flare rate after that, and this is quite prominent with pegloticase and even other drugs that drop serum urate levels. But in this study, when compared when compared to placebo, there was no increase in flat gout flare adverse events. We have more analysis to do on this, but this is a very.

0:4:53.520 --> 0:5:1.60
Peter Traber
Positive finding and could be a differentiator of this this therapeutic approach.

0:5:2.20 --> 0:5:7.850
Peter Traber
Uh, so it the overall we believe that the observations.

0:5:7.960 --> 0:5:28.760
Peter Traber
A of efficacy and safety that we found in these two DISSOLVE 3 trials really suggest that this is a potential new treatment solution with once monthly dosing versus more complicated regimens that are already out there.

0:5:29.440 --> 0:5:48.130
Peter Traber
And you know, Thomas, I think that while I have some backup slides that I could refer to because we wanna get into the Q&A, I don't think I'll go over those. I tried to cover them in, in this in this summary and we can move to other comments and then the Q&A.

0:5:50.540 --> 0:6:2.490
Anders Ullman
OK. Thank you very much, Peter. And this is Andersson. So let me ask commandos because I I yes want to emphasize that the combined select.

0:6:4.60 --> 0:6:33.370
Anders Ullman
Sobi team here are very, very encouraged and positive about the outcome of these trials. And and I are talking also about my personal reaction to to this my first of all, we we should not forget the fact that we have a large and largely underserved population here with, with with the significant disease burden and with the only roughly 5% of the patient population being on chronic treatment.

0:6:33.850 --> 0:6:37.600
Anders Ullman
Today we we are now demonstrating a.

0:6:38.340 --> 0:6:39.660
Anders Ullman
Well tolerated.

0:6:40.530 --> 0:7:5.440
Anders Ullman
Treatment with high level of sustained efficacy on top of that, we do demonstrate the value of the immunomodulator by the clear juice response and we have immunomodulator that clearly helped to create this favorable response with a still very favorable.

0:7:6.390 --> 0:7:8.190
Anders Ullman
Tolerability profile.

0:7:8.990 --> 0:7:9.640
Anders Ullman
So.

0:7:10.500 --> 0:7:41.150
Anders Ullman

With this we we of course we'll have to continue to to learn more about this and we should also remind ourselves here that these are really the top line data. We have multiple additional E secondary endpoints that still remains to be analyzed at cetera. So there will be more information coming out from this and and we will communicate in due time in, in, in various scientific media and and and meetings. But I would be very surprised if this is not.

0:7:41.220 --> 0:8:3.380
Anders Ullman
Being, well, very well received and the other day but by prescribers and as well as spaces. But maybe Tania, as you you are the only one around the table that have actually been treating these patients and and I know that you are excited about the results from, from, from your personal experience with these patients. Maybe you want to share your thoughts.

0:8:4.700 --> 0:8:13.820
Tania Gonzalez-Rivera
Sure. Thank you. Anders, I think you covered the main points. There is clearly an augmented in this population and as a a rheumatologist.

0:8:14.780 --> 0:8:45.650
Tania Gonzalez-Rivera
I personally face the challenges of dealing with a population that needs to be treated, has multiple comorbidities, and it's a challenge to find their right therapy for them. I think what this data filter through demonstrated that there's a significant difference from placebo at both thoses and are very favourable safety profile and then once monthly dosing as you mentioned can be appealing both to patients but also to healthcare professionals. So with that said, I'm very excited to have seen this result.

0:8:46.50 --> 0:8:51.870
Tania Gonzalez-Rivera
And very excited about the partnership that we have with with our our selector colleagues moving along with program.

0:8:54.330 --> 0:8:54.790
Anders Ullman
Thank you.

0:8:53.990 --> 0:9:9.280
Thomas Kudsk Larsen
Thanks, Tania. I think with that we'll we'll have more for Q&A. And I think there is a list of people already with the raised hand. I mean you can raise the hand, maybe we go through those five people now and then if you have further, please, please just chip in, I think first we have manners and manners from Deutsche Bank in London.

0:9:16.620 --> 0:9:17.480
Thomas Kudsk Larsen
Can you hear us, Manos?

0:9:19.120 --> 0:9:20.10
Thomas Kudsk Larsen
You may be on you.

0:9:20.870 --> 0:9:22.120
Anders Ullman
And this isn't mute I can see.

0:9:28.70 --> 0:9:37.220
Thomas Kudsk Larsen
See if I can unmute. Uh Manos, I cannot. Manos, can you just go back in the in the queue then we take the next person that is phone number. So I cannot see who it is.

0:9:38.70 --> 0:9:40.240
Thomas Kudsk Larsen
It's ending in 5909.

0:9:51.160 --> 0:9:55.790
Thomas Kudsk Larsen
That doesn't work either, as we go to next to that's Alistair and then we can certainly put C and also here Alistair.

0:9:57.600 --> 0:10:24.190
Campbell, Alistair
OK, look, thanks very much and I really appreciate you doing this today. It's it's super helpful and well done on the positive trial. So the data are good, but I wonder if I could just be devil's advocate on a couple of points and the first one is the not the absolute response rates, but if I was to think about placebo adjusted response rates in one of your trials resolved 2, there was a fairly significant placebo response rate and if I was to adjust for that, I could argue that.

0:10:24.880 --> 0:10:54.550
Campbell, Alistair
Placebo trusted response rights is sort of, you know, low 40s percent doesn't doesn't look that different from what you see from KRYSTEXXA monotherapy. So maybe you can just touch on that to see the response rate why you think that might be different in some of the trials there. And then the second question is just thinking about duration of response. So again, you've got obviously 75% of responders stay responsive after the additional six months. See if a file seems say a 50% response rate in the first six months, 75% or more of them.

0:10:54.730 --> 0:11:16.460
Campbell, Alistair
Are responders at 12 months, then you're down to an overall response rate of about 40% over that 12 month window. And again, if I look at the KRYSTEXXA data on the label, they're probably getting some like a 30% response rate after 12 months, but it's about 60% for a constructor plus methotrexate. So again, it's sort of comment on the duration effect and how you think that stacks up. That would be super useful. Thank you.

0:11:18.570 --> 0:11:19.260
Thomas Kudsk Larsen
Anxiety.

0:11:18.390 --> 0:11:37.260
Peter Traber
Yes, I I I can. I can. I can start on that. Yeah, thank you for those questions there. Very insightful

questions. So let me start with the placebo response. First, there were some, there are some design issues in the in our trial that might have given a higher placebo rate.

0:11:38.540 --> 0:11:52.450
Peter Traber
Yeah, me and specifically the entry criteria for serum uric acid, which in our study was greater than seven. And in the KRYSTEXXA studies, was greater than eight, so.

0:11:52.530 --> 0:12:23.350
Peter Traber
And so there is a possibility that individuals that are enrolled might drift under 6 by the six month and indeed Alistair, that's what happened. Yeah, for the majority of of those of those subjects they they basically entered a trial they then you know change their lifestyle, went on a diet, lost some weight. I'm I'm just saying things that they might have done and.

0:12:23.440 --> 0:12:29.340
Peter Traber
And then they they drifted down so that in the month six they were just below 6.

0:12:29.980 --> 0:12:47.420
Peter Traber
Now they didn't benefit at all from a marked reduction in serum urate over the course of the six months, which decreases tissue stores of urate. But by the criteria that we had, they they ended up being responders.

0:12:48.120 --> 0:12:51.770
Peter Traber
In the clinical trial we uh specifically.

0:12:52.450 --> 0:13:23.420
Peter Traber
The had a for the lower, for the placebo rate, about a 5% placebo rate anticipated in the statistical analysis and we hit that pretty much in the in the US study. It was a little higher in the in the DISSOLVE 2 study in the global study, the higher incidence was in Eastern Europe and we don't have a real understanding of that at this point why there might be differences other than just the random nature.

0:13:23.510 --> 0:13:32.940
Peter Traber
Of of controlled trials O your point is is well taken on the on the placebo rate.

0:13:34.480 --> 0:13:42.330
Peter Traber
But I think that it's a, you know, still, you know, 55 to 10% is pretty pretty low.

0:13:44.90 --> 0:13:51.190
Peter Traber
The the other the other question that you bring up about the long term?

0:13:52.640 --> 0:13:57.560
Peter Traber
Effects in the percentages. I think that's correct. Also, I don't want to.

0:13:58.280 --> 0:14:2.540
Peter Traber
Uh, the calculations you've done on the 12 month?

0:14:2.610 --> 0:14:16.150
Peter Traber
Ohh, the period sound correct, but we still have additional analysis to do on the overall data set before we say you know what percentage actually ended up.

0:14:17.0 --> 0:14:20.960
Peter Traber
And completing treatment period 12.

0:14:21.870 --> 0:14:27.40
Peter Traber
But the calculations you did certainly make sense.

0:14:27.600 --> 0:14:35.350
Peter Traber
Umm. What I the the other thing that I would say, Alistair and you didn't really ask this, but let me shift to this is.

0:14:36.430 --> 0:14:43.80
Peter Traber
The the comparison of SEL 212 to KRYSTEXXA.

0:14:43.800 --> 0:14:45.180
Peter Traber
In our view is clear.

0:14:46.340 --> 0:15:0.830
Peter Traber
Versus Chris Dexa alone, SEL 212 is better. It's more efficacious, it's much less, has much fewer infusion reactions and is overall a better looking drug from the phase three trials.

0:15:2.680 --> 0:15:20.800
Peter Traber
It's the comparison that with methotrexate plus uh KRYSTEXXA, where the real issue comes in and 71% at six months is better than any if 5056 versus 65%.

0:15:21.480 --> 0:15:34.190
Peter Traber
But in a in a clinical situation, it's not, in my view, significantly better to lead a physician and a patient to choose one over the other when there are other factors.

0:15:35.30 --> 0:15:49.840
Peter Traber
First of all, there is there are a number of reasons why you don't want to put somebody on methotrexate. And as you know in the horizon trial, they excluded people who had more than three drinks a week.

0:15:50.770 --> 0:15:55.580
Peter Traber
I don't know about Europe so much, but in the US, that's not many drinks a week.

0:15:56.880 --> 0:16:12.130
Peter Traber
And in this patient population, it's not. There's an issue of methotrexate and people with renal failure or renal insufficiency. And then furthermore, there's at least 20% of people who are intolerant of methotrexate.

0:16:13.0 --> 0:16:32.790
Peter Traber
So when thinking about that percent difference, the way I think about it as a physician is I'm sitting in front of a patient and I'm gonna tell them, well, we could give you SEL 212 and we will have a name for that. I'm sure soon, but we could give you this once a month.

0:16:33.580 --> 0:16:36.60
Peter Traber
You come in, we give you an infusions, you go home.

0:16:37.770 --> 0:16:58.530
Peter Traber
Or we can have you take methotrexate weekly and folic acid daily for a month. Then we can give you krystexxa every other week while continuing weekly methotrexate and heavy and daily folic acid. And your response rate in clinical trials may be 10% higher.

0:16:59.920 --> 0:17:5.440
Peter Traber
Those patients and physicians are going to say give me the monthly SEL 212.

0:17:6.130 --> 0:17:17.840
Peter Traber
Uh, which has the same or better in rate of infusion reactions than methotrexate? Plus KRYSTEXXA and I only have to come here once a month.

0:17:18.820 --> 0:17:37.430
Peter Traber
The physician's gonna like that because they don't have to worry about whether the the patient takes their methotrexate, whether they take it properly. You probably know that methotrexate is the number one cause of death due to medication errors of any medication.

0:17:38.60 --> 0:17:40.470
Peter Traber
Because if you take methotrexate?

0:17:41.670 --> 0:17:58.610
Peter Traber
Every day versus weekly to you get severe liver toxicity. So I I I'm just pointing out that the comparison is not strictly related to 71% versus 55 or 65%.

0:18:0.360 --> 0:18:1.480
Thomas Kudsk Larsen
You know, thanks to that.

0:18:1.560 --> 0:18:2.310
Thomas Kudsk Larsen
Yeah, yeah.

0:18:0.440 --> 0:18:6.850
Campbell, Alistair
Yeah, that, that's that's very clear, Peter. Thanks for that. And as a wine drinker, I'll be pretty good and SEL 212 gets approved. Thank you.

0:18:9.410 --> 0:18:28.210
Thomas Kudsk Larsen
You know, we actually got the the question that Manos wanted to ask, but Manos had some issues with his teams connection. So this is Manos from Deutsche Bank asking for. And I think it's good to do it now because it's better than what we just discussed. You wanted to ask about the size of the subpopulation and how many, what percent of patients are in editable from its traction.

0:18:30.170 --> 0:18:46.230
Peter Traber
Yeah, that's that's a very good question. Uh, monas you, you know the the the the number of patients in both trials over 50 over age 50 was 70% average about 70%.

0:18:47.100 --> 0:18:56.930
Peter Traber
Uh, so it's, uh. And in fact, if you look at a real world data of prevalence of it's a little hard to sort out those that.

0:18:57.970 --> 0:19:6.440
Peter Traber
That have chronic refractory gout, but it is at least that in the real world and in clinical practice and probably higher.

0:19:7.110 --> 0:19:17.510
Peter Traber
Umm, so it's 70% and your other your. Your other question was ohh yeah so.

0:19:19.110 --> 0:19:28.170
Peter Traber
We have not analyzed that over 50 population to look at potential contraindications to methotrexate.

0:19:29.530 --> 0:19:46.760
Peter Traber
I can say a couple of things about generalities. Number one, in a study done of people with with gout, the number of drinks over the number of people that drank more than three drinks per day.

0:19:47.430 --> 0:20:18.380
Peter Traber
Per day now, not per week was like 23%, so a pretty high proportion of that. I don't know about less

than 50 versus over 50 in terms of alcohol use. The other key thing though is that as you get over 50 in this patient population who is obese, has diabetes, hypertension, multiple concomitant medications that a lot of other things increase, for instance diabetes and.

0:20:18.440 --> 0:20:41.230
Peter Traber
And hypertension. It'll cause renal insufficiency, a lot of the drugs that that people are taking is concomitant medications for all these diseases can interact with methotrexate or any other drug, any other immunosuppressive drug. So. So I think that there's a variety of both comorbid diseases.

0:20:42.630 --> 0:21:3.210
Peter Traber
Concomitant medications and disabilities related to the diseases that people generate and accumulate as you get over 50, that means the safer, more convenient, straightforward treatment is going to be the more reliable one.

0:21:3.900 --> 0:21:4.830
Peter Traber
Uh, so?

0:21:6.740 --> 0:21:13.740
Peter Traber
I I I can't answer your question based on our data specifically, but I those are the general thoughts I would give you.

0:21:14.500 --> 0:21:19.600
Thomas Kudsk Larsen
Thanks, Peter. So I think we take the next question that is from Las at the Danske Bank. Please go ahead, Las.

0:21:21.330 --> 0:21:36.740
Lars Kristian Hevreng
Yeah, thanks. Can I just ask about the some of the side effects mentioned in the release such as the, I mean the cases of anaphylaxis, what, how did they resolve? And also on on what's mentioned on on stomatitis, what do?

0:21:37.410 --> 0:21:39.500
Lars Kristian Hevreng
People actually do when that happens.

0:21:40.420 --> 0:22:1.410
Peter Traber
Yeah, that those are both very good questions. First of all, let me take the anaphylaxis and infusion reactions. So each of those infusion reactions occurred during the infusion. So the infusion of the pegadricase, the your case enzyme is over a couple of hours.

0:22:2.720 --> 0:22:3.260
Peter Traber
And.

0:22:3.360 --> 0:22:3.890
Peter Traber
Uh.

0:22:5.350 --> 0:22:10.400
Peter Traber
20 minutes to an hour and a half into the infusion of they got the reaction.

0:22:12.260 --> 0:22:41.210
Peter Traber
The infusion was stopped and all the patients they received supportive care, which was fluids, antihistamines and some of them steroids, and they all resolved quickly and they all went home following the the resolution of the infusion reaction. So they were all handled readily without any sequelae. Now the important thing about this, I think, is, as you see on this chart.

0:22:41.290 --> 0:23:11.760
Peter Traber
The the Thomas has put up that all of the infusion reactions occurred in within the first three infusions. After that all the way through month 12, there were no other infusion reactions. So therefore it happens early in the course. It happens during the infusion, while the patient is monitored and in a medical setting and treatment complete, stopping the infusion and treatment completely reverses it.

0:23:12.0 --> 0:23:44.330
Peter Traber
With no adverse events after that, so that that piece of the infusion reaction, I think that answers your question about that. Now going to the stomatitis for those of you on the call or not familiar with stomatitis, stomatitis, any of you that have ever had a sore in your mouth like a a little ulcer in your mouth, a painful ulcer at this ulcer, virtually everybody, every human has had that at some point. So you may have experienced that?

0:23:44.900 --> 0:23:56.990
Peter Traber
Uh, that's stomatitis and that's an atheist ulcer and it's a well known adverse event that occurs with rapamycin treatment.

0:23:59.40 --> 0:24:12.820
Peter Traber
And by the way, it also occurs with methotrexate treatment. So just as a FYI, if you look up adverse events with methotrexate after this ulcers and stomatitis are complication there.

0:24:13.770 --> 0:24:20.140
Peter Traber
In so we have seen in previous studies and we saw in this study an incidence of stomatitis.

0:24:20.990 --> 0:24:23.200
Peter Traber
Uh, it occurred.

0:24:24.570 --> 0:24:32.660
Peter Traber

Early in the treatment periods, it happened mostly in treatment period. One or two if it was going to happen at all.

0:24:34.300 --> 0:24:45.870
Peter Traber
It did not stop anyone from continuing on it with therapy, so it was not. It was not severe enough that they didn't come back.

0:24:46.930 --> 0:24:48.540
Peter Traber
Of where their next dose.

0:24:49.200 --> 0:25:0.170
Peter Traber
Uh, over 60% were were mild and the rest were moderate in nature. There were no severe reactions.

0:25:0.880 --> 0:25:23.350
Peter Traber
And the way it's the way it's handled. If necessary, you can take a mouthwash with some steroids in it for that can help for the pain and in the study and in our previous studies, we do offer people that mouthwash if if it's bothersome enough and.

0:25:24.730 --> 0:25:42.990
Peter Traber
Virtually nobody accepted that. They just said no, it's not that bad. And then went on. We have used it in the past and it's available. So basically the stomatitis is a real adverse event that is related to rapamycin.

0:25:43.570 --> 0:25:55.100
Peter Traber
Uh, yeah, but it's mild to moderate occurs in the first couple of infusion periods and stopped nobody from continuing the the medication.

0:25:57.40 --> 0:26:5.960
Thomas Kudsk Larsen
And Peter, I think you will probably will find it if they look at the label for you know revenue, I think next obvious Ian from Jefferies. Please go ahead, Ian.

0:26:6.790 --> 0:26:14.830
Eun Yang
Thank you. So I have one question to your doctor, Tania Riviera and a couple of questions to Sobi. So.

0:26:16.180 --> 0:26:42.850
Eun Yang
That the Riviera in your practice, what percent of chronic outpatients? Who would be good candidates for Chris takes the plus methotrexate but have not been able to take the combination drug due to, you know, comorbidity medications or heavy drinking overweight, whatever the reason. And what would it be the percentage of patients in your practice?

0:26:44.270 --> 0:27:14.780
Tania Gonzalez-Rivera
But the clarify I currently I part I I work absolutely so I'm currently not seeing patients I have prescribed respects that in the past in terms of percentages. I think Peter did a really nice shot at summarizing some of the data that is known about patients with dramatic PCs and potential contraindications to methotrexate in terms of comorbidities such as alcohol intake potential liver disease.

0:27:15.530 --> 0:27:41.810
Tania Gonzalez-Rivera
So so I think it it it, it really felt to 12 would be able to add to the armamentarium of room apologist that would feel hesitant to prescribe patients who have communications to methotrexate and it would fit nicely in that toolbox to treat chronic graph factory gout patients, which clearly there's still not might need and less than 5% of patients right now are being treated by creased except.

0:27:42.890 --> 0:28:3.760
Anders Ullman
I I think on top of that as a I Once Upon a time also as a practicing Dr. and to to really knew the truth on the patients alcohol habits is quite a bit of a challenge. And I would say and I have been treating pulmonary patients with methotrexate. And I would say that if I.

0:28:5.20 --> 0:28:29.910
Anders Ullman
I hope that I will not be in a situation where I would be the subject for chronic treatment with methotrexate it it's not, it's not a trivial chronic treatment to take. So if there are options with more favourable safety profiles, I I think you with or without absolute contraindications, I I don't think that methotrexate is is a very light drag for chronic treatment.

0:28:31.580 --> 0:29:2.450
Eun Yang
Thank you. Umm, so in terms of manufacturing, it's done by third parties in the US filing has been delayed because you needed some more work on the manufacturing side. So could you kind of a level elaborate on what's needed in order to Firefox program in the US and then a second question to SOBI is the Chris Taxi is quite expensive. So I will not ask you how you are thinking about the pricing in the US and how about ex US?

0:29:2.630 --> 0:29:9.960
Eun Yang
Aware you may not have such a pricing power as this may not be considered as a orphan disease.

0:29:10.650 --> 0:29:11.110
Eun Yang
Thank you.

0:29:15.410 --> 0:29:25.680
Anders Ullman
And I should yes, I understand the first part of your question. So you asked for what, what additional work that we need to need to do before we can fight, was that your question?

0:29:26.210 --> 0:29:26.700
Eun Yang
Yes.

0:29:28.60 --> 0:29:28.300
Anders Ullman
Yeah.

0:29:26.150 --> 0:29:29.120
Thomas Kudsk Larsen
Yeah, exactly. And and focused on CMC on us.

0:29:30.380 --> 0:29:38.450
Anders Ullman
Yeah, I mean, I've first of all and I we we are we have yes got the top line result of to large.

0:29:39.800 --> 0:29:59.720
Anders Ullman
And and complex studies that so, so, so we we need to complete the analysis we need to do all the reports and etcetera out of of that there are some then ongoing preclinical activities and manufacturing sync issues that and and.

0:30:0.520 --> 0:30:0.970
Anders Ullman
And.

0:30:1.920 --> 0:30:32.820
Anders Ullman
Which which have been a little bit slower than originally planned and and to a large extent driven by some COVID related things with the closure of labs and and hoping the time etcetera with collaborative partners as suppliers. So. So this is the, this is all kind of standard operational work in the hands of professionals in our organization. It will take a little bit more time to operate and live with this than we initially planned but but.

0:30:32.890 --> 0:30:33.160
Anders Ullman
Yeah.

0:30:33.480 --> 0:30:49.580
Anders Ullman
And wait, wait, wait. It it's a. So wait, wait, wait. I brought this up with that that time. But but we we we did not think that there this is anything that is the adding and any considerable risk to to a favorable submission in in.

0:30:50.510 --> 0:30:52.580
Anders Ullman
In Internet not too distant future.

0:30:53.930 --> 0:30:57.840
Anders Ullman
In terms of pricing etcetera, that that that is.

0:30:59.170 --> 0:31:5.720
Anders Ullman
Beyond my scope and Gator, you want to give any comment or or I guess it may be a bit too early.

0:31:11.970 --> 0:31:25.700
Guido Oelkers
Sorry, I know. Yeah, no, I think this is a very explained. You know, we had some issues, I mean that you that were mostly covered related and as a consequence we had to tackle this. But we feel that we are in charge.

0:31:26.480 --> 0:31:37.780
Guido Oelkers
And we will, we will deal with this. So that's the reason why we laid out the timeline as we have done, but we don't see a showstopper and what we feel is that we have a product.

0:31:39.910 --> 0:31:42.350
Thomas Kudsk Larsen
And and then the pricing question, you know.

0:31:45.190 --> 0:31:45.460
Guido Oelkers
Uh.

0:31:39.830 --> 0:31:46.220
Anders Ullman
But it it is taking part of the questions. What what what what? What? What? What what about the pricing strategy in relation to cross sexual prices and?

0:31:46.650 --> 0:32:17.120
Guido Oelkers
Uh, yeah, sorry. The pricing one is simple. You know we we don't see that any need to you know we at this juncture I mean it's too early but you know we don't see any any reason with such a great product to discount. So we we think you know that we can if you position it at parity it's a good way with this is our base case but you know we will update our base case close to launch but this is how we're thinking about it it's a I mean this data we think are very strong as a consequence we will stick by the product.

0:32:18.300 --> 0:32:20.990
Eun Yang
How about ex US uprising? Excuse me.

0:32:22.290 --> 0:32:32.920
Guido Oelkers
Yeah, ex US pricing, you know, to be honest, I wish we could dictate this. You know, in Europe we will be in the hands, obviously off the reimbursement authorities historically.

0:32:34.460 --> 0:32:37.250
Guido Oelkers
Obviously, the attempts from horizon were not that.

0:32:37.430 --> 0:32:44.140
Guido Oelkers
The the successful and we will I think come forward and see what the opportunity is.

0:32:45.650 --> 0:32:48.160
Guido Oelkers
I think there's some room for differentiated pricing.

0:32:48.970 --> 0:33:20.720
Guido Oelkers
But I think that's that's too early to to discuss because simply, you know the I mean as you ignore the the European pricing also reverse went authorities are quite stressed right now with paying for the bills of COVID and after you and you know, Ukraine war hasn't helped, you know to to fill the pockets of the government. So as a consequence, you know, there's a bit of stress I think we will tackle this when we are there. But you know we will definitely make an attempt to see whether we can make it economically work.

0:33:20.820 --> 0:33:23.390
Guido Oelkers
But you know, there's a bit of flags, but you know, within reason.

0:33:24.850 --> 0:33:25.500
Guido Oelkers
I did.

0:33:26.480 --> 0:33:26.830
Guido Oelkers
Yeah.

0:33:24.350 --> 0:33:41.450
Eun Yang
But can I ask you one more question on the XPS filing you guys are planning for it, but I guess you also needed this the CMC work to be done. So do you expect ex US filing to be in a in a similar time ranges the US filing?

0:33:42.220 --> 0:34:12.130
Guido Oelkers
No, I think this will be will be more subsequent. I think there will be some time delay, but we have working out now the timelines. We are gratified that we have the product now and with this fantastic data and and now it's a it's we will have to work this out. We basically only guide at this stage or the US beach is which would be enough for the to make the case work for an hour books it's a it's a significant opportunity but we will go beyond that now and we will update the market on information on and other in other USD.

0:34:12.220 --> 0:34:12.490
Guido Oelkers
Options.

0:34:13.730 --> 0:34:14.230
Eun Yang
Thank you.

0:34:15.130 --> 0:34:15.710
Guido Oelkers
Thank you again.

0:34:16.260 --> 0:34:28.520
Thomas Kudsk Larsen
I think we have about 7 minutes left and we have two questions. So if we can maybe keep questions and answered a little bit shorter than we have time for everyone. So Victor at the nadias next please, please go ahead, Viktor.

0:34:29.660 --> 0:34:45.910
Sundberg, Viktor
Yeah. Hello. So sorry, I attended the this call little bit late, so sorry if my questions are already covered, but I as wondering about this in fusion reactions, how we should compare them to KRYSTEXXA? So it was about 3.5% infusion reactions.

0:34:46.850 --> 0:34:49.360
Sundberg, Viktor
In the DISSOLVE one and two studies.

0:34:49.440 --> 0:35:9.530
Sundberg, Viktor
Yeah, yeah. Are there any confounding factors we think about when we compare that to KRYSTEXXA is noticed that in your study, the definition was one hour post infusion? And I think increased text, it was two hours or are there any other things which should have in mind here when you think about the future reactions and how we should compare them?

0:35:10.500 --> 0:35:16.700
Peter Traber
Yeah, it's a good question. And we did talk about this, but I'll be, I'll be brief in this. First of all the.

0:35:17.540 --> 0:35:48.130
Peter Traber
The the infusion reactions in in in both with both KRYSTEXXA and SEL 212 were defined by common criteria, so they were the definition was the same except for the one versus 2 hour. I did look at all of the infusion reactions and the one hour definition would have encompassed all of the KRYSTEXXA infusion reactions and vice versa. Obviously, there are two hour would have encompassed our one hour, so there's really no difference in the definition.

0:35:48.410 --> 0:35:49.890
Peter Traber
Yeah, that resulted.

0:35:51.880 --> 0:36:1.960
Peter Traber
The the infusion reactions all occurred during the infusion and they were adequately treated with stopping the infusion.

0:36:2.420 --> 0:36:21.790
Peter Traber
Uh. Fluids, antihistamines and steroids. Everybody recovered and and went home with no fur with

no sequelae. So and they all occurred in the first within the 1st 3 doses of the drug, and then in those that continued on through 12 months there were no.

0:36:22.930 --> 0:36:48.540
Peter Traber
There were no infusion reactions out through 12 months, so R 3.4% is quite favorable in in comparison to the over 4%. I think 4.44 point 5% in the methotrexate plus plus KRYSTEXXA trial. I I don't know that that's really different, but it's it is a lower percentage in our trial.

0:36:49.800 --> 0:37:10.10
Sundberg, Viktor
At a very quick follow up questions. Also I noticed that in the subsequent 6 month period, 76% of the patients that responded in the first six month period continue to have our response to the drug. Is that in line with KRYSTEXXA or higher or lower or if that's already been covered?

0:37:11.860 --> 0:37:36.430
Peter Traber
You know, we, we we didn't report on that and earlier we had a question from Alistair who had done the math and you know you can you can do some of the math to see whether it's the same or different. But I think the response rate is quite high and quite robust after after six months with the SEL 212.

0:37:39.160 --> 0:37:43.60
Peter Traber
Yeah, probably leave it at that rather than redoing Alistair's math.

0:37:44.160 --> 0:37:46.70
Sundberg, Viktor
Thanks. OK, thank you. That's all for me.

0:37:47.400 --> 0:37:52.830
Thomas Kudsk Larsen
Thanks, victor. I think the last question so far at least is from Peter at the Perito. Please go ahead, Peter.

0:37:54.300 --> 0:37:55.830
Peter Östling
Yes, thank you. Can you hear me?

0:37:56.570 --> 0:37:57.830
Thomas Kudsk Larsen
We can. Yeah, indeed.

0:37:57.600 --> 0:38:13.340
Peter Östling
Yeah. OK. Thank you. Thank you for arranging this interesting Q&A. Two very quick ones. First, is there any milestone payment related to the presentation of the face, the top line results that you have to pay to select the?

0:38:18.590 --> 0:38:25.270
Guido Oelkers

But I think you know the the milestone spared man will become. No, it will become due when we submit.

0:38:26.450 --> 0:38:29.860
Peter Östling
OK, OK, great. And and finally, uh.

0:38:30.730 --> 0:38:34.0
Peter Östling
Previously you have presented the 212.

0:38:34.690 --> 0:38:40.990
Peter Östling
Uh. Potential or only as more or less US?

0:38:41.530 --> 0:38:48.510
Peter Östling
Uh. Potential. So why are we are we? Are we talking about ex US?

0:38:49.70 --> 0:38:56.620
Peter Östling
Yeah, marketing here since that has never been on the table when we have discussed 212 in the past.

0:38:57.330 --> 0:39:29.860
Guido Oelkers
Yeah. I mean it's an option. I think it's an option and you know and we will review this because you know there are, you know a patient that needs were in order also in obviously in Europe and other eurusd diction. People are suffering from chronic refractory guard, pay us, have a different perspective on the treatment at least historically. So but you know we we will feel encouraged still to to go to them but at this stage I would not make this part of your of your of your valuation I think it's it's not necessary because you know.

0:39:29.940 --> 0:39:35.390
Guido Oelkers
It's such a boss opportunity anyway, but you know, as soon as we have more feedback.

0:39:36.520 --> 0:39:43.670
Guido Oelkers
From from, from agencies, we will obviously provide to us and see you know in what way we should think about this.

0:39:44.260 --> 0:39:54.30
Peter Östling
Yeah, just a quick before we we end this session. Can you talk anything about the cost of goods? Is this an expensive?

0:39:54.930 --> 0:40:1.610
Peter Östling
Combination to manufacture or is Cox in the normal formula on the formal level.

0:39:59.960 --> 0:40:7.830
Guido Oelkers
Yeah. No, I think, yeah, I think you know, in terms of gross margin impact, I think it's, it's new to.

0:40:8.770 --> 0:40:10.730
Peter Östling
OK. Thank you. Thank you guys.

0:40:11.360 --> 0:40:11.950
Guido Oelkers
Thank you.

0:40:12.620 --> 0:40:22.850
Thomas Kudsk Larsen
Thanks. Thanks Peter for that question. Yeah, are there any last question we have about a minute left if there is a quick one last from Danske Bank has last question here please last.

0:40:24.20 --> 0:40:42.930
Lars Kristian Hevreng
Yeah. Thanks. I I just wonder about the the time gap between the rapamycin component and the the peg. Let the downstream component, what's I I should know that, but what what is that and that's that does that have any correlation with the immunogenic profile or or or the infusion reactions etcetera?

0:40:43.670 --> 0:40:51.410
Peter Traber
Yeah, I know the the infusion of of the M tour, which is the nano encapsulated wrapper mycin is given first.

0:40:52.90 --> 0:41:6.760
Peter Traber
And then 30 minutes later, the pegadricase of Euro case component is given. So it's always 20 to 30 minutes following the revised and dose and that's that was standard throughout all of our studies.

0:41:8.410 --> 0:41:9.210
Lars Kristian Hevreng
All right. Thank you.

0:41:10.700 --> 0:41:33.480
Thomas Kudsk Larsen
Range last. So with that question, I think we closed the session for today. I would just like to say thanks to everyone that they had time to dial in. I know you're busy with other companies as well and also thanks to our friends at Selecta, including Peter for for making themselves available to help answer the photo on questions from yesterday. And if there's anything else, please let me know. I'm happy to get back by e-mail or phone later on.

0:41:35.780 --> 0:41:36.110
Peter Traber
OK.

0:41:37.0 --> 0:41:37.410
Thomas Kudsk Larsen
Thanks.

0:41:36.10 --> 0:41:39.80
Guido Oelkers
Yeah. Thank you so much for your interest. Very much appreciate it. Thank you.

0:41:39.770 --> 0:41:40.450
Peter Traber
Thanks so much.

0:41:38.790 --> 0:41:41.50
Anders Ullman
Thank you, everybody. Thank you. Thanks, bye, bye.

0:41:40.190 --> 0:41:41.970
Guido Oelkers
Thank you. Thank you. Bye.

0:41:43.440 --> 0:41:43.990
Peter Östling
Thanks.