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ADMS - Adamas Pharmaceuticals, Inc. - Special Call

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CORPORATE PARTICIPANTS

Ashleigh Barreto

Gregory T. Went *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

Rajiv Patni *Adamas Pharmaceuticals, Inc. - Chief Medical Officer*

Richard A. King *Adamas Pharmaceuticals, Inc. - COO*

CONFERENCE CALL PARTICIPANTS

David A. Amsellem *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Irina Rivkind Koffler *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

Jason Nicholas Butler *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

Kenneth Charles Cacciatore *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Serge D. Belanger *Needham & Company, LLC, Research Division - Senior Analyst*

Timothy Francis Lugo *William Blair & Company L.L.C., Research Division - Co-Group Head of Biopharma Equity Research & Partner*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Adamas Pharmaceuticals conference call. (Operator Instructions) As a reminder, this call is being recorded. I would now like to turn the call over to your host, Ashleigh Barreto, Director of Investor Relations and Corporate Communications at Adamas. You may begin.

Ashleigh Barreto

Thank you, operator, and good afternoon, everyone. Joining me on the call today are Dr. Greg Went, our Chairman and Chief Executive Officer; Richard King, our Chief Operating Officer; Dr. Rajiv Patni, our Chief Medical Officer; and Alf Merriweather, our Chief Financial Officer.

Before I begin, I'd like to remind everyone this call will contain forward-looking statements, which are subject to risks and uncertainties. Please note that these forward-looking statements reflect our opinions only as of the date of this call.

We undertake no obligation to revise or update these forward-looking statements in light of new information or future events. Information concerning factors that could cause actual results to differ materially from those contained in or implied by such forward-looking statements are discussed in greater detail in our most recent Form 10-Q and other SEC filings.

I would now like to turn the call over to Greg. Greg?

Gregory T. Went - Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO

Thank you, Ashleigh, and good afternoon, everyone, and thank you for joining us today. This is a banner day for people with Parkinson's disease, their care partners and their physicians trying to manage their patients. Since the introduction of levodopa over 50 years ago, Parkinson's disease patients and their physicians have struggled to balance OFF time when the effects of levodopa wear out and the symptoms of Parkinson's return with the occurrence of dyskinesia, characterized by involuntary, non-rhythmic movements during morning and waking hours that are purposeless and unpredictable. Dyskinesia represents a turning point for patients in their journey. Frustration, embarrassment, isolation, risk of injury, social withdrawal, anger, depression, poor quality of life and increased care burden, decreased income are all challenges borne by these patients and



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their care partners. Up to now, the primary option has been to reduce or fractionate the dose of levodopa, often resulting in more OFF time, until today.

For this orphan population, approximately 150,000 to 200,000 patients in need, the wait for a treatment of dyskinesia is over. I would like to thank all those patients who participated in our clinical trials, their families, their physicians and clinical staff, the many partners who invested in clinical trial capabilities and endpoints, like Michael J. Fox Foundation, the Parkinson Foundation and the Movement Disorder Society.

And this is a momentous day for Adamas. GOCOVRI is our first approved product that we plan to launch yourselves, our second overall and hopefully with many more to come. It represents a validation of our approach and our belief in the power and promise of medicines derived from a deep understanding of time-dependent biology. GOCOVRI is the first and only FDA-approved medicine for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapies with or without concomitant dopaminergic medicines. GOCOVRI is a high-dose, 274-milligram amantadine equivalent to 340 milligrams of amantadine hydrochloride taken once daily at bedtime that delivers consistently high levels of amantadine in the morning and throughout the day when dyskinesia occurs. GOCOVRI is also the first and only medicine to show statistically significant and clinically relevant reductions in dyskinesia and secondary reductions in OFF time with a very favorable benefit safety profile. On the call today, Rajiv will review the clinical program and the label, and Richard will update you on the commercial launch plans. Over to you, Rajiv.

Rajiv Patni - Adamas Pharmaceuticals, Inc. - Chief Medical Officer

Good afternoon, everyone. The FDA approval of GOCOVRI is the culmination of a successful development program that included clinical pharmacology, a Phase II/III dose-finding trial, 2 replicate Phase III trials and an ongoing open label safety trial.

Before I comment on the label, it is important to emphasize key aspects of our clinical program, namely the study population. All patients were required to have at least 1 hour of troublesome dyskinesia time and experience at least mild functional impairment of their dyskinesia. All patients were on a stable dose of levodopa, and the dose could not be changed during double-blind treatment. This is an essential point because before the FDA approval of GOCOVRI, the primary way to manage dyskinesia was levodopa dose decrease and/or fractionation. This may no longer be necessary.

The primary endpoint in our studies was the Unified Dyskinesia Rating Scale, or UDysRS, developed and validated by the Michael J. Fox Foundation and the Movement Disorder Society. This scale has a patient and physician component and, therefore, in our view, represents a holistic measure of the intensity and visibility associated with dyskinesia.

On to the data. In Section 14 of the label, the results of the 2 placebo-controlled pivotal studies are described. In Study 1, the reduction in dyskinesia, as measured by the UDysRS, was 37% compared to 12% for placebo. In Study 2, the reduction in dyskinesia was 46% compared with 16% for placebo. For the primary efficacy analysis, the p value was highly statistically significant at 0.0009 and less than 0.0001, respectively. The clinical meaning of these results can be put into perspective with the diary data, also contained in Section 14 of the label. For instance, in Study 1, GOCOVRI-treated patients gained an additional 3.6 hours of functional time each day, defined as ON time without troublesome dyskinesia, compared to 0.8 hours for patients receiving placebo. In Study 2, GOCOVRI-treated patients gained an additional 4 hours of functional time each day compared to 2.1 hours for patients receiving placebo. This substantial gain in functional time is due to both a reduction in OFF time as well as a reduction in troublesome dyskinesia time.

The safety sections of the package insert, sections 5 and 6, are based on the safety data amassed in the Phase III program. Despite GOCOVRI being a high-dose amantadine with a fourth titration dosing regimen at 1 week, I want to emphasize that the safety data have remained consistent. There have been no surprises during clinical development. There are 6 warnings and precautions: falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations and psychotic behavior, dizziness and orthostatic hypotension, withdrawal-emergent hyperpyrexia and confusion and impulse control/compulsive behaviors. Patients should be observed for the occurrence of hallucinations, dizziness and orthostatic hypotension throughout treatment, but especially at initiation and during dose increases. This information is useful for the treating urologists, who has to manage the other known risk factors for these adverse reactions. While important for physicians to understand, I should also comment that the warnings for falling asleep during activities of daily living, withdrawal-emergent hyperpyrexia and impulse control behavior are class labeling for dopaminergic PD medicines.



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Besides hallucinations and dizziness and orthostatic hypotension, the remaining most common adverse reactions included dry mouth, peripheral edema, constipation and falls. Most adverse drug reactions were of mild intensity. The rate of discontinuation on GOCOVRI due to any adverse reaction was 20% versus 8% for placebo, indicating that most adverse drug reactions did not constitute significant morbidity in the majority of GOCOVRI-treated patients.

The dosage and administration section of the label is based on the approach we took in the Phase III clinical trials, namely a protocol-mandated fourth titration. Patients were initiated at a dose of one 137-milligram capsule at bedtime and increased to 2 capsules at bedtime after 1 week of dosing. We did this to enable patients to reach the recommended GOCOVRI dose of 274 milligrams promptly. We note that while patients with mild renal impairment can be treated with standard doses of GOCOVRI, patients with moderate or severe renal impairment should have their doses halved. GOCOVRI is contraindicated in patients with end-stage renal disease.

In Section 12, clinical pharmacology, we have included the time to maximum concentration, or tmax data. We are very pleased with this label.

Additional published data with GOCOVRI has been well received by the neurology community. As published in our Phase III papers, GOCOVRI was invented with a prolonged time to maximum concentration and a reduced initial rise in plasma concentrations during the night. This is why bedtime dosing is so important. As a result, sleep-related adverse reactions are modest, and an approximately 1,500-nanogram per milliliter amantadine concentration is achieved in the morning and maintained during waking hours when dyskinesia occurs. As published in JAMA Neurology, the effects of GOCOVRI on both dyskinesia and OFF time were maintained out to 24 weeks of double-blind treatment. The durability of the effective GOCOVRI on dyskinesia and OFF time is further supported by the open label safety data out to an additional 64 weeks, as measured by the MD-UPDRS Part IV score published in the Journal of Parkinson's Disease. I strongly encourage you all to read these papers.

With that, I will hand the call over to Richard.

Richard A. King - Adamas Pharmaceuticals, Inc. - COO

Thank you, Rajiv. Now I'm sure as you can imagine, the entire team at Adamas is thrilled at the ability to continue our rented progress towards bringing GOCOVRI, the first and only medication approved for the treatment of dyskinesia in Parkinson's disease, to patients in significant need. And they are in significant need. Dyskinesia patients have long suffered with no effective approved therapy. Dyskinesia is characterized in patients by involuntary movements during waking hours that are non-rhythmic, purposeless and unpredictable. These movements are distinct from tremors with Parkinson's disease. Dyskinesia is a consequence of dopaminergic therapy. Dyskinesia has an impact on many activities of daily living, including speaking, writing, eating, dressing, personal hygiene and walking, to the point that many patients do not anticipate in public or private social interactions. It is important to remember that nearly 50% of patients in our Phase III clinical trials were of working age of less than 65 years old. In these patients, dyskinesia may have an even greater effect, both in terms of quality of life and economic impact. Also, this condition affects both patients and their care partners, who often avoid exposure in public settings due to feelings of embarrassment. Without a proven treatment of dyskinesia, physicians have been challenged to address the stability of the situation for and with their patients and their care partners. GOCOVRI will now provide physicians the opportunity to have meaningful dialogue about dyskinesia.

Also, with GOCOVRI, neurologists can now treat dyskinesia without undermining effective dopamine-based Parkinson's disease therapy. In fact, not only does GOCOVRI significantly reduce dyskinesia, it also reduces OFF time by approximately 1 hour. As of January 2018, we plan to launch GOCOVRI as a high-dose 274-milligram amantadine taken once daily at bedtime that delivers consistently high levels of amantadine in the morning and throughout the day when dyskinesia symptoms are most troublesome. As Rajiv outlined, our package insert allows us to support statements that have proven important to physicians in market research. For example, physicians were not only impressed by GOCOVRI's approximately 30% reduction in dyskinesia at week 12 and a 45% reduction in OFF time, but also by the fact that GOCOVRI-treated patients in our studies gained almost 4 hours of functional time from baseline each day. Let's stop and think about that for a moment. That is half of an 8-hour workday each day. These clinically meaningful effects were observed as early as week 2 and sustained through 12 weeks. We will also be out to educate neurologists that GOCOVRI is associated with a familiar and manageable adverse event profile. Based on our quantitative market research, this product profile will be a welcome addition to the neurologists' toolkit to help people with Parkinson's disease reflected in an anticipated usual recovery in over half of their patients with dyskinesia. This will come from patients who are currently not being treated for dyskinesia, from patients who have been considered for carbidopa/levodopa dose modification or fractionation, and from patients who are being considered for addition of other product



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therapies, such as dopamine agonists or IR amantadine or MAO-B inhibitors. Between now and January 2018, we are in full launch preparation mode. I am pleased to announce that we have made offers to 6 outstanding regional business director candidates. These RBDs come with tremendous backgrounds, including an average of 13 years of managerial experience in the industry and 7 years of neurology experience. Their appointment prepares us well for the next step, which is recruitment of 59 neurology account specialists, whom we plan to have onboard by Thanksgiving.

Prior to making GOCOVRI available, we anticipate announcing the price to GOCOVRI, which we continue to project will be in the range of \$10,000 to \$30,000 per year. Adamas is committed to ensuring access to GOCOVRI on behalf of people with Parkinson's who have dyskinesia. To that end, we have partnered with a prominent U.S. pharmacy organization via the specialty pharmacy group to support patient access under the banner of GOCOVRI Onboard. This specialty pharmacy will work with patients, their families and physicians to facilitate access by reimbursement support, prescription fulfillment and financial assistance. This program is designed to deliver seamless product assistance and financial support services to patients in need. In the fourth quarter, we anticipate GOCOVRI will be available for physicians to prescribe through this specialty pharmacy with all of its patient support services going live at the same time. In addition to this team, we will be deploying a team of care account managers, who will be interfacing with payers to ensure familiarity with GOCOVRI and to ensure access for the product to place in our formulary. Also, in the fourth quarter, we anticipate deployment of a team of medical science liaisons, who will be reaching out to the neurology key opinion leader community to respond to any questions they may have regarding the product. We just saw our second pivotal Phase III published in a prominent peer-reviewed journal, the conclusions of which I am sure will interest neurologists and movement disorder specialists.

Finally, our 59 neurology account specialists will be disease state and product-trained in December, leading to full deployment in early January 2018. We look forward to sharing more details on our commercialization plans with you at the investor meeting scheduled for September 18, and perhaps, more importantly, to bringing GOCOVRI to patients in significant need as quickly as possible.

I would now like to turn the call back over to Greg.

Gregory T. Went - Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO

Thanks, Richard. As Richard and the entire company prepare for the launch of GOCOVRI, we will continue to advance our development pipeline, including our programs for MS walking and for epilepsy. We will shortly be announcing Phase Ib data on ADS-4101, our high-dose glucosamine candidate for patients with epilepsy, where up to a quarter of patients continue to be uncontrolled by available treatment options, and where the desire for clinical benefit and a once-daily dose product remains high. We plan to discuss a possible Phase III program with the FDA in 2018 if those trials are successful. We also continue to execute on our plans for taking ADS-5102 forward into Phase III for MS walking, where there's currently only one drug available, which is believed to be effective in only a subset of MS patients. We will continue to explore additional indications for ADS-5102 as well. Combined, these programs give us a robust pipeline of drug candidates and potentially capable of generating multiple long-term revenue streams. We look forward to continuing to be the leaders in discovering products based upon our unique understanding of time-dependent biology effects that can drive increased clinical benefits to patients suffering from CNS disorders. Again, this is a momentous day for Adamas. GOCOVRI is our first approved product that we will commercialize ourselves. We are ready to change the Parkinson's disease treatment paradigm with GOCOVRI. I'd like to end with my thanks, again, to all the people who've contributed to this effort and this moment. I would like to acknowledge the families of Adamas employees, the board, advisers, without whose support we could not have achieved this milestone for patients. And to our dyskinesia patients, we look forward to serving you.

With that, I would like to open the call to questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from David Amsellem with Piper Jaffray.



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David A. Amsellem - Piper Jaffray Companies, Research Division - MD and Senior Research Analyst

Congratulations. My question is regarding the ON time without troublesome dyskinesia, the add in the label, and also the OFF time data. So that that's clearly in the label. Should we think of that as potentially expanding or changing the underlying opportunity given that, yes, you've got an indication for LID, but you've also got OFF time and ON time without troublesome dyskinesia in the label. So just in terms of overall positioning, given the dynamic, how should we think about that?

Gregory T. Went - Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO

David, thank you very much for the question, and I would start with I don't think this changes the opportunity at this point in time. This remains a product indicated for the treatment of dyskinesia in patients with Parkinson's. They should be taking levodopa with or without concomitant dopaminergic medication. As you know, that's the population we sought to develop this product for. It's the population we studied in our robust Phase III program -- Phase II program, Phase III and open label program. And of course, we do look forward to examining ADS-5102 and other indications as we go down the road. But at this point, we're very pleased with what we saw in the label with regards to the effects that we measured at the primary endpoint time. Rajiv, do you have anything to add?

Rajiv Patni - Adamas Pharmaceuticals, Inc. - Chief Medical Officer

I would just add that the way table 1 and -- table 2 and table 3 in the label are constructed are informing the prescriber on, as Greg mentioned, the primary efficacy data and the key secondary endpoint data that was replicated in our 2 Phase III trials.

David A. Amsellem - Piper Jaffray Companies, Research Division - MD and Senior Research Analyst

Okay, that's helpful. And then just a clarification question regarding the specialty pharmacy distribution. I just wanted to make sure I was clear on this. There will not be a retail distribution component. So will this just be a specialty component? Or will there be -- will that be part of the supply chain?

Gregory T. Went - Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO

Richard, you want to take that?

Richard A. King - Adamas Pharmaceuticals, Inc. - COO

Sure. So David, no, there will not be a retail component to distribution of GOCOVRI. It will be exclusively through a specialty pharmacy distribution.

Operator

Our next question comes from Ken Cacciatore with Cowen.

Kenneth Charles Cacciatore - Cowen and Company, LLC, Research Division - MD and Senior Research Analyst

Congratulations, guys. This is exciting news, and congratulations on the label. Great to see. A couple of questions, just that you're taking a little bit of time to get prepared for the launch in early next year. Can you give a sense of what you think the coverage will look like at the time of launch? I know you gave us a pricing assumption here that's a little bit wide, just -- but can you give us a sense without -- I'm sure you're not going to narrow



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it for us on the call, but just talk about the mechanics to getting coverage, both commercial and Part B? And then second question is, on the 59 reps, what percent of prescribing PD neurologists is that going to cover? Maybe a little bit of nuance on what that coverage gives you.

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

Ken, thank you very much for the call and, well, we'll accept your congratulations on the label. Let me just start with we're not announcing pricing at this time because we are still in the process of completing our research to come to a decision on that. And we will be announcing it prior to loading the drug in the channel here this fall. Richard, let me pass the rest to you with regard to coverage and the reps.

Richard A. King - *Adamas Pharmaceuticals, Inc. - COO*

Sure. So firstly, in terms of coverage, obviously, prior to this date, we've been reaching out to payers to start to inform them about the potential approval of the GOCOVRI and the potential interest that we have in this dyskinesia population. Those efforts will accelerate significantly now, and we will be able to have very open dialogue with payers along those lines. Obviously, the commercial arena will inevitably have a process of a formulary review for GOCOVRI and, ultimately, formulary adoption. So far, we're not anticipating anything but formulary adoption for GOCOVRI. It's a singular product approved in a singular indication, which I think is as important from a payer standpoint to provide support for patient population. I think with Part D, there's a slightly different process. Clearly, what we need to do there is to gain support from CMS. That's reimbursement for Part D under GOCOVRI. And that we don't anticipate will take -- we're too late at this stage to be included on the formulary for 2018, but we will be included for consideration for 2019. And in fact, the payers will likely adopt to Part D formulary and support ahead of that 2019 date.

So that is coming from a coverage standpoint. From a rep standpoint, we cover about 95% of the prescribing neurologists population that deals with dyskinesia patients in Parkinson's. So we'll cover the vast overall majority of that neurology population.

Operator

Our next question comes from Tim Lugo with William Blair.

Timothy Francis Lugo - *William Blair & Company L.L.C., Research Division - Co-Group Head of Biopharma Equity Research & Partner*

I'd like to pass on my congratulations as well. And with GOCOVRI being the first approved therapy for LID, can you maybe talk about the high level current state of awareness of LID in the tradition population? And then maybe for the price range, is there something in the label specifically which would push you to either end of the low end or the higher end of the range that was given? And maybe will you give us more clarity at the upcoming analyst event?

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

Tim, thanks for your question and the congratulations. Let me answer the second half of the question. And I know Richard and Rajiv have been out talking about the product profile, and I'll let them handle where the physicians are in terms of their awareness appreciation and excitement. I think we'll be in a good position as we get closer to Investor Day to talk about pricing and the actual range. Where we've been is in this range between where Parkinson's drugs have priced here and where -- and below honestly the range where movement, some of the movement drugs have been pricing in the tardive area. We look very carefully at the value we're providing, centering, as you know, on the magnitude of this clinical effect and the effect it has on the amount of good time that people have during the course of the day, what that means to those patients' lives, what that means to their families' lives, what that means to the health care system and what that means overall economically. So we're really very pleased to sort of complete this last round of research here. And those factors, along with making sure we can get access to patients, as Richard mentioned, on the commercial side as well as on the Part D side, will all factor in to getting a price in which we can support our patient population and get the drug over to them. In terms of the physicians' reaction, we just think this is an amazing opportunity, this being the first and only after all of these years. But Richard, maybe you can comment on that.



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Richard A. King - *Adamas Pharmaceuticals, Inc. - COO*

I think your question was specifically related to familiarity and awareness to dyskinesia at the physician level. I think they're acutely aware, the physician population, of dyskinetic state the patients emerge into after -- over time associated with Parkinson's therapy. And I think that the frustration at the physician level is just not having a treatment that's able to actually provide support for these patients. And as a result, it's also difficult to have a conversation with a patient about the obvious dyskinetic situation that many of these patients exhibit. So I think that the experiences that we've seen and the feedback we've had is the provision of a medication that quite clearly will provide benefit to a population that so far they've been unable to treat is a significant event in the ability to manage Parkinson's more effectively. And for that, we're delighted with the approvals there.

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

Just one more comment on the movement disorder neurology side. These data, they find very noteworthy because now there's a medicine in the population we studied, as Greg mentioned, that reduces and treats dyskinesia, but also has a secondary benefit on OFF time. And that represents a really new medicine in the Parkinsonology community.

Timothy Francis Lugo - *William Blair & Company L.L.C., Research Division - Co-Group Head of Biopharma Equity Research & Partner*

Understood. And were there any post-approval commitments or additional studies planned?

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

There are no post-approval commitments required by the FDA.

Operator

Our next question comes from Jason Butler with JMP.

Jason Nicholas Butler - *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

Let me add my congratulations. First is the label talks in several places about how you see lower rates of certain adverse events in patients under 65. I think Richard mentioned it in the prepared comments, but can you just reiterate what proportion of patients in the Phase III program were under 65? Is that reflective, you think, of the broader patient population? And then what was the discontinuation rate and benefit that those patients saw relative to the overall patient population?

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

So on your first question about the discontinuation rate, that's not contained by age. That's not contained in the label, and I can come back to you and answer that question about discontinuation rates by age. With respect to efficacy, and we published these data, it's in the supplements of the papers, you can see the effect of GOCOVRI is consistent when you look at age breakdown in the younger and the older.

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

And I would just, Jason, follow up on the epidemiology. About 45% of the patients in the Phase III programs were under the age of 65. Based upon our epidemiologic modeling, that's actually pretty close to the population that we're going to be going in and treating. This indication tends to



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skew a bit towards the younger because of 2 factors. Early-onset patients typically are at higher risk of developing dyskinesia, and patients who are at that stage of their treatment journey tend to treat themselves more aggressively. They really don't want to be off. They really don't want to be dyskinetic. They want to continue to enjoy their lives because they don't consider their lives towards the letter. And so it's pretty close.

Jason Nicholas Butler - *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

Great. And then just one more question. Can you just remind us of the patent exclusivity that you currently have for the drug, what that -- the duration and what that IP comprises, and then where you stand on gaining additional visibility on orphan drug exclusivity?

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

I'll do the first part first and the second part second. On the first part, we have multiple patent families that we are prepared to list in the Orange Book protecting elements of the time dependency that we have embedded into GOCOVRI. They have a range of expiry dates without extension, ranging from 2028 to 2034 right now. And it'll be easier to answer that question after we make the listing, and you can see the decision that we make on those issued patents. We still have multiple families of pending patents as well that we continue to pursue, that protect the time-dependence of GOCOVRI, which we will continue to pursue. With regards to orphan designation, we are designated. It is our understanding that it has -- now we have an orphan-protected product, the agency will inform us in a timely manner. And that will also be then listed in the Orange Book subsequent to that.

Operator

Our next question comes from Serge Belanger with Needham & Company.

Serge D. Belanger - *Needham & Company, LLC, Research Division - Senior Analyst*

I'd like to offer my congratulations to you, Greg, and your team. My first question for Raj is, in the discussion of the Section 5 of the label, the warnings and precautions, you've kind of highlighted 3 of them. I think it was hallucination, dizziness and the hypertension that we need monitoring. I guess, can you just describe on how that monitoring will take place? And is it just a question of dose adjustment? Or this could lead to discontinuations?

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

So thanks for the questions. with respect to the warnings and precautions that I mentioned, the recommendation labeling is to monitor patients for these adverse reactions. As per good clinical practice, there's nothing specific required for GOCOVRI. As expected, these adverse reactions would more likely occur at initiation or dose increase. With respect to discontinuations, as I commented in the overall program, the discontinuation rate due to adverse reactions was 20% in GOCOVRI-treated patients versus 8% in placebo-treated patients. And then the label provides detail about specific adverse reactions. I'd lastly point out that in the vast majority of cases, the adverse reactions were mild in intensity and did not require additional clinical intervention.

Serge D. Belanger - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. And then, Greg, I guess, can you just describe your overall interaction with the FDA throughout this process, and how receptive they were to the label you were seeking?



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Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

Well, I wasn't directly involved, Serge, but I will tell you that we continue to enjoy, I think, a great working relationship with the agency on this and our other programs. Adamas has been in the position of pioneering regulatory pathways, in addition to products that generate differentiated clinical data. So every conversation ends up being based upon a precedent that we're trying to create together. So I think that continued through to here, and we're very pleased with where we sit today. There's a lot of smiling faces around the table.

Operator

Your next question comes from Irina Koffler with Mizuho.

Irina Rivkind Koffler - *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

Congratulations from me as well. I'm relieved. I wanted to just explore a bit about the differences by gender in adverse event profiles. If you could just comment on explaining those a little bit more. And then also, how does the label here -- I guess, what does it imply for the potential future MS label? And what have you learned in this process in terms of what you expect now going forward with that indication?

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

Over to you, Rajiv.

Rajiv Patni - *Adamas Pharmaceuticals, Inc. - Chief Medical Officer*

So on your first question about adverse reactions by gender, if you look at the data as recorded, the adverse reactions, which occur more in women, for example, livedo reticularis, that's actually not surprising. And similarly, we saw more peripheral edema in men, more dizziness in men and, again, very much aligned with what's clinically known and observed about amantadine. So nothing surprising at all, first. And second, there is an increasing focus by FDA to provide safety data broken down by age and gender. So this is not something done unique to the GOCOVRI label, but is really becoming standard label construction. With respect to your second question, as you know, we had a Phase II meeting, and we had good feedback. Thanks for your question, Irina.

Operator

Thank you. I'm seeing no further questions in queue. So I'd like to turn the conference back over to Greg for closing remarks.

Gregory T. Went - *Adamas Pharmaceuticals, Inc. - Co-Founder, Chairman & CEO*

So obviously, a very happy day here at Adamas. A happy day going forward here for the Parkinson's community dealing with this condition. I also want to thank the folks who have supported the company financially over the years. Without your efforts as well, we can't do what we enjoy doing, which is inventing, developing and bringing these types of innovative treatments to patients. So we thank you. We look forward to speaking with you here in September. We look forward to our next news that will be coming forward here in our epilepsy program, and thank you for participating today.

Operator

Thank you. Ladies and gentlemen, that does conclude today's conference. Thank you very much for your participation. You may all disconnect. Have a wonderful day.



AUGUST 24, 2017 / 8:30PM, ADMS - Adamas Pharmaceuticals, Inc. - Special Call

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