U.S. FDA Approval of Afrezza in Pediatrics | Mannkind | May 29, 2026

Moderator:

Good afternoon and welcome to the Mannkind Corporation Conference call to discuss the US FDA approval of the Afrezza in pediatrics. As a reminder, this call is being recorded on May 29th, 2026 and will be available for replay on the Mannkind Corporation website shortly after this call for approximately 90 days. This call will contain forward-looking statements. Such forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from these expectations. For further information on the company's risk factors, please see the Form 10Q for the period ended March 31st, 2026, this morning's press release and the slides prepared for this presentation. Joining us today from Mannkind are chief executive officer, Michael Castagna, and senior vice President, therapeutic area head for diabetes, Dr. Kevin Kaiserman. I now like to turn the conference over to Mr. Castagna. Please go ahead, sir.

Michael Castagna:

Thanks, operator, and good afternoon, everyone. Thank you for joining us on today, which is a truly historic moment for Mannkind, for the diabetes community, and most importantly, for children and adolescents living with diabetes. Our founder, Al Mann, always dreamed this innovation will be available for kids and we're honored to be able to fulfill that dream today. Our agenda today is with Kevin and I will lead the discussion and our president, Nick Marasco will be available during Q&A. Our goal is to walk you through why this milestone is so critical to driving an inflection in Afrezza's future growth over the coming years. In fact, we've already received our first two patients in the last hour.

As of this morning, Afrezza is now approved for pediatric patients living with diabetes ages six and older. This is more than a label expansion. It is bringing a fundamentally different experience to children and families who manage diabetes every day. This is the first alternative to mealtime injections in 100+ years of pediatric treatments. First, I want to thank the FDA for their collaboration and support to help get us across this finish line. I also want to thank the investigators, our patients, and the parents who are part of this study. We are really excited about the label we received ages six and older covers approximately 95% of all children diagnosed with type one diabetes. This is a broad and meaningful indication. What makes Afrezza so unique is its differentiated clinical profile that simplifies mealtime management, reduces the need to carb count, and manage the timing of your insulin administration.

And most importantly, we're going to make Afrezza available for $35 for anyone less than 23 years old, regardless of insurance coverage, as we want to remove any barriers to patient access. This is a new chapter for Afrezza and for Mannkind. Before we get into the pediatric data, I want to ground everyone on what makes Afrezza a fundamentally unique insulin. On the left side, you see the natural insulin profile of a healthy pancreas, peak concentration at 45 minutes and on the right side, you see how closely Afrezza mirrors that profile with peak effect also 45 minutes and insulin action that clears around two hours right around the food, right around when food is generally clearing. Compare that to injectable rapid-acting insulin, which doesn't start to kick in until about 45 minutes here on the gray line and doesn't reach its peak effect to about 90 minutes.

That delta between the magenta and the gray is the mismatch that patients often struggle with years. It's a big reason why insulin pumps and pods were developed to try to modulate that gray line and close the gap. But whether you deliver the insulin in a pump, a pod or a pen, it's the same insulin. The delivery device changes to not alter the pharmacokinetic profile materially. The only things that could get closer to Afrezza's profile would be an implantable pump or a cure for diabetes, which we all hope for one day. Short of that, Afrezza was designed to help patients close the delayed effect we see in every dose of

injectable mealtime insulin. This is more important today than ever as the majority of pediatric patients are using CGM to help manage their diabetes.

Why does this matter? At the one-hour mark, 90% of injectable insulin's glucose lowering effect is still remaining. Only about 10% of the work has been done. With Afrezza, nearly half the insulin effect has already occurred. That's a twofold difference at just 60 minutes. By 90 minutes, the gap widens to 3X and by two hours, nearly 90% of Afrezza's effect is complete, minimizing the risk of insulin stacking and it's approximately when your food is finished being absorbed while injectable insulin still has roughly half of its effect left to go over the next several hours. This mismatch insulin's still working long after the meal is cleared, has been the single biggest challenge of mealtime control in both adults and pediatrics. Afrezza brings insulin action closer to real-time eating and this slide shows you exactly why.

So, how does this translate to clinical practice? On the left side, you see the head-to-head meal challenge results from our pivotal trial, INHALE-3 in adults. The Afrezza reduced postprandial glucose excursions by more than 35% versus multiple daily injections over the first two hours. And keep in mind, the injectable insulin was dosed 15 minutes before the meal while Afrezza was given at the start of a meal. On the right side, you see the meal challenge data from our INHALE-1 pediatric trial. The peak glucose excursion with Afrezza in pediatric patients is very consistent with what we saw in adults. This consistency in the absorption profile between adults and children was the foundation for establishing Afrezza in the pediatric population.

Why is this important? Because better postprandial control should translate to more patients getting to goal. In INHALE-3, we looked at a subset of patients who switched from MDI or AID systems, pumps and pods such as Tandem and Omnipod to Afrezza. At baseline, 21% of these patients were meeting their A1C target of less than seven consistent with the national averages. By 30 weeks, that number doubled to 42%. Twice as many people getting the goal by switching off the standards of care is a meaningful number. And this makes sense as patients approach an A1C of seven, the impact of postprandial glucose control becomes increasingly important. That's exactly where Afrezza's profile makes the biggest difference.

Over the past decade, we've made a deliberate investment in data generation and this slide shows you the breadth of that commitment. Rather than scaling up commercially with a label we had, we focused on getting the label right. That meant building the clinical evidence base for pediatrics, establishing a clearer understanding of our clinical safety and efficacy and addressing questions that matter most to physicians and regulators. This data generation has given us the ability to correct one of the earliest setbacks. The original label conversion ratio underdose patients on their very first dose and caused many to drop off before they ever experienced the full benefit of the product. The updated label that we got in January of this year now reflects a simplified two to one dosing ratio that sets patients up for success from the start. This new dose conversion has been used in our recent clinical trials, including the pediatric. All of this data has now gotten Afrezza recognized in the ADA standards of care. Last year, the 2026 standards of care were updated to recommend that clinicians evaluate inhaled insulin as an option at every patient visit.

This help set the stage for launch. These updated guidelines are a fundamental shift. For years, Afrezza wasn't on a level playing field and now it is. The ADA standards of care are what HCPs, payers, and health systems use to guide therapeutic and formulary decisions. An inhaled insulin is now recognized right alongside the other standards of care, multiple daily injections in AID. In fact, recent market research showed three out of four patients were not offered choice consistent with the ADA guidelines. This new approval brings Afrezza to routine standard of care conversations, which is exactly where it needs to be. The pediatric approval sets us up to relaunch Afrezza in a truly meaningful way.

Now I'd like to introduce Dr. Kevin Kaiserman. Kevin is a board certified pediatric endocrinologist with more than 30 years of clinical and academic experience. He joined Mannkind in 2020 right in the middle of COVID. Kevin's insights into the lives of children and families living with diabetes were critical to our development of this innovation. You couldn't ask for a more qualified person who have led the clinical program to help us prepare for this launch and gain FDA approval. With that, I'll turn it over to Kevin to talk about the unmet needs in pediatrics and why we're here today.

Kevin Kaiserman:

Thank you, Mike. So, what are some of the challenges that children and adolescents face in diabetes management? One of the major issues is missed insulin doses. Up to one in five doses are missed, regardless of whether you're using multiple daily injections or pumps. The result, less than 20% of adolescents with type one diabetes are achieving the glycemic goal of having an A1C less than 7%. And when you look at why, functionally, you have changing insulin sensitivity and irregular eating patterns. Socially, there's discomfort with injections or pump site activity in public and fear of having hypoglycemia in front of your peers. And emotionally, you're dealing with injection anxiety, fear of needles, and disease exhaustion from managing ever-changing food timing and activity levels. These are the realities of managing diabetes as an adolescent and they're exactly the types of barriers that Afrezza is designed to address. INHALE-1 was our phase three open label randomized controlled trial in youth age four to 17 with type one or type two diabetes conducted across 38 US sites.

230 subjects were randomized one to one, 117 to the Afrezza plus basal group, 113 to the rapid-acting injectable plus basal group. Both groups used Dexcom G6 continuous glucose monitoring. There was a 26-week randomized treatment period followed by a 26-week extension period where all subjects used inhaled insulin plus basal. As previously disclosed, the primary endpoint was nominally missed driven by the impact of a single subject with a very high A1C level who was documented as being not adherent to therapy. Once this single subject was removed, the sensitivity analysis demonstrated the non-inferiority margin was met. One of the notable benefits we saw in the trial was the lack of weight gain with Afrezza. Body mass index percentile, which accounts for age, gender, and weight showed no change in the Afrezza group over 26 weeks. In the rapid-acting insulin analog group, BMI showed a 3.6% increase and the difference between groups was statistically significant.

Another important finding was treatment satisfaction. Both teens and parents reported significantly improved treatment satisfaction with Afrezza compared to subcutaneous insulin. When you pool the results, the difference between treatment groups was statistically significant. Very importantly, pulmonary function was monitored over the full 56-week

... study period. There was no difference in change in percent predicted FEV1 between the Afrezza and RAA groups. Also, after week 26, all subject used inhaled insulin. So the dash line here represents the group that started on subcutaneous insulin for the first six months and then switched to Afrezza. You can see that when they switched over, there was no change in their percent predicted FEV1 over the following six months. With that, I'll turn the call back over to Mike to talk about the launch strategy.

Michael Castagna:

Thanks, Kevin. Let me start with how we're thinking about the entry point. Type one diabetes in pediatric is the focus of this launch. There are about 360,000 children and adults aged between six to 22 living with type one diabetes, and approximately 30,000 are newly diagnosed each year. The reason we highlight age 22 is that many of these patients stay with their pediatric endocrinologists through college, so the addressable population is larger than many people think. This is also a strategic entry point that compounds over time as they progress into adulthood. We believe as children transition from pediatric

endocrinologists to adult treating endocrinologists, those physicians will see the positive outcomes these patients have had on Afrezza firsthand and begin to use it more widely as their go to mealtime insulin, just as they've used this playbook for insulin pumps, pods, and CGMs. And beyond type one, with once weekly basal insulin getting approved this year for type two, we now have a roadmap to enter the much larger type two market with higher dose cartridges, which we'll discuss shortly.

Pediatric type one is the entry point. It's where the unmet need is the highest. It's where being the first insulin a child uses creates a long runway for the brand, and it gives us a focused high impact launch with the ability to expand over time. Critical to launch success is the foundation of how we're approaching this launch differently than the adult market. There are real reasons the adult opportunity never reached its full potential. Physicians weren't trained on the product or its pharmacology during their training. Awareness of our data is low despite a robust clinical data publication and presentation strategy. We've pressure tested our strategy against these real world barriers and built specific solutions into our launch model. And let me walk you through each one. The first is awareness. The reality is that Afrezza hasn't historically been top of mind due to our limited commercial footprint.

Pediatrics is a concentrated market made up of roughly 60 key institutions consistent of approximately 1,000 prescribers that treat the majority of pediatric patients. 38 out of these top 60 centers participated in our clinical trial so they already have hands-on experience with the product. Unlike our adult clinical program, which is primarily international. Our talented field infrastructure of key account managers, MSLs, and patient navigators are hitting the ground running today. Additionally, we have a concerted effort on direct to patient effort running alongside our prescriber engagement. When a parent asks for Afrezza by name, that's a powerful catalyst for continued adoption.

Second is long-term safety. Lung safety has been one of the top objections since approval. We now have two independent studies published this year confirming long-term lung safety. A third mankind study will be coming out shortly and one year of pediatric data that Kevin just shared with inhale one showing no impact on FEV1, as well as over 10 years of post-approval safety and surveillance. No one can credibly argue the safety of inhaled insulin at this point. Third is FEV1 testing. Spirometry can feel like an operational hurdle, especially in a pediatric practice that may not routinely perform lung function testing. We've created starter kits with FEV1 devices that can be used at the point of care, removing a perceived barrier. Fourth is dosing complexity. We've got our label changed, we've built a on stop shop hub for an online dosing calculator, a prescriber portal, EMR integration, as well as pre-printed forms, all designed to simplify dose selection and prescribing from the very first prescription. Clear tools that will give physicians confidence from day one.

And then finally, prior auth and affordability. The pediatric population is primarily commercial and Medicaid. We are in active discussions with payers to minimize friction for pediatric patients. We have a white glove service that will ensure every patient can get Afrezza for $35 or less regardless of insurance coverage, and Afrezza delivered to the doorstep within 24 to 48 hours. As a pharmacist by trade, I can tell you that cost at the pharmacy counter is one of the biggest barriers for families trying a new therapy. We're removing this potential barrier upfront and hope to improve the prescriber experience and fulfillment process. Every known barrier has a specific funded and operational solution behind it. This is a system built to convert awareness into prescriptions, prescriptions into starts, and starts into long-term patients.

We touched on the market research on previous calls, but I want to come back to a few of these numbers because they really inform how we're executing and how excited we are about this opportunity. Two out of three pediatric endocrinologists tell us they're likely to prescribe Afrezza. About half sight eliminating mealtime injections as a primary driver. One out of four indicate they would consider Afrezza in a newly diagnosed patient consistent with our inhaled first population and a strong

signal of why we launched this study. Our patient shared potential range is 23 to 37% indicating an opportunity of three to $500 million in revenue coming from pediatrics, which will compound over time to adults. That indicates a compelling opportunity ahead.

I also want to mention that we have a significant presence at the American Diabetes' scientific sessions later this month, we have nine poster presentations, and we're going to have an immersive virtual reality experience where people can actually follow the powder through the lungs into the bloodstream. There'll also be educational dinner programs and many executive encounters and one-on-ones. We're excited about leveraging our new creative campaign, Insulin in the Moment, which captures exactly what Afrezza delivers, insulin that works in the moment right when kids eat and live. It's the centerpiece of our prescriber and consumer messaging, and this is the most significant presence mankind has ever had at ADA, and the timing is right after our approval could not be better. Now I want to close by talking about our roadmap for growth. Starting with Inhale 1st, this is our pediatric study evaluating newly diagnosed patients.

The strategic question we're trying to answer is can Afrezza be the first mealtime insulin a child ever uses? When you think about it, a newly diagnosed kid will have to live with diabetes for the next 70 years. The first 10 patients enrolled in Inhale 1st gives us optimism that Afrezza can be the first insulin when you're newly diagnosed. As we look to future innovation in Afrezza, the pediatric launch is a catalyst, but it's not the end of the Afrezza story. Starting with the two unit cartridge, which we expect to file with the FDA by year-end, will give us the flexibility for smaller dose adjustments and is exactly the kind of dose granularity that some healthcare providers and patients have been asking for. Next is our Inhale Q digital ecosystem that detects and tracks Afrezza dosing alongside CGM. We also expect to build dosing calculators into the platform.

These digital tools are what physicians and patients increasingly expect. We're also advancing Afrezza high concentration formulation that could enable up to a 20 units in a single dose cartridge opening up to type two market further. And finally, the pediatric approval and the release of our long-term safety PMR opened up the opportunity for global expansion. Together, these represent a multi-year roadmap of Afrezza innovation that will support growth well beyond its initial pediatric approval both domestically and internationally.

We had three major catalysts for '26 and we celebrate our treatment of the first one, pediatric approval today. On Monday, we'll be back focused on achieving these next two catalysts, which are equally transformative to driving shareholder value. Before I close, I want to mention that we'll be at the Jefferies Healthcare Conference next week in New York and we look forward to engaging with many of you there. With that said, operator, I'll now turn it over for Q&A.

Moderator:

Thank you. At this time, if you would like to ask a question, please click on the raise hand button, which can be found on the black bar at the bottom of your screen. When it is your turn, you will receive a message on your screen from the host allowing you to talk and then you will hear your name called. Please accept, unmute your audio and ask your question. We will wait one moment to allow the queue to form. Our first question comes from Ben Burnett. Please unmute your audio and ask your question.

Ben Burnett:

Hey, thanks very much and congrats on the progress. I wanted to just ask how quickly do you expect the pediatric sales to influence the overall sales of Afrezza?

Michael Castagna:

Thank you, Ben. And thanks for dialing late on a Friday here. I think June will start to get the early foundation laid out here, but I would say we want to see probably a quarter behind us, see how many prescribers come into the fold, how many repeat patients we get. So I think you'll start to see it build in Q3 and ultimately Q4 to set us up for a really nice '27.

Ben Burnett:

Okay. That's great. And then I appreciate all the comments around some of the price dynamics. Where do you see the average price going from here? Would this change materially long term?

Michael Castagna:

The pediatric population from a percent of insulin units in a payer is very little and most of the payers we've talked to wanted to see the approval, number one, they want to see the demand, number two, but they've indicated their desire to remove any friction for children. They don't want to be on the news for that. They've been very collaborative. We do have contracts that have been outstanding. So they could move it up to preferred, they could move it up to single steps. But we're just trying to remove the friction from the process and so far most of our discussions with the top PBMs have been very positive, and we'll be hitting the ground Monday trying to push them even harder. But we expect like an October 1st or January 1st formularies to get easier and easier. And the reason we put it at $35 is our commercial patients generally pay that or less, and Medicaid patients will pay less. And so we don't expect, even as you get formulary changes, that the cost of the patient will change much. We're trying to make that as seamless as possible.

Ben Burnett:

Great. Thanks so much.

Moderator:

Our next question comes from Roanna Ruiz from Leerink Partners. Please unmute and ask her question.

Roanna Ruiz:

Hi afternoon everyone. A couple from me. One question I was thinking about is you talked about removing barriers, like making sure patients can access Afrezza for $35 or less. Are there any other barriers that you're planning to proactively mitigate? And could you just give us an update of how smooth or what's the ultimate goal here in terms of streamlining the process for prescribers?

Michael Castagna:

Hey, Roanna. I'm going to punt this one to Nick. And

Nick, maybe talk about our launch strategy in the institutions and how your focus on the centers of excellence.

Kevin Kaiserman:

Yeah, so thank you for the question. The pediatric market is quite different from the adult market, which we've talked about prior. As Michael had mentioned a few moments ago, a majority of the pediatric business tends to be concentrated in roughly 60 key academic institutions and across a much smaller population of prescribers, roughly 1000 pediatric endocrinologists. And so we've been able to adapt our

field forces to account for a more streamlined focus on that target market. We've deployed key account managers. We have medical science liaisons as well as patient navigators that will support one of the key friction points, which was the ease of prescribing as well as ensuring that the prescription makes its way to the hub and ultimately to the patient with proper training. And so, some of the friction points, I would say, beyond just the access and payer is a more enhanced and proper prescriber education and awareness, parent and child education and awareness, certified diabetes educators, school nurses.

And so a surround sound of education, which ensures most parties that are involved in the diagnosis and treatment selection are trained, and educated, and aware of inhaled insulin as an option. And then ultimately ensuring that the patient journey is smooth. So when the physician decides that she or he wants to write a prescription, understanding how it's dosed, writing the prescription properly, ensuring that all of the necessary clinical and medical information is attached to the prescription, submitted to the hub, and ultimately ensuring a more rapid prior authorization process and ultimate, ensuring a coverage of the prescription to the patient.

Michael Castagna:

And then the other thing Nick's going to be doing is we got centers of excellence, five every week or two. We're going to be launching and that's going to work out any kinks that we identify in the first 30 days. So that's another key part of the launch, is figuring out where we may have missed something or how we self-correct as we continue to evolve each week.

Roanna Ruiz:

Okay. That's super helpful. And I also noticed you mentioned that the addressable pediatric population could be larger than people think. Could you frame a little bit more what's supporting that perspective? And it also sounded like some of that might come from targeting teenage or college age individuals. Can you talk a bit more about that?

Michael Castagna:

Yeah. If you think about, especially as kids get to adolescents, and Kevin can comment if he wants. The barriers in there of people wearing insulin pumps and the activity in sports and some of the college habits of kids, they don't all want to be treated the same. And so a lot of times if you think about it from 18 to 23, let's just call that five years. And if there's 30,000 new kids a year, that's about 150,000 kids that live in that 18 to 23 range that are still covered by ped endos for the most part. So that's where we talk about this. The market's not just, yes, it's 16 and below, but we have not been calling on ped endos for the last 10 years. And so only this year are they getting to know MannKind and therefore that population was typically treated by ped endos, not adult endos and that's opening up an opportunity. And that's been one of our focus, is if you saw we launched a scholarship fund to try to build awareness of MannKind out there in the college community.

Roanna Ruiz:

Yep. Makes sense. Thanks.

Michael Castagna:

Okay. Thank you.

Moderator:

Our next question comes from Olivia Brayer from Cantor Fitzgerald. Please unmute and ask your question.

Olivia Brayer:

Hey guys, congrats on today's approval. Really looking forward to this launch. Can you talk about some of the launch prep that you've been doing just in terms of identifying patients to put on therapy now that you are approved? And Mike, you mentioned that you already have two patients ready for treatment. What other indicators of early success are you maybe seeing from your field teams that may be shaping how you're thinking about the initial launch curve in these patients?

Michael Castagna:

Sure. I'm going to kick it off to Nick and I can close with any further comments.

Kevin Kaiserman:

Yeah. I would just say the key account managers have been deployed into the institutions over the past seven to nine months. We've been working with the institutions to understand, through our medical affairs, proper patient identification of middle school, high school, early college years. And so I would say we've had a nice head start in working with some of these key institutions, not to mention, as Michael mentioned, at least two-thirds of these institutions have been involved in our INHALE-1 or other clinical trials. So I think there's been quite a bit of prep work in patient identification and laying the groundwork appropriately.

Michael Castagna:

Yeah. The last thing I'll say is we have a series of travel events that I'm pretty sure my family won't see me for the next six months. We're going to be on the road. We got a lot of speaker programs, we got a lot of KOL interactions with Kevin, Grand Rounds, CME events. There's going to be a lot to kick off going forward. And I think the last part I would say is it's the first time, we've been here a long time, but hearing doctors say, "Monday morning I got my patients lined up. I'm going to be making phone calls. I'm going to be sending in people." We were expecting to launch Monday morning, not end of day, Friday. And so we was happy to see when we're already seeing referrals come in today. So we'll see how quickly it goes, but we want to be cautiously optimistic given the history here, but we've done everything we can to get the best people on the ground, to be on the front lines of this company, to make the biggest difference for patients.

Olivia Brayer:

And then a quick follow up on the payer angle. What's your actual plan to communicate just progress on the reimbursement side, but both on Medicare and commercial? Is that sort of a quarterly cadence update that we should expect on earnings calls?

Michael Castagna:

I think if we were to get like a big formulary win or a national formulary, we would announce that publicly at that time. We're not aiming for preferred status, just to be clear. We want to get preferred status, but I think at the end of the day, that preferred status has to happen if someone maybe... Remember, most people are already on insulin that we're targeting, and that's mostly what insurance

companies want. They want people to know they tried and failed the preferred insulin. We get it, we understand it. And that's been some of our discussion with the payers, is when you fail the first insulin, what happens? You go down the insulin pump routes, and that is the journey that we put most families on forever. And many times you get to adults, they've been attached to their pump longer than their spouse.

And so this is really part of the discussion with payers, is don't look at it against injectable insulin, look at about the alternative that people are going down and what is that lifelong cost and journey. And so far those discussions with payers have been resonating to say, we're not trying to displace all insulin that's out there, really try to help these kids get access as quickly as possible. And so far, it seems like that's the right tone.

Olivia Brayer:

Thank you. Congrats guys.

Michael Castagna:

Thank you.

Moderator:

Our next question comes from Gregory Renza from Truist Securities, Inc. Please unmute and ask your question.

Anish:

Hi, guys. It's Anish on for Greg. Congrats on the updates this afternoon and for taking our questions. Just firstly, maybe if you could help us assess the range of your peak market share projections of 23 to 37% for Afrezza. What gets you from one bookend to the other? I know we're at the launch phase here, but that would be helpful for us. And secondly, just revisiting the label with the requirement of basal insulin in type one and like before Afrezza use being perhaps contraindicated in patients with asthma, how might that gate the illegible pediatric pool? Thanks so much.

Michael Castagna:

Yeah, you can say one out of five people on the high end would have COPD or asthma, and that seems to be consistent as we look across the population. So we kind of take that out of our own forecast projections, number one. I'd say number two, what drives some of the range of the forecast is we are actively focused on kids who are on multiple daily injections and to our surprise, there's a lot of clinicians who said, "I want to use this as my first insulin now." There's nothing preventing them from doing that. Our label allows it and the dosing, as long as they need four units or more, they're good. So we were also surprised at how early that initial insulin uptake could happen in the naive setting. So we had started INHALE first to get ahead of it, but it just turns out that's going to be a nice bonus to support it as much as anything.

And I think what drives the range is we don't know... There is a large insulin pump and pod segment. We're not actively saying there are not good devices. Most clinicians have used them for decades and they're comfortable with them. And we really want to focus on the adolescents who are on MDI, most of them who are like eight and above A1C to try to help get experience there with the providers so they can see the benefits of the product. Over time in our market research, we saw a range of patients who could come from the pumps and pod market, and that's probably what gives you the greatest variability

in the forecast, is how much do you want to assume could switch from that or try this or go back and forth or even use it on top of those devices.

And so that's why you have a range here. There's a certain assumption on MDI and then there's another assumption here that gets you to the higher end if people start really trying this instead. So I think the market will bear that out over the next 18 months, but I think we'll hopefully see that trajectory as we exit the year and which direction we're headed.

Anish:

Great. Thanks, Mike.

Moderator:

Our next question comes from Brandon Folkes from H.C. Wainwright. Please unmute and ask your question.

Brandon Folkes:

Hi, thanks for taking my questions and congrats on the approval. Maybe just two from me. You talked about compliance. So can you just give us your view on compliance and potential for missed doses with Afrezza in pediatrics? How do you look to address this or assist in the compliance early in the pediatric patient's journey, especially as they sort of going to school and some of these places where they may not be under adult, well, parent supervision, I guess, early on in their launch to drive it as habit?

Michael Castagna:

Yeah, I would say a couple things, and that's where Nick talked about the educators, the nurse educators, and the schools, the camps. We're putting a lot of energy on that over the summer and back to school. I think in terms of compliance, even in our trial, we saw similar dropout rates to the adults, so it's not that kids had a worse dropout rate. It was consistent, if not slightly below what we expected. Kids are no different than anyone else. A lot of times, I've been to the camp with Kevin here and you talk to some of these kids, they have much bigger issues than worried about their insulin control, but you want to find the best tool that meets their life. And if it's fitting their lifestyle, they're going to be compliant and yes, they're going to miss doses. They're kids, but many times, like when you go to the camp and you see it firsthand, they're dosing blindly their insulin.

They're not sure if they're going to eat one chicken nugget or five, one ball of mac and cheese or none. And that's really the challenge I think parents face, is how do you properly dose your child? How do you keep up with them? What are they doing in school? And now you can clearly see what's happening. With Afrezza, it does start to see that CGM move in the first hour, hour and a half. So you'll know what your child is doing pretty quickly, but just like anyone, there's always going to be compliance issues. And I say if someone's a 9.5 or 10 and

... they're struggling, then maybe insulin pumps are the right product, get some insulins better than none. But I think anyone that really wants to bring their sugars down and improve mealtime control, that's where I think we have a big opportunity. And if you really think about children, their alternative is going to be wearing an insulin pump or a pod or getting an injection. I think most kids would rather say, "Okay, I'll take my medicine and let me take it." So this is much easier. And I'll never forget a few months ago we had an ad board and one of the doctors said, "Thank you for bringing this forward. The hardest part of my job is telling a family that their child's going to require injections to live the rest of their life. And I hate doing that every single day." And this is going to say, "Give them hope that maybe they don't

need to give injections the rest of their life. They're going to need a basal, but maybe we can eliminate the three to five injections a day, mealtime or boluses they got to take with their pump."

Brandon Folkes:

Great. Thanks very much. And maybe one more. During those ad boards or discussions with KOLs, has there been any discussion about use of Afrezza in patients with eczema that may actually not be diagnosed with asthma just yet? Sort of any hesitation there or any discussion or view on that? Thank you.

Michael Castagna:

About hesitation about undiagnosed asthma? Is that the context?

Brandon Folkes:

Yeah. Just sort of ...

Michael Castagna:

We allowed some patients in the trial, I think in the INHALE-3 that may have had a history and we could see people that may have thought they resolved childhood asthma, had slightly more cough or challenges. But I think in the kids, Kevin, we allowed the same. And there wasn't a big difference in FEV1s or anything there. So we have some of that clinical data we can go back and see. I can't remember it was like 10 or 20 patients that had asthma historically or somehow diagnosed during the trial and there was no major issue. So we'll have that data as a medical response if doctors have that question.

Brandon Folkes:

Great. Thanks for taking my questions and congrats on the approval.

Michael Castagna:

Thank you, Brendan.

Moderator:

Our next question comes from Yun Zhong from Wedbush Securities. Please unmute and ask your question.

Yun Zhong:

Hi, good afternoon. Thank you very much for taking the questions and congratulations on the approval. On the label, first question on the label, did the FDA tell you why the label is for children six years and older instead of four? That's the age enrolled in INHALE-1. And INHALE-1st, I believe the study is enrolling patient above the age of 10. So how are you going to get to those patients below the age of 10 that are treatment naive? And the second question, I believe in the 8K that you put out yesterday, the following mentioned that there is still post-marketing requirement for you to confirm safety and maybe efficacy in pediatric patients. So are you able to provide any additional details related to what needs to be done here, please? Thank you.

Michael Castagna:

Sure. I'll start with that question first. So there was four PMRs when Afrezza got approved in 2014. We completed three of them including... I would say the last one wasn't a completion. It was an agreement with the FDA that we were released from our long-term safety study, which was great to have right before pediatrics. The last one is the pediatric study, which we did. And so now that we have the approval, we now have to file that with the FDA and it has to be released from that last PMR. So there's no additional work to be done. This study should satisfy that post-approval commitment that we did as a result of the study. They've indicated that it will be the case, but it's a formality now with FDA that we have to go through. So we don't expect any challenges, but that'll be the next step.

Your next question is a good insight there you caught, is we expected four to 17. And I think as part of the FDA in the discussion, we realized there wasn't enough patients or really any patients below six in the trial. So it's kind of hard to argue for four and five year olds when they just didn't enroll. There was a couple in the control arm, but they weren't in the active arm. And so we didn't really have much of a debate with FDA on that one. It was, we'll be happy with six. It's really about how many units the patient needs as opposed to age, but we really didn't have any four and five year olds in the trial to have any real debate with the FDA on that topic. And it's important, but it's not critical. What I'd say is there are patients there, doctors can make their own clinical judgment.

We can always run a post-marketing study in that population if we need to, but I don't think it's going to be a significant barrier to success. I think as we get to two unit cartridge, that's probably going to be more important for that population than the four units we have today. And your last comment or question was around INHALE-1st being 10 to 17. At the time we started this trial with the FDA, we were pretty confident that the 10 and above would be approved. We weren't sure where the FDA would land below 10 as there wasn't as many patients. It wasn't sized for each age range. And so now that we have the approval down to six, we are going to ask the investigators, should we go down to six years old or stay with 10? There's no clinical reason we can't go down to six at this point.

Yun Zhong:

Great. Thank you.

Michael Castagna:

Okay. Thank you.

Moderator:

Our last question comes from Anthony Patron with Mizuho. Please unmute and ask your question.

Anthony Patron:

Oh, great. Thanks. And congratulations to the team here on the approval, big milestone for the company and patients. Maybe just in terms of the market opportunity, Mike, when you think of 360,000 target patients, you're mentioning the two unit dose, you have the four unit dose. I don't know if eight and 12 is at play here and then you have a 20 unit dose in the prepared materials here. So when we think about just dose distribution in pediatrics, how do you think it plays out from two unit cartridges all the way up to 20 unit cartridges? And I'll have a couple quick follow-ups.

Michael Castagna:

Okay. Anthony, thanks for calling in late on a Friday day in New York. And I'd say the average dose in pediatrics was 12 to 20 units a meal. So we weren't seeing as much in terms of the low doses being... People wanted two unit cartridges because they want to give the fine-tuned doses between four and eight, and eight and 12, but we didn't have that available in the trial. But we saw most people going to the higher doses, especially those adolescents who are growing, going through hormonal changes and need much higher insulin needs. So that's generally what we see. The two high concentrations we're working on are really to get to like a 16 or 20 unit cartridge and that's really to get people to one dose instead of two that'll ultimately reduce the cogs, reduce the utilization of the cartridges and it will help for like places like India and international where we do see people needing much higher doses in type 2s or international markets.

Anthony Patron:

No, that's helpful. And then the follow-up is just, you have the 35 out of pocket, but when you look at just retail pricing or even also acquisition costs and price Rx, you're kind of ranging at 450 to 1500 a month and that's the four to 12 unit range. You're adding two and going up to 20. So I don't know, when we think about it, are we ranging the net price to MannKind at like 250 up to 2000 a month? Is that kind of the way to model it out? And then the last one real quick is just ADA next week, do you expect a bump in new prescribers coming out of ADA? Congratulations again.

Michael Castagna:

Thank you. I think on pricing, we have time to figure that out, meaning two unit, maybe a flat price to four, maybe slightly cheaper, but as you get to the higher doses, they're actually more efficient to make. So I don't know if we'll still continue linear pricing out that way. And so it might be, from a modeling perspective, I would just assume whatever the average price prescription is today in that continuum is how I would look at it. And you can manage a similar gross to net until we give different guidance of where we are, but I wouldn't expect that the prices will keep going up exponentially with higher doses.

Anthony Patron:

That's helpful.

Michael Castagna:

And then-

Anthony Patron:

And then just talk about ADA.

Michael Castagna:

And then ADA, it's a big conference. I'd say more than half the attendees are international and then the other half, I'd say half practice medicine, half are just awareness thought leaders. And so it's really making sure our engagements with the half that matters that are coming to our dinner events, the one-on-one meetings and that they do go back and they are aware of the data. We're getting really good feedback on the new standards of care. We keep reminding people that this is a choice and these should be a choice that's offered to patients. And we think as clinicians go back and do that more and more, the patients will choose this as an option and we think that's an important aspect. But more importantly,

the PDN knows, I don't know, Kevin, it's not the biggest conference they attend, but there's quite a few there. So I think we want to make sure we're in the field. Right after ADA, we're training our team next week live and they'll be out there right after ADA hitting the ground.

Anthony Patron:

Thank you.

Michael Castagna:

Well, thank you everyone and thank you for dialing in so late on a Friday, especially for those on East Coast. I know you're waiting for happy hour. I am too. I have a big reason to celebrate. I've spent 10 years of my life here at MannKind making sure we get this available option to children. It's a really proud moment for me and the team and all the hard work despite many obstacles. To the patients and the families who participate in our trial and other pediatric studies who believed in this program, our regulatory team, our medical team, commercial team, Nick, Kevin, our pediatric leadership group, this approval is the result of your years of dedication and hard work. We didn't get here overnight. We got here because people refused to accept the status quo and give up on the idea that kids one day deserve this option versus mealtime injections. With that, operator, I'm going to close the call. We look forward to launching this successfully and meeting you at the future conferences. Thank you.

Moderator:

This concludes today's call. We thank you for your participation. You may now disconnect at this time.