# Cantor Global Healthcare Conference 2025 Fireside Chat Transcript

## Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Hey, everyone. Welcome to our next session with Ascentage. My name is Li Watsek, a Biotech Analyst at Cantor. It's my great pleasure to have Veet – joining me today are the fireside chat. Veet, welcome back to Cantor and congratulations on your new role as the CFO of Ascentage. And I think the company is in a really sort of exciting time right now.

Now, you are sort of sitting on the other side of the table, I will love to hand it over to give us a quick overview of the story.

## Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Yeah. Thank you so much, Li. And it feels good to be in a place that's kind of – feels kind of same and different at the same time, if that makes any sense!

Yeah. So, very fortunate to have recently joined Ascentage Pharma. And I want to convey some, some key things about the company because I think even though this is a company that has a long history that actually started in the US as a private company in 2003 known as Ascenta and now evolved into a global dual listed Hong Kong, Nasdaq company, but I think about the company that especially for the US audience, be great to increase awareness about.

So, in China we have two novel products approved. The first product that was approved was actually in 2021 for a third generation TKI called Olverembatinib for CML. The company in 2021 got what's known as a conditional approval, which is very similar to accelerated approval in the US and eventually got approval, full approval as it relates to the CML patients that are with or without mutations.

So, what that did was broaden out the label as it relates to patients who are resistant and/or intolerant to first and second-generation TKIs and the intolerance opens up, kind of a segment which we think of as 1.5 line. So not quite second line. So that was a good opportunity for us.

And we got NRDL approval there and we just reported our interim recently. We doubled our sales for this first half period to the $30 million level, and we're very fortunate to have a second product approved back in July 8th, Lisaftoclax, which is the second Bcl-2 selective inhibitor approved globally. So, this has been a market that has been exclusively Venetoclax until us for nine years by AbbVie for variety of hematological large market indications. And so we're very pleased to have Lisaftoclax now approved. And we have a very deep pipeline and out of that pipeline, six disclosed assets that are all in clinical stage.

So, very pleased to also have done a financing in July, utilizing our liquidity in the Hong Kong Exchange. And we recently reported that our pro forma cash position is $420 million. So that gives us good runway through 2027.

And finally, I'll say that by this point, not a quick snapshot, but finally I'll cap it off by saying we have an option agreement with Takeda, which has the third generation TKI, ponatinib, that will lose exclusivity soon. The option

agreement along with the China approval validates olverembatinib. And, you know, obviously there's Asciminib by Novartis, but that's a different mechanism of action - it's an allosteric inhibitor. So, very pleased to have a option agreement with Takeda.

### Li Watsek
*Analyst, Cantor Fitzgerald & Co.*

Okay. That's a great overview. Maybe with Olverembatinib launch - so, you mentioned the NRDL listing that would help with the sales trajectory. Maybe talk to us about what you see, it goes for the second half of this year and go into 2026, especially, from the hospital coverage and market penetration perspective?

### Veet Misra
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah, certainly. So, getting NRDL provides good clarity as it relates to pricing visibility and stability. It's very important because for the first couple of years, it was that folks had to pay out of pocket, on the order of RMB 10,000, RMB 15,000 per month. So, that is a quite a burden on families and NRDL, as you all know, opens it up to 70% population coverage in a large very important pharmaceutical country.

So, what that does for us now is giving the ability to fully leverage the sales force we have in place, where we have our partnership with Innovent. We have a 50/50 split there. And I want to say before I forget is that it's a distinct sales force from Lisaftoclax. So, with Lisaftoclax, we were planning for success there. We actually doubled our sales force in three months and that's prior to approval. And so, we're up to 200 just for Lisaftoclax alone. And, we're actually planning to increase even more to get to 400 boots on the ground to sell Lisaftoclax on our own China.

So, going back to Olverembatinib, as it relates to China, we're going after follow-on indications there. And we're doing US registrational studies as well with Olverembatinib. So, that's also applies to Lisaftoclax as well. Therefore, a lot of developments including here in the US.

### Li Watsek
*Analyst, Cantor Fitzgerald & Co.*

You talked about in the beginning the partnership with Takeda. I guess just from a milestones and cash flow perspective to Ascentage. And can you just tell us about, you know, what to expect in the coming years?

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Certainly. So, what we've said publicly as it relates to Takeda, they came in specifically with the option agreement in June 2024 that involved $100 million cash upfront. Takeda also took a a $75 million equity stake in the company, which actually provided tailwinds for the Nasdaq dual listing approach that we took. So, what we've disclosed publicly is that the total milestones associated with the deal totals up to $1.2 billion, and also, there's a royalty. So, the geographic rights that they have is ex-China, ex-Russia. For the royalty, we get a tiered structure starting from 12% going all the way up to 19%.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Okay. Thanks for that. And you mentioned there might be some expansion opportunities. I know you guys surrounding the POLARIS-1 study, so I think that's in front line, Ph+ ALL.

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Sure.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Talk to us about what the opportunity might be, if you get a positive readout just considering some patients already, use it off-label.

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Yeah, absolutely. So, what's interesting, what's special I think about frontline ALL is that it's a real testament to the now, over 10,000 people plus real-world exposure in terms of the safety and efficacy profile of Olverembatinib. Now, those are going after large market indications like CML and ALL. And what's interesting there is that we can go after a very important population of pediatric patients with a combination approach of Olverembatinib plus low-intensity chemotherapy in frontline.

So, we have shown after one cycle of that therapy alone, we can get very meaningful responses. That's going to be, I think a very important aspect of POLARIS-1 and I'm glad you brought this up in the discussion. The years of work and dialogue by the company with the FDA have resulted in the ongoingregistrational studies. We’re positive so far about the communication with the FDA and expect in the not too distant future to give a lot more clarity on the PH+ ALL trial and initiation itself. I think that's a very important area representing a high unmet need and we have other approaches there as well. But this one I think makes a lot of sense.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

Okay. And then you have global trials ongoing as well, that's POLARIS-2 and POLARIS-3. What can you tell us about when we would expect a top line from those trials?

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yes.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

And what is sort of the financial impact to Ascentage?

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah. So, very two kind of different profiles - POLARIS-2 is a truly global trial. It's essentially going after a population in CML and the key for that is it's a global study. So, it's very important to choose the right sites and get scale in terms of number of sites and the right country balance as well, because the regulators – and this is common for multiple countries, which is to get a nice balanced enrollment population so that it's reflective of their respective geography.

So, what's going to be important for POLARIS-2 is just continuing to execute. And we have been actually increasing our enrollment rate and the number of sites and clinical operational employees including bringing in very relevant additions to the company for execution and real focus. So, I think as a company, we are going to provide first enrollment status in various trials in the months ahead and then we'll give more clarity at the right time as it relates to estimated trial completion timing.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

Maybe switch to Lisaftoclax. So, that's your second approved drug. So, I believe it's a second approved Bcl-2 inhibitor globally.

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Globally. Yes.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

So, that's certainly very impressive. And that's in the CLL post-BTK inhibitor. So, tell us why historically it's so challenging to develop a good Bcl-2 inhibitor. I think we've got Venetoclax and right now we're probably seeing BeOne has one.

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

So, maybe touch on the differentiation as well versus Lisaftoclax?

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Yeah. So, I think those who can create drugs against variety of apoptotic targets deserve deep appreciation. In particular, when looking at these particular drug targets, they represent the business side of the apoptotic proteins. They represent substantially large, relatively large, surface areas. We're talking about the binding pockets that are druggable, about 12-13 amino acids. So, one has to be very adept at computational biology, I guess they call it AI now, for drug design. And it's a real testament to our co-founders, our Chairman and CEO, Dr. Dajun Yang, and Shaomeng Wang, both from the University of Michigan which is where the IP actually comes from. And going back to Georgetown when they first conceived of the idea, actually in the late 90s, to essentially go after Bcl-2.

As a target, Bcl-2 actually was first discovered in 1984 and not in CLLs, it was discovered in follicular lymphoma 14;18 chromosomal translocation. And at the second attempt by Abbvie was the culmination of venetoclax, which got approved in 2016. So, it took nine years and we were proud to have the second Bcl-2 inhibitor globally. The other interesting aspect now, bringing in Sonrotoclax into play, and also Venetoclax, is the dosing strategy.

So, with Venetoclax, when you go after a fundamental target like Bcl-2, the potency of Venetoclax is exquisite, so much so that it needs to have a specific dose ramp-up schedule. Otherwise, patients, and this is a life-threatening side effect, can experience Tumor Lysis Syndrome. So, as it relates to the specific dosing of Venetoclax in the label, they have a five-week ramp-up period as kind of the suggested guideline there in the label.

With Lisaftoclax, due to the very different characteristics as it relates to half-life - the half-life of Lisaftoclax is 5 hours, whereas with Venetoclax it's more like 20, 25 hours - so, we could actually use a much quicker ramp- up strategy. So, we can get to our target dose after a five-day ramp-up. We're at our target dose at day six. Now, with Sonrotoclax, their recommended Phase 2 dose goes into multiple weeks. Okay. So, this is something that – this is one of the areas from a biochemical PK/PD standpoint where we're differentiated. And, in development strategy as well, is different as well from BeOne, which has just done a phenomenal job as relates to getting zanu into the market as a very strong showing BTK inhibitor, showing strong post-marketing efficacy, and also Sonrotoclax, of course - two potentially big franchises and putting them together.

But our approach with the GLORA and GLORA-2 studies is pairing Lisaftoclax, specifically in BTK-experienced patients, that's GLORA and then GLORA-2 paired with acalabrutinib, AstraZeneca's acalabrutinib. So, I think our narrative is slightly different. It's important to point that out. The narrative ties into our development program versus BeOne.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Okay. What can you say about Lisaftoclax's launch given you already have, commercial infrastructure in place? It seems like there is a lot of synergy that you can perhaps leverage. And you guys talked about sort of the dual entrant commercial strategy. What does that mean? And also on NRDL listing front, so what is the timeline there?

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Yeah, absolutely. So, already established a distinct sales force target of 400 in the next year or two. The key for China, you got to hit the hospitals. And given our first mover advantage there, we're aggressively, first of all, covering the 100 hospitals. We've covered the Tier 2 over 200 hospitals, but our goal is to actually cover over 500 hospitals in China. Once you cover that level, you have got 80% of the hematology market in China.

So, that is our goal, full stop. Like, so pricing right now is a very interesting. We are at a price equivalent to Venetoclax in China, but we do give a little bit of a charity discount as it relates to the dose ramp-up phase. We put in some extra dosage during that particular phase before hitting the target dose. And then, as it relates to NRDL, China has a very fixed timeline where if you get approval in the first half, you look towards the start of the next calendar year for activation approval. So, we're definitely going to be applying in the 2026 window for 2027.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

I guess, what sort of sales can you guide to this year versus next year? Obviously, NRDL is a huge part of the sales growth and it's probably too early in the launch to give specific numbers. But just directionally, how should investors think about the sales trajectory?

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

So, you've seen with Olverembatinib, as we talked about the inflection NRDL like allows. Yes, Lisaftoclax, we just launched, and we'll certainly be giving updates on kind of the market penetration, no question about it. I think like there's pros and cons of guidance, but I think it's always good practice to essentially not give guidance until there's kind of more visibility. Everything needs to come together more in terms of obviously more sales history and investment in the pipeline as well as a company.. Now, there's enough history in the company where everyone can understand our cost structure. China allows for the whole entire value chain to be cost effective.

So, hopefully people will follow closely. The market will follow closely, the levers we can pull in terms of being breakeven commercial versus investing in the pipeline and tracking how revenues help to manage cash burn overall.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

And then going back to the global GLORA trial that you just alluded to. So, that's in BTK-experienced CLL patients, but it's not truly a second line. It's sort of like 1.5 line. That's my understanding.

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Right.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

So, explain to us, how does that work? What the trial is trying to do and what is the measure for success?

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah, no, it's a very interesting question. So, again, going back to the kinetics, right? So, one interesting aspect of Lisaftoclax, which actually is distinct from Venetoclax, is the – we have not seen to date any significant DDI, drug-drug interactions. So, we can actually pair it quite nicely with BTKs because that has been an issue with Venetoclax. So, there needs to be a run-up to get the patient tolerized first before pairing the two together.

So, we think that, we'll – and we'll be giving more details on GLORA as well as GLORA-2 on more on the design. I think like this year, we've spent a lot of time in front of the FDA and that – that GLORA and GLORA-2, as well as GLORA-3 in AML. We're going to be giving a lot more information about those. But you're exactly right. Like, it's another way that our narrative will evolve to match our development plan here. So, this distinguishes us with BeOne.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

So, I think we talked about maybe AML is a very big opportunity outside of CLL. If you look at Venetoclax, I think AML is probably their biggest indication.

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yes.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

So, I know you guys have showed us some combination data with aza.

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yes.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

So, maybe just put that data into perspective for us, how does that stack up against, aza+ven, which is the standard of care right now in frontline AML, especially in unfit population.

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah. So, I'm actually going to answer this question with kind of maybe an unexpected angle because this news is relatively recent, which is details on that VERONA trial by AbbVie, right, in MDS. Long awaited to get the results of that. So, yesterday at SOHO, AbbVie presented the survival curves as it relates to ven+aza versus aza in MDS. And obviously, it has implications because MDS conversion to AML as well.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

Yeah.

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

On GLORA-3, we're actually going to be taking the same approach of ven+aza vs. aza. So, what's interesting is that these patients had a median survival of about 22 months. That was the – where the curves were very much in overlap. The hazard ratio was 0.908 and that's after a median follow-up of 41.2 months.

So, that actually is an interesting way to think about what is the bar for success rate for AML. To your point, thanks for pointing that out, as it relates to patients that had been exposed to Venetoclax, we've seen high overall response rates, in relatively small N, less than 30 patients. We've seen overall response rates of around 32% and added that slice about close to 20% CRis and about 5% CRs. So, putting those two together, I think it's quite interesting how we can approach this very difficult disease with applicability from MDS to AML, but also the design is quite similar to the VERONA trial.

So, I think that helps to define and it also more importantly shows that we can clear that bar. Like there's a very high confidence we can clear that bar in terms of overall response rate.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Okay. So, you're in GLORA-3 for the AML trial. Have you said in terms of timeline, well, we might be able to see an and you're using the overall survival as sort of the endpoint?

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

We'll be providing updates on the endpoint.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Okay.

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

That's right. So, I don't have exact timing when we'll give the update, but it won't be too long because it's really with the FDA project Optimus, we want to make sure that we had the full discussion, make sure everything is, in place before we give guidance. But directionally, we believe the dialogue is very good, but yeah, that's – the topic of endpoint, and then, as you look at MDS, though, we have a dual endpoint there. We have complete response and overall survival.

### Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Okay.

### Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

I think that's going to be as far as potential catalysts - I think the GLORA-4 study in MDS - I think there's going to be a lot of focus on that study as a major potential catalyst for us.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

Okay. And then in AML, we're seeing some companies actually persuaded the agency to use MRD in activity CR as surrogate endpoint. Is there any possibility here for you guys to maybe talk to the FDA and say, hey, can we go in and use MRD?

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah. No, I think that's a really good point. No, I think that's all part of the discussion. And we'll give some clear guidance on what that looks like.

**Li Watsek**
*Analyst, Cantor Fitzgerald & Co.*

Okay. And going back to GLORA-4, as you alluded to, when we look at a VERONA trial, obviously that's not a successful trial. So, I guess, is it really related to you to guys in GLORA-4 or what gives you the confidence that you might see something different?

**Veet Misra**
*Chief Financial Officer, Ascentage Pharma Group International*

Yeah. So, it's very interesting. Like really we're on the edge of our seats waiting for clarity on VERONA. So, I'd say there's three important things to highlight there. One is, what exactly is the outcome of that study that guides us to, how we carry out GLORA-4, right? The company has been asked that question quite a bit.

Second, I think is also very important is that the GLORA-4 protocol that we – there's 100% identical between China, Europe and US, that's pretty rare. And now we have, I think, a straightforward design that we can adapt so to execution and concordance with the regulators. And I think that helps give market – the market clarity as well in terms of probability of success.

And then, also the important thing to keep in mind is that there has not been a targeted therapy approved in HR-MDS in over 20 years. So, that's why having this momentum here with the recent FDA green light and announcing that and hopefully we're going to be doing the same relatively soon with ALL as we talked about, Ph+. So, with that, yeah, we're very pleased with the with the progress there, with the way the GLORA-4 turned out.

## Li Watsek

*Analyst, Cantor Fitzgerald & Co.*

Okay. Great. So, I think we're out of time here. So, Veet, thank you very much for the chat.

## Veet Misra

*Chief Financial Officer, Ascentage Pharma Group International*

Thank you so much.

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