



Galapagos NV

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Laerke Engkilde: Welcome everyone to day four and the final day of the J.P. Morgan Health Care Conference. I'm Learke Engkilde, European Pharma and Biotech analyst, and it is my great pleasure to introduce from Galapagos, the CEO of Onno Van de Stolpe.

Before I hand over to Onno for his presentation, I would just like to remind everyone that you can post your questions at any point throughout this presentation through the conference portal. I will then ask your questions for you once we get to the Q&A portion of this session. With that, over to you Onno, welcome to the conference.

Onno van de Stolpe: Thank you, Learke. Thank you for giving me the opportunity to present, and thank you all for joining this presentation by Galapagos, which is somewhat of a milestone because it will be the last presentation where I will be representing Galapagos.

After 23 years, I will be retiring this year, so it's a lot of unfortunate that it has to be virtual, but that is the reality of today. Let's go to the disclaimer. Please take a moment to read that in your time, but we don't have time to go through all that today. 2021 has been a very challenging year for Galapagos.

We had a number of serious roadblocks and that has resulted in clearly a loss of confidence of the investors, a drop in the stock and a re-organization within the company as well. I'm very optimistic that in 2022 things will revert. We will be heading with a new CEO into new directions.

We hope to be announcing the appointment of a new CEO in weeks rather than months, so there will be a new view on the company, and the person who will be heading it has a fantastic legacy to start with.

We have our proprietary target discovery platform with everybody, with all the technologies in there to bring molecules towards the clinic and to the patients. We have a pipeline that is early

but clearly very differentiated.

We have a product on the market. Jyseleca so filgotinib where we are marketing that in Europe. We have the fantastic collaboration with Gilead, a 10-year alliance where we joined together in early-stage research with the idea to together bring new mode actions to the patient and with a fantastic cash balance with 4.9 billion Euro in the bank. We are one of the best-funded biotech companies out there.

If we look at the portfolio, it's clearly very differentiated with different therapy areas in inflammation, in fibrosis, and some other areas where we are in early research exploring new mode of actions.

The problem, of course, compared to last year, is that we have lost out on a couple of late-stage assets. We had a failure in our IPF program and a failure in our OA program. Therefore, you now see a discrepancy between our product filgotinib on the market and the other programs that are in Phase 1 or Phase 2.

Today, I will be highlighting our TYK2 program as well as our Toledo the SIK class, and I'll talk a little bit about the ADPKD, a program that is currently in Phase 2. It's clear that we need to bridge the gap here in the pipeline between where we are today and where filgotinib is and that we are in need of a later stage asset.

We have a massive BD effort ongoing to see if we can supplement our pipeline with an attractive molecule throughout, in-licensing, or through an acquisition. Let's start with our TYK2, '3667 is a molecule that we developed internally.

It inhibits TYK2, and we tested it in Phase 1b in psoriasis, you see here quite compelling scores with the '3667 high dose compared to the placebo and the low dose. We were very encouraged by this data, and we are currently exploring how to proceed with this molecule from here on. Safety was fine.

The activity was consistent across different endpoints, and we clearly hadn't reached the plateau after three weeks. With this, we know we have a strong inhibitor of TYK2, and that opens up a number of possible indications that we can develop this molecule in.

We're looking at ulcerative colitis, psoriasis, of course, but also other indications. Of course, there are concerns regarding the TYK2 by the FDA. Will they label this in the same class as the JAKs

which would mean the same black box warnings, which would be a big hinderto bring this to the market in the United States. We are looking here at BMS with Deucra, who are ahead of us. That is also a TYK2, although a different mechanism, and it's an allosteric inhibitor. We are going to see how the FDA is going to treat Deucra and determine based on that what the development strategy of TYK2 for Galapagos is going to be.

It's an attractive program that we will develop from here on in a Phase 2b study, hopefully, this year. Let's switch gears here and go to the SIK to lead a program where we believe we unlocked through our target discovery platform a very attractive mechanism to restore the immune balance of the patient. If you look at this graph, it's in the illustration. You see that in a disease there are too many pro-inflammatory cytokines active, and the immune-regulation is out of balance.

That causes the disease where the current therapies are restoring this by actually inhibiting the pro-inflammatory cytokines. We believe that a better way is to increase the immune regulatory proteins together with inhibiting the pro-inflammatory cytokines.

That mechanism is the basis of the SIK approach, the Toledo approach to inhibit those targets and restore that balance. We had our first clinical programs here delivering with '3970, which is a SIK2/3 inhibitor.

We saw promising activity in psoriasis at week six, where we saw compared to the placebo a nice reduction in psoriasis clinical activity. However, when we looked at UC we saw activity, but not dramatic. We saw a reduction in the impact on the endoscopic lesions.

We saw an improvement in the endoscopic readout as well as the histology score, as you can see here, compared to placebo. The data were not as profound that we could based on this, continue the program as is.

We need to find inhibitors to the SIK that are more active and likely more selective in inhibiting SIK2 than '3970 itself. What we found, though, is that SIKs have a pioneering role in inflammation.

They confirm our initial assumption that they play a role in inflammation and we unlocked a new mechanism here. The early results are encouraging, although not strong enough, for continuation of '3970.

We're going back to the portfolio of molecules that we have, and we're going to find the ones that

have a higher target engagement and likely more selective for SIK2 and/or SIK3. We're going strong on the SIK class. It's the biggest research program that we have within the company, and we remain together with Gilead, very enthusiastic about this program going forward. Let me spend a minute on autosomal dominant kidney disease.

This is a program which we inherited from our CF collaboration at the time, where we identified a target that could play an important role in this very malignant disease. It is a cyst growth leading to kidney failure.

It's an orphan disease, but with a high unmet medical need, and we believe that our molecule could provide very interesting Phase 2 data. They are expecting early 2023. It takes a long time to do these trials, so our trial is running for a whole year.

It's fully recruited, and we anticipating the first day, the data in the first quarter of next year. Here you see the trial design. We got 40 patients on drug with 20 on placebo. These are adults with rapidly progressing ADPKD, and we're looking at the kidney volume, safety, and tolerability, of course. Interesting program, high risk, but with potentially very high upside.

Couple of words on cystic fibrosis. This is a program we have spent many years in research to develop in collaboration with AbbVie. In 2018, we decided to out-license all our rights and all our activities to AbbVie, who continued on the basis of our program with the CF program.

They are making progress. They anticipate Phase 2 data, both of the triple, as well as the double in 2022. Interestingly enough, it looks like two of the three molecules that AbbVie is testing originate from our own portfolio, which would be a very interesting relationship to the royalties.

We are eligible for royalties depending on how many of our molecules end up in the triple and if it would be two out of the three, we would be above the 10 percent in royalties that we would get on global product sales, which would be an attractive future for this program for Galapagos.

We also get some additional milestones, 175 million. Let's cross fingers that AbbVie is able to come up with a competing product to the franchise that at the moment is completely dominated by Vertex.

Let's switch gears and talk about Jyseleca, our preferential JAK1 inhibitor, filgotinib is the molecule that that we developed. We discovered the target and developed filgotinib in-house together with Gilead, completed the Phase 3, and now marketing this molecule in Japan and in Europe.

Galapagos has taken over the full marketing of this product in Europe. We are the marketing authorization holder and we launched it both in RA, as well as in ulcerative colitis. It's a product with two indications approved at the moment.

This program, as a stand-alone in Europe, has a positive MPV. It's a profitable business case, but it takes time to get there. It takes a massive investment to build up commercial infrastructure throughout Europe and all the different countries and to build a base on which to sell this product to the patients.

We have previously communicated a peak sales of this product of about 500 million in Europe, which we anticipate to reach by the second half of the 20s. At that moment, we will get a margin at about 50 percent. That's attractive. It's not massive like if we would have multiple products in the commercial organization, you would get to margin between 60 and 70, but clearly, it's profitable by itself. We now have the full commercial structure in place. We've taken over a lot of the activities of Gilead, those employees have transferred to Galapagos and all the people are now employed by Galapagos in the commercial organization throughout Europe.

We anticipate to be break-even and cash flow positive in 2024. After 2024, it's going to contribute to the cash in Galapagos and contribute to the profitability of Galapagos in the future.

We still have a long time to go to patent. Exclusivity runs until 2035, so there are many years between the breakeven of 2024 and 2035 when the patent lapses. The launch in Europe never goes very fast.

You have to get not only the authorization which got through the EMA last year, but you have to get reimbursement in all the different countries, different structures, different rules, and therefore it takes a long time before all the countries are on board.

The last ones came on board in recent months, and you see the sales going up nicely. You see, an inventory situation in the summer, in June and July. For the rest, this is developing, as we had anticipated in our plan. You also see in orange, the part of the sales that are done by Galapagos, the grey is by Gilead.

You see, that is phasing out, and we are now doing all the sales of Jyseleca in Europe by ourselves. It's going clearly according to plan into the right direction. Although the numbers are still very small next year, it should be substantial higher.

Do you see the reimbursement that we were able to obtain, we've reimbursed in 14 countries at the rapid speed in a couple of countries, the procedures are still ongoing, and we have in grey, in the rest of Europe in agreement with Sobi, where there they are our licensee partner, and bring it on the market in those countries.

It's interesting how the JAK market continues to grow in Europe, basically against all odds, because humira has gone generic, so there's a lot of cheap competition towards the higher-priced JAK class.

There was negative news this year around Xeljanz, an early date JAK inhibitor from Pfizer that based on that, FDA decided to add additional Black Label warnings on the JAKs in the US. The EMA has not agreed to the pessimistic view that the FDA has on this class. There are no black-box labels here on the JAK class, and you see the JAK class doing extremely well in Europe still growing against all these odds.

You see it on the total market share, but more importantly, even on the dynamic markets, which means the patients that switch more and more, they are going towards the JAKs, and as you can imagine, they are going less towards Xeljanz and more to the new JAKs, including filgotinib. That is a good bode for the future.

The reason patients and doctors are going towards the JAK class is the advantage that it has over the biologics. It is fast mode of action in a couple of weeks. It's an oral once-a-pill day, and as it's in the small molecule, you don't have the autoimmune antibodies that you have when you are starting to treat with an antibody.

There are many reasons why the oral JAK class will continue to grow in Europe, and we think filgotinib Jyseleca can profit from that. If we switch to UC ulcerative colitis, you see that the JAK class is only very small, represented here by Xeljanz, the first tofacitinib, the first molecule brought into the UC space.

We now have approval in this space. We have started marketing and selling Jyseleca in UC and Germany, and the Netherlands, and the rest will follow in this year when all the reimbursement discussions are going to conclude with health authorities in all these countries.

At the moment, you see with 73 percent that the anti-TNF still has the dominant role here, but rather than in RA, the treatment of ulcerative colitis, remains extremely challenging. The

remissions are suboptimal. There is a corticosteroid dependence. There are many safety concerns, and the treatment is very complex.

There is a need for new treatment options, and we believe that the JAK class and especially Jyseleca, can play an important role here. It's an opportunity because of our rapid response sustained clinical remission where you can taper the corticosteroids, a very good experience with that.

Physicians are very excited about it. We have demonstrated safety and tolerability profile and as I said earlier an oral JAK is convenient with a single dose once daily.

A couple of data, here you see the partial Mayo Clinic score, and you see the effect compared to placebo, both in biologic naive as well as insufficient responders.

In both cases, we see a very nice effect of Jyseleca versus placebo, and this is as fast as week two. It's a very rapid onset of action, but also in maintenance. You have induction and maintenance in UC.

You see here maintenance three different scores, the clinical remission, very important histological remission, and six-month corticosteroid free clinical remission. You see that in all three scorings, filgotinib Jyseleca does very well compared to placebo. We have high hopes and expectations regarding filgotinib in ulcerative colitis.

We launched it in Germany and the Netherlands already, and the rest we will roll out this year where the discussions with the health authority and insurance companies are ongoing. What does that mean for our financial outlook? We have given guidance for last year of around 550 million burn.

You see that about 40 percent of that is associated with the buildup of the commercial organization. That's not paid back by the sales of the program yet, but we believe that in 2024, the total program will be breakeven.

From that on, we'll start to contribute and more and more over the years to come, and Jyseleca will help to reduce the burden of the remaining part of the company that at the moment is, as you've seen in the pipeline, based on a number of programs that are moving forward towards the patient.

Our cash burn guidance of 2021 was between 530 and 570 and we're expecting to not increase

over the years to come clearly.

With that, I can conclude, if you look at the foundations for future growth, we remain committed to new mode of actions, novel targets that we discovered through our engine and move forward from target discovery all the way to approved products, commercial with the rollout in UC, and commercialization in RA.

We have high hopes for filgotinib going forward.

Business development, as I said in the beginning, we need to bridge the difference in pipeline maturity between the early programs and Jyseleca being commercial.

We are looking forward to getting a deal done, being a license or an acquisition. We will continue to have stringent cost discipline. We understand that with the current pipeline, we have to be very careful not to spend too much money.

We got a lot 4.9 billion Euro in the bank, but we got to be very prudent in making sure that we get a maximum turnout of that in new mode of actions that we can bring to the patients. 2022 will be a year of change, clearly because the new CEO coming on board which will bring different views, different strategies, and a new energy.

We are excited about it. We are excited about Galapagos going into a new direction, but after 2023 years with me at the helm, it's time for somebody to take this on and take Galapagos into the next future, which we believe will be very bright and we will rebound from the lows that we have seen over the last year. With that, I hand it over to Laerke.

Laerke: Thank you very much, Onno, and before we kick off with the Q&A, let me just remind everyone that you can post your questions through the conference portal. With that, maybe I'll just kick-off.

You mentioned about the hope to be able to announce a new CEO in the coming weeks, even. Could you just remind us what kind of person the board is seeking to hire and personally for you, what do you think is going to be key for him or her to get right?

Onno: Yeah. The board has communicated that they are looking for a seasoned executive with a strong R&D background, which makes perfectly sense for the status of the company we are in.

We need to come up with further programs in development to bring to the clinic to give

commercial a broader base to further grow the organization in Europe. And I think that the challenges for the new CEO will be to identify and license or acquire products to fill the gap that we currently have in the pipeline for both areas.

For one, we have a large development organization that we need to use to bring molecules forward. That is in place, and it just needs more ammunition to go. Secondly, for the commercialization organization, we need more products in there than just Jyseleca. That's the big challenge.

For the rest, I don't think there is a lot that needs to be fixed. We got a fantastic organization. We got a fantastic culture, fantastic people. We just need to refocus and to start to dream again in the new set of products that we're moving forward.

Laerke: Very clear, and I've got a question here from an investor asking about your confidence in the cystic fibrosis program at AbbVie and how you view the potential upside for Galapagos there.

Onno: Yeah, maybe it's good to hand it over to Walid, our CMO, to answer that. Walid.

Walid Abi-Saab: Thank you Onno. Good morning, good afternoon, everybody. There's been a diligent work between us and AbbVie for a number of years and there were strong building blocks with the corrector '2222, and the potentiator '3067 that is being used now as part of the triplets.

From knowledge about the details of the program after it was handed over to AbbVie, we have not been kept informed of the details, so to speak.

Then, that's fully understood because AbbVie is now responsible for the program and leading it forward, but knowing them and knowing the criteria that we had set together forth about what we need to see to make it forward to make it a success, I would be very surprised if AbbVie would take something that would have a chance to not be competitive. We're looking forward to the results of the triplet this year, this quarter, I should say, as AbbVie guided and they will be in the best position to decide about the next steps, whether this will be competitive or not. For patients, it's always better when you have more than one option. That's AbbVie should be commended for pushing this forward. Thank you.

Laerke: Thank you very much, and maybe sticking to sort of pipeline, but turning to your own internal pipeline. You spoke about your excitement in the presentation on the Toledo program.

You have a follow on SIK2/3 in the clinic. I believe we're also expecting Phase 1 data from your SIK3 inhibitor '4399 this year. What are your latest thoughts on inhibiting SIK3 alone versus SIK2 and 3 combined? At this point in time, what do you believe is the winning approach based on the data seen to date?

Walid: That's excellent question. You're right. Our compound that's furthest advance in the clinic is '3970. As Onno described, this will not have the legs to go forward. Behind that, there's a selective SIK3 which is '4399, where we're finishing Phase 1 right now.

Based on the results, we will decide on the appropriate next steps. Behind that and the pre-IND-Phase, there are a number of molecules targeting SIK2/3 with a better target engagement, as well as more selective SIK2 and SIK3.

What we are in the process of doing just because we now are well-positioned to do so is to take into account all the data that we have across the salt inducible kinase programs. We've advanced more than nine molecules at various levels in discovery, and three of them into the clinic.

We're taking all of these data with the relative inhibition of SIK1 versus SIK2 versus SIK3 to improve our understanding what would be the right approach going forward. Today, our working hypothesis is SIK2s will be better positioned for inflammatory bowel disease, whereas SIK3 inhibitors will be more positioned for rheumatologic diseases.

The key question that you ask what does an SIK2/3 bring more than as SIK2 alone or SIK3 alone. This is something that we are currently able to test because we have the selective molecules and it is part of our objective.

Again, when you're exploring a brand new class of compounds like the salt inducible kinases, we just have to build that puzzle one piece at a time. We are the best-positioned company to figure out what is the potential of this class of compounds in autoimmune disease, but based on what we know so far, I feel quite positive about the future. We'll keep you posted. We will be sharing data with you, preclinical and clinical to justify our next steps and why we're heading where we're going.

Laerke: I look forward to that Walid, and maybe sticking to your pipeline, but moving, switching gears to your TYK2 inhibitor '3667, I'm curious, given the failure of Bristol's TYK2 inhibitor in ulcerative colitis, what is it that gives you the confidence to potentially continue to pursue that indication with a Phase 2 trial start?

Valid: Yeah, it's a very good question. It could be a question of dose. BMS signaled that that could be the case. We're eager for Bristol to share more data about their study. Right now, we only have what was shared in a press release.

It will matter whether there was a movement, but it was not strong enough, and they missed the statistical significance versus if there's nothing at all, then we need to scratch our heads because TYK2 inhibitors should block IL-23 signaling. We know our IL-23 inhibitors do work in ulcerative colitis, so we need to scratch our heads and see what's going on. We're evaluating this depending on what is the highest exposure or highest dose we can use with our compound. We were just finishing Phase 1 literally as we speak. In the next month or so, we will know what are the highest doses we can take forward.

If we can achieve better inhibition than Deucra, then it might be worthwhile evaluating UC. Otherwise, we will be evaluating also, other indications, as Onno mentioned. This could be along the lines of interferonopathies as we know TYK2 inhibitors strongly inhibit interferon-alpha, and these will lead to some potential new indications that we could pursue.

Laerke: Great, thank you very much. Beyond the Toledo program and your TYK2 inhibitor, another asset that you shed light on during the presentation today was your asset in polycystic kidney disease. Could you remind us what data is that you've seen to date that makes you excited about that Phase 3 Mangrove readout in the first half of 2023?

Valid: Actually, it's a Phase 2 study Proof of Concept, our first foray into that space. The data that we had were preclinical in nature, where we in two or three different models for this disease where there's a huge unmet medical need.

We demonstrated clear efficacy, and the mechanism of action, which is to block sodium chloride channel lends itself to have a positive effect on the cysts and the volume of the cyst, which is inherent to the polycystic kidney disease.

Based on that, we embarked on this Proof of Concept study. Now the difficulty with these studies is that it's a slowly progressing disease, so to be able to detect a signal there long and duration. We finished recruitment. We have one year treatment period, and we should have results about this time next year, a little bit later, maybe then this time next year.

Our fingers are crossed. We have all the reason to see a positive response. Let's hope it

translates to the clinic. As you know, science sometimes it's very humbling. You've got to do it step by step, and that's what we're doing.

Laerke: Absolutely. That's what makes this field so exciting as well as unpredictable. Maybe switching gears from your pipeline to your to Jyseleca, your drug that's now in the market has been for a while. You spoke about the early launch in rheumatoid arthritis and your preparations in UC following the recent approval in November last year.

Curious, could you give a bit more color in terms of what the physician feedback has been and maybe how we should think about the launch in UC versus RA?

Onno: Yeah, thank you. Who better than Michele Manto, our Chief Commercial Officer, to answer that? Michele?

Michele Manto: Yes, thank you. Thank you for the question. It's exciting to talk about our first launch, first approved product, and the product we have a marketing authorization for in Europe now.

The launch in RA has been good, as you mentioned. We had the reimbursement in the 14 countries in time, which is aligned with the best launches had in the past by the other JAK inhibitors and biologics. That was the first milestone step in the launch.

Also, we saw the remaining interest in high interest for JAK inhibitors and for a JAK1 preferential inhibitor in rheumatoid arthritis. Onno showed also the growing share of JAK inhibitors. We participated in that growth by adding another product.

We see that feedback as a physician needing another therapeutic instrument for their patients in rheumatoid arthritis at all stages of treatment. From data we have from Germany, which is the richest country for data, we see that more or less one-third of the patients are in biologic naive.

It means that physician rheumatologists feel comfortable in using the Jyseleca, before also, they use anti-TNF or other biologics. The other third they used after biologics and the other third after JAK inhibitors, which also indicates another need of cycling through JAK inhibitors and one concept that comes also from a rheumatologist is about the first generation and second generation of JAK inhibitors. Seeing Jyseleca as a JAK1 selected or preferential, and therefore also having a profile that fits better in terms of strength and balance between efficacy and safety, which is a very relevant point recently after the oral surveillance data.

That also in a different way, then moves to ulcerative colitis, we got approved in November. First patients in, and the reaction was also very enthusiastic and fast. Physicians prescribed in Germany and the Netherlands, where the reimbursement is granted immediately in the first hours or days after they could do that because there the need is even stronger.

You've seen less therapies approved. There are younger patients who need treatment for a longer time and therefore a product profile of Jyseleca, so fast-acting, long-duration steroid, free remission, overall convenience, that brought a very interesting opportunity. Thanks.

Laerke: Very helpful, and maybe as a follow-up with the launch in ulcerative colitis, what do you think will be the required step-up in SG&A to maximize that opportunity in 2022?

Michele: Look, we have most of the organization that we built in terms of infrastructure backbone was done for RA for the first indication. Now, depending on the countries, we had to increase our capacity to fulfill the need to see different physicians. It's not linear. In some countries, you just had to do marginal increases because the hospitals are the same.

We are using more or less the same sales force and then add some additional capacity to address that. For the market access for the other functions is already set. In other places, we have to want it to be present like an office-based physician, like in the German case, to maximize the opportunity. It's a mixed situation.

Our approach has been to go from the customers, understand what is the best customer engagement model that maximizes the efficiency there, and not necessarily being limited by the structure we have in RA.

Laerke: We've spoken about the pipeline. We've spoken about Jyseleca. Onno, you mentioned during the presentation that Galapagos is excited to do a deal to be able to bridge that gap. Is it fair to assume that such a deal would have to wait until the new CEO is in place?

Onno: Yeah, it's with my mentioning that it is rather weeks and then months before that person will be announced. It's clear that we need a new CEO on board now to make the decision. The board has said OK for us to do an acquisition in the therapy area that is our focus information, but it's clear that it's much more beneficial if we have the new CEO on board to jointly make that decision. Maybe, Andre Hoekema, Chief Business Officer, maybe you can tell a little bit about our efforts that we're doing there.

Andre Hoekema: Thank you, Onno. Good morning. Good afternoon. We're using this very J.P. Morgan week to meet with a lot of companies. As Onno mentioned in his introduction, Galapagos has a very strong balance sheet. Well, we're not a bank. We want to use our cash to strengthen our pipeline.

These very weeks, we're meeting with a large number of companies that have sort of the opposite to Galapagos, a number of assets in the pipeline that they are willing to license and the need for cash. We think that there is a chance to bring in some assets. We hope to do that this year such that our pipeline will look stronger again as it did before. Thank you.

Laerke: We're almost at the top of the hour, but maybe I'll try and squeeze in just a final question. Just to round off as we look into 2022, what are the key events that you believe could change investor sentiment and that you would like to focus investors' attention to?

Onno: Well, the big changing moment will be the new CEO. It's clear that investors have been in a holding pattern waiting for who that individual will be to lead Galapagos forward. If the new CEO comes on board and he or she is going to come up with a strategic vision on where this company is going to go from here, will it be an additional therapy area on top of inflammation and fibrosis?

Then, clearly, with a strategic vision, there will be a renewed interest in where this company go. That's one part. The other part is Jyseleca. This year is the year that we should see substantial sales of this drug in the European market.

If that confidence that Jyseleca has a good launch and is delivering will come to the investors, we'll get in the reset of the Galapagos equity story.

Laerke: With that, I would love to continue, but we're at the top of the hour, and that's a good place to end. I would like to thank Onno, and everyone for being here with us today. I hope you enjoy what's left of the conference.

Onno: Thank you, Laerke.

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