Q4 2019 Genfit SA Earnings Call

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TEXT version of Transcript

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Corporate Participants

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* Carol L. Addy

Genfit SA - Chief Medical Officer

* Dean W. Hum

Genfit SA - COO & Chief Scientific Officer

* M. Pascal Prigent

Genfit SA - CEO

* Naomi Eichenbaum

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Conference Call Participants

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* Antonio Eduardo Arce

H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst

* Jean-Jacques Le Fur

Bryan Garnier & Co Ltd, Research Division - Analyst

* Mayank Mamtani

B. Riley FBR, Inc., Research Division - Research Analyst

* Thomas Jonathan Smith

SVB Leerink LLC, Research Division - Director of Immunology and Metabolism & Senior Research Analyst

* Yasmeen Rahimi

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Presentation

Operator [1]

Greetings, and welcome to Genfit Reports 2019 Year-end Financial Results and Corporate Update Conference call. (Operator Instructions) It's now my pleasure to introduce your host, Naomi Eichenbaum. Please go ahead.

Naomi Eichenbaum, [2]

Thank you. Good morning, everyone, and thank you for joining us on Genfit's full year 2019 financial results and corporate update conference call. Last night, we issued a press release with the updated 2019 financial figures and corporate updates which can be accessed on our website at ir.genfit.com.

Prior to beginning, I would like to note that during our call, we will be making forward-looking statements. This webcast contains certain forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995 with respect to Genfit, our expected future performance, business prospects, financial guidance, events or plans, including timing of the announcement of the top line interim results of our Phase III RESOLVE-IT clinical trials, timing of our NDA submission for elafibranor in NASH, timing of clinical and regulatory milestones, regulatory and developmental timelines for our NIS4 technology and its availability as an LDT beyond the clinical research environment and our ability to continue supporting activities and to minimize potential delays on our business once the COVID-19 pandemic subsides.

These forward-looking statements are based on assumptions and estimates by our management, which, although believed to be reasonable, are subject to numerous known and unknown risks and uncertainties which could cause actual results to differ materially from those expressed in or implied or projected by the forward-looking statements. These forward-looking statements speak only as of the date of this webcast. Other than as required by applicable law, the company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

Following the prepared remarks, we will open up the call for approximately 20 minutes of questions that will be addressed by Genfit management; Pascal Prigent, CEO; Dean Hum, COO; and Carol Addy, CMO. Please limit yourself to 1 initial question to allow time for other questions.

I'll now turn the call over to our CEO, Pascal Prigent.

M. Pascal Prigent, Genfit SA - CEO [3]

Thank you, Naomi. Good morning, everyone, and thank you for joining the full year 2019 financial results and corporate update conference call, especially under the current circumstances.

So to begin, this past year has been one of great positive change and evolution for Genfit. Significant proper milestones have been achieved, And the one greatest, our top line Phase III RESOLVE-IT trial for NASH is almost upon us with interim results expected to be communicated by the end of May 2020. We will discuss it in greater detail on this call.

With that being said, we are in the midst of an ongoing COVID-19 pandemic. This virus has impacted us and the world in unprecedented ways, and we at Genfit are trying hard to remain agile in order to adapt to the recommendation of the health and safety of regulatory bodies on implementing practices to secure safety of our employees, clinical trial sites and patients. These protocols have changed the way we operate our organization and have demanded creative positioning. Yet, we remain focused on protecting our team and preserving business continuity so that we remain on track to deliver corporate milestones to the extent appropriate and possible given the circumstances, of course.

Over the past year, we have made significant changes to the corporate structure, executive team and government to best prepare for the transition from a development organization to a commercial one. I guess it begins with my own Genfit evolution.

In 2018, I joined as Executive Vice President, Marketing and Commercial. And about a year later, in September 2019, on the company's 20th year anniversary, I was appointed to the role of CEO. In detail, the former CEO and Chairman is also founder of Genfit, Jean-Francois Mouney, to take a full-time position as Chairman of the Board.

It was personally a key point in my career, and I understand my responsibility with a significant -- the near-term milestone and potential elafibranor could bring to the NASH market. The opportunity to lead a late-stage company, such as Genfit, has allowed me to build on the strong foundation created by Jean-Francois, and start refining the future commercial strategy and launch plans, beginning with the onboarding of new management and internal promotions.

In 2019, our global headcount grew from 148 to 194 employees across market access, commercialization, medical affairs and some acquisitions. All key areas that are involved with a shift towards the more mature corporate and commercial structure.

We also hired skilled experts such as Dr. Carol Addy, who has joined as Chief Medical Officer in our Cambridge office. Carol is an endocrinologist by training, and she brings over 20 years of experience in the diabetes and obesity space as well as a comprehensive acumen of drug development for metabolic and chronic diseases. So we believe she's an ideal addition to aid in the build-out of our NASH program.

Dr. Addy is joined in U.S. by Dr. Dean Hum, our CEO for many years that I think most of you know, and he is newly appointed President of Genfit Corp, and he recently relocated to East Coast and is now based out of our Genfit Corp. headquarters also in Cambridge.

In addition, we recognized achievement from within, and we promoted Dr. Suneil Hosmane to Head of Global Diagnostics. Suneil is overseeing our innovative NIS4 program. So all of these changes were part of a multi-pronged approach and an ongoing strategy, transitioning Genfit from being a strictly French-based company to a more global one with a strong U.S. footprint.

As a matter of fact, we now have roughly half of our executive team that is actually U.S. based. So this footprint was further strengthened by a successful U.S. IPO on NASDAQ last year. Being listed on both the ONEX and NASDAQ has not only opened up opportunities from a financial perspective with the inclusion of new and specialized health care investors, is also aligned with our positioning as a global pioneer in NASH and (inaudible).

Finally, I would say that being equal on NASDAQ improved our visibility in the U.S. and in particular, it's helping us attract the right caliber of talent we need to further strengthen our team.

So I chose to focus my opening remarks on our team, Genfit Human Capital, because it's their dedication and testament in terms of prosperity, but even more so in times of challenges, such as the current circumstances of COVID-19 that make a difference. And ultimately, they will be the ones making possible the delivery of solution to provide taking inventory with unmet medical needs.

So let's now talk about our novel noninvasive diagnostic program and new technology, NIS4. In 2019, it has made substantial progress from both a clinical and regulatory perspectives. As a reminder, the clinical reference standard to diagnose and stage NASH is a liver biopsy. As you all know, it's an invasive, costly procedure that may be officiated with procedural complications and that only a limited number of practitioners

can order -- conduct overview.

So we all realize biposy is not a scalable option. And given the prevalence of the disease and the high number of suspected patients in need of fibrotic evaluation, a noninvasive diagnostic solution optimized for leaving NASH still remains a high-end net need.

With an eye on biomarker discovery at the time of our Phase IIb GOLDEN-505 trial in NASH, Genfit recognizes the need for noninvasive diagnostic tests and developed NIS4. The following [algorithm] capable of identifying at risk NASH patients or patients that should be treated, so specifically patient with NASH with significant fibrosis. And that's based on 4 biomolecular panels.

Additionally, recent research presented in November at ASLD 2019 demonstrated that Mitral was also able to outperform over noninvasive diagnostics by identifying NASH with fibrosis in people with type 3 diabetes, which we know is independently a non-moving chain resistance, a non-risk factor and driver of NASH through this progression. And these data actually expand on the late-breaker presented at ASLD in 2018 that showed robust performance across multiple clinical asset population.

So this highlights that Mitral has the necessary accuracy to identify the patient population with a higher risk of disease progression, the capability that will be integral for identifying patients who could potentially benefit from pharmacotherapy and provide healthcare professional with a tool to solve the significant challenge in the current and future commercialization of any NASH therapy.

The Mitral program advanced towards commercialization in January last year when Genfit signed a licensing partnership with LabCorp-Covance for the implementation of Mitral in the clinical research laboratory network.

In November '19, Mitral was launched globally by Covance. In just a few months, it has been sold to multiple sponsors for using their NASH clinical development program. Within this context, Mitral is being utilized to help these patients with identification and recruitment in different NASH clinical trials, and it's also being explored as an interim technology to assess patient's response to therapy.

We believe that Mitral will ultimately lead to substantial cost savings to trial sponsors and will also minimize unnecessary harm to patients by eliminating biopsies in patients deemed to have a low-digit severity and that will -- likely to be ineligible for clinical trials. We are eager to expedite NIS4 access, and we are working on the dual-track commercial strategy. We are exploring opportunities to enable further licensing to support central partner launch of Mitral, as a laboratory developed test, also known as LDT. And in parallel, we are also actively pursuing formal approval for 2 regulatory body submissions, the FDA and EU regulatory body to seek approval of an individual diagnostic IVD, which is a different version of Vitro of course approve -- anticipate to -- in the first half of 2021.

So in the meantime, we have, of course, significant efforts underway exploring elafibranor, our lead asset, which is a PPAR alpha/delta agonist, for both Primary Biliary Cholangitis, or PBC, and in NASH.

Our PBC program has shown great potential, demonstrating statistically significant Phase II results. And this data have been provided and they've provided early confirmation of efficacy on endpoints used for regulatory drug approval that was presented at result '19 and the elafibranor in PBC consistently shows robust improvements on markers, of course, that fit with a metabolism, reduction on immune/inflammation as well as decrease in bile acid precursors.

These promising results are also encouraging as elafibranor has not closed our work in pruritus. And in fact, our study showed a potentially meaningful trend on improving pruritus, as measured by [Vitesco]. The efficacy profile in conjunction with favorable safety and priority profiles are extremely inspiring for Genfit and the PBC community as a whole, and we will be confirmed in a Phase III trial, of course.

Elafibranor, I hope to be granted breakthrough therapy designation by the FDA and orphan drug designation by both the FDA and EMA, showcasing the agency's recognition of the potential of elafibranor. So we strongly believe that there is significant unmet medical need in PBC, and therefore, we are committed to developing elafibranor for this indication. That being said, we are, of course, saver in development of elafibranor in NASH.

In 2019, elafibranor continued to show a consistent and favorable safety and polarity profile. Over the course of 2019, the DSMB performed a 36-month and a 42-month review of RESOLVE-IT of NASH Phase III clinical trials and recommended the continuation of the study without any modification, taking into consideration safety data of patients who received trials for 4 years.

So looking back, over 2,000 patients of Phase II data of elafibranor has now been achieved. In particular, since there has been a recent question, we have seen no issue of -- [in to Phase II] databases, which, I guess, is for the reason to the distinction between different types of PPAR agonist. We believe the side effect and safety profile of elafibranor highlights the real-world opportunity for elafibranor's potential usage in NASH. Indeed, we know that in a silent disease like NASH, side effects can negatively impact compliance.

And since NASH is associated with increased cardiovascular risk, we feel it is relevant that in past trials, elafibranor has actually consistently improved (inaudible) such as (inaudible) , (inaudible) distance, (inaudible) or (inaudible). So thanks to its sable efficacy and safety profile, Genfit is actually the first company to initiate a study that evaluates elafibranor as the potential therapy for pediatric patients with NASH.

Asides from the Phase III development in NASH, Genfit continues to explore the role of elafibranor in multiple clinical programs, including a combination study of elafibranor with GLP-1 agonist and SGLT2 inhibitors and elafibranor's impact on hepatic lipid composition on patients with NAFLD.

2019 was also a year where we made significant progress on the commercial front. So first we signed a very meaningful partnership with the licensing of the commercialization rights of elafibranor for NASH and PBC in Greater China with Terns Pharmaceuticals. Aside from the financial benefit from this agreement where we secured a $35 million upfront payment with potential sales of $193 million based on milestone, this opportunity also incorporates an exciting R&D collaboration for individual and combination assets targeting NASH. These studies will be disclosed as the program materializes.

Legal commercialization strategy for Greater China is published. We also have allocated considerable amount of time and spend to U.S. and to new market access plan. In preparation for the commercial launch, Genfit has developed a clear approach of the payer landscape based on rigorous area research of finding highlights that payers anticipate, including NASH therapy from the formularies regardless of endpoint and the main contingencies around price point. Preliminary findings indicate that biopsy requirements will be dependent on price with an option to (inaudible). So in other words, if price is reasonable, the majority of payers are not currently compensating the actual requirements.

We also learned by the positive metabolic profile -- it's seen as meaningful by a significant number of payers and healthcare professionals, even though a lot of education and awareness building remains to be done in the next stage. We continue to develop the pricing strategy that

we hope will enable an encumbered access for potential patients while driving intangible value for our shareholders.

Additional energy and resources have been developed towards a greater launch with partners, including the build out of a medical front relaunching for scientific information recognition, this team will be deployed in 2020. We also worked on the campaign for HCPs and patients for launch, conducted several HCP and payer advisory board meeting and build educational awareness packages for both elafibranor and NIS4.

So looking towards 2020, and I guess it was not anticipated that results of the year, we expect to announce the interim results of our resulted study by the end of May 2020 -- so end of next month, actually. So if you recall our previous guidance from February, we were about to work with [Anova], which we are awaiting FDA's feedback to underline the trial. So we were anticipating a feedback by the end of March with announcement of topline results a few weeks later.

So where are we now? We did log the database as planned at the end of February, and we are very happy to say that we just got the FDA's feedback. So we are actually very thankful that the current situation did not have a material impact on their panel. So we are now updating the study protocol and statistical analysis plan based on this recommendation. And of course, that means that at this stage, we remain blinded to the data.

We are working closely with our CRO, and we are excavating all processes as quickly as possible to incorporate the FDA's feedback. But of course, we also need to adjust accordingly to our parameters, and most importantly, perform necessarily QC and validation and all the checks and balances.

Of course, the COVID-19 pandemic is not making the work across the different teams involved in Libya, but everybody involved has been giving 110%, and we feel confident we will be in a position to announce topline results by the end of May.

As a reminder, the Phase III RESOLVE-IT study was initiated in 2016 is evaluating the efficacy and safety of elafibranor 120 milligrams versus placebo, in patients with NASH and fibrosis. The trial is a 72-week multicenter, randomized, double-blind, placebo-controlled study, and the data is out -- is positive, of course, will be supportive of submitting in NDA for approval on just about age in the U.S. and conditional approval in Europe.

If successful, this could be the certain only pivotal Phase III trial to achieve master position without the worsening of fibrosis standpoint, addressing the underlying code of national (inaudible). So we are hopeful for confirmation of this expectation.

As previously communicated and as the COVID-19 pandemic continues to unfold, Genfit has taken all precautions by posing the initiation of new studies and put all ongoing Phase I and Phase II clinical trials on hold, including those supportive of elafibranor's NDA NASH. And we are a just bit unclear at this stage when the COVID-19 pandemic will subside, and therefore, we will be able to reduce those efforts which is why we are guiding now for NDA submission for elafibranor in NASH is expected to occur in the first half of 2021. However, the company continues to remain steadfast in preparing all associated regulatory reviews, leading up to that signing as well as launch readiness initiatives. The extension phase of RESOLVE-IT for clinical outcomes remains ongoing, aside from a few adjustments to protect

patient safety in light of the COVID-19 pandemic. And all additional clinical support functions continue to progress in an effort to limit any further interruptions when the pandemic crisis subsides.

And to conclude briefly addressing our financials, cash equivalents and marketable securities, Genfit has a solid cash position of EUR 277 million as of December 31, '19, versus EUR 207 million at the end of 2018. So this increase, obviously, can be directly attributed to a successful global financing and U.S. IPO in March 2019, which raised gross proceeds of $155 million and the $35 million upfront payment paid by Terns Pharmaceuticals to Genfit in July '19.

Genfit anticipates that expenditures in 2020 will strongly depend, obviously, on the nature of the topline results from RESOLVE-IT Phase III clinical trial, which remain unknown as of today. And for a detailed overview of our operating results for the period ending in December '19, I refer you to our press release that we issued yesterday.

So I'd like now to turn the call over to the operator for the Q&A session. Operator?

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Questions and Answers

Operator [1]

(Operator Instructions) Our first question today is coming from Thomas Smith from SVB Leerink.

Thomas Jonathan Smith, SVB Leerink LLC, Research Division - Director of Immunology and Metabolism & Senior Research Analyst [2]

First, I was hoping you could provide a little more detail around the key secondary endpoint you've elevated in RESOLVE-IT related to the changes in metabolic parameters. Can you just give us a little more color on what specifically you're measuring here and what type of feedback was provided in the recent FDA communication?

M. Pascal Prigent, Genfit SA - CEO [3]

Tom, thanks for the question. So the additional key secondary endpoints that we have now were actually start of secondary. We just elevated that related to key [figures]. And those are endpoints that have to do with changes in metabolic parameters because all of you was -- because much patients are at a particular cardiovascular risk and because NASH is a metabolic disease, it was really important information for potential prescribers of elafibranor to have better information. And we felt that as key secondary, we would have stronger data as, of course, we control for the [IFRS]. So those key secondary endpoints are actually composite endpoints and we do not disclose it like over things that is in there, but they have to do with glucose and liquid metabolism seems like -- the endpoint seems (inaudible) et cetera, et cetera. So that's what we've done and what we have also agreed when we say we are modifying the protocol as a statistical plan is also included FDA feedback related to histological endpoints with the statistical method used in our analysis as well as additional analysis for descriptive statistics. So that's what we have.

Thomas Jonathan Smith, SVB Leerink LLC, Research Division - Director of Immunology and Metabolism & Senior Research Analyst [4]

Okay. Got it. And can you, I guess, just help us understand, from a statistical perspective, measuring these changes like the compositive endpoint around changes in metabolic parameters, how that's going to be looked at relative to the histological endpoint? Is it a higher archival analysis? Are there any changes to, I guess, powering assumptions around potentially showing a benefit in fibrosis? Just help us understand where these changes in metabolic parameters are going to fall relative to that other key secondary endpoints?

M. Pascal Prigent, Genfit SA - CEO [5]

Yes. So this change has no impact whatsoever on the analysis for the primary. With regards to the actual statistical methods, Dean, do you want to comment on this?

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [6]

Well, I think the most important point is that, of course, the statistical powering of the primary end point is not impacted whatsoever. So for the key secondary endpoints, there is a gatekeeping approach that is in place. And once we hit on the primary, then we will be addressing both the fibrosis and the metabolic endpoints. So it's important that both the fibrosis and the metabolic endpoints will be looked at the key secondary endpoints.

Thomas Jonathan Smith, SVB Leerink LLC, Research Division - Director of Immunology and Metabolism & Senior Research Analyst [7]

Okay. Got it. And just one last question. Can you just talk a little bit about the paused Phase I and Phase II studies and just help us understand which of these need to be completed prior to the NDA submission for elafibranor?

M. Pascal Prigent, Genfit SA - CEO [8]

Sure. Dean, do you want to take that?

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [9]

Yes. So the secondary -- sorry, the Phase II trials, the issue there, of course, with COVID is the patient recruitment, which has to be halted according to recommendation and guidelines from the regulatory agencies. For the Phase I trials, of course, as any programs or different Phase I trials throughout the course of the program and there are several ongoing -- that were ongoing for our program. So as it stands now, they have to be put on hold as well. And so once the COVID crisis is over, we will be looking to restart those as soon as possible. And there are a couple of those, which absolutely needs to be done before we can submit for NDA submission. And as you can understand, there are some Phase I trials, which just has to be done later on in the program. Just to give you an example, Tom, if you consider that for the commercial tablet, there had to be some adjustments made as any other program, things like changing the colors and things like that. So you do that, you do need bridging study and so on. So that's an example of the Phase I, which had to be started later on in the program and which has been completed before we can submit for NDA.

Operator [10]

Our next question is coming from Yasmeen Rahimi from Roth Capital Partners.

Yasmeen Rahimi, Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research [11]

The first question I have for you is just a clarification. The statistical modification that was just put in place does not -- doesn't affect the statistical preparation of one point improvement of fibrosis, the biopsy endpoint that is a key secondary. And then the second question for you is, what will you present a top line ITT and core protocol population? Can you share with us how you define the 2 to the extent you can give us color? And then I have a quick follow-up.

M. Pascal Prigent, Genfit SA - CEO [12]

Yes. So thanks, Yasmeen. On the first question, no, it does not meet or allow that we're in the definition of other key primary or key secondary that was fibrosis. Dean, do you want to take the second question?

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [13]

Yes. For the ITT and per protocol definition, the recommendations -- the recent recommendations from the FDA does not impact that whatsoever, okay? So it was as defined as since the beginning of the trial. So no impact on that whatsoever.

Yasmeen Rahimi, Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research [14]

And then Dean and Pascal, can you comment on whether we will see also the data? I know you had a cohort of patients that were F1 at risk, is that going to be part of the total analysis that's going to be presented at the top line as well?

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [15]

So yes. I mean, the F1 cohort, of course, is an exploratory cohort, and we will be getting data from that cohort as top line analysis.

Operator [16]

Our next question today is coming from Mayank Mamtani from B. Riley FBR.

Mayank Mamtani, B. Riley FBR, Inc., Research Division - Research Analyst [17]

So clarification, the first part of my question, on the components of FDA feedback. So beyond the metabolic efficacy endpoints, was safety also part of the dialogue, including maybe consideration of data from another in-class agent? And has there been a DSMB review in 2020? And then the second part to that question was, have you looked at the baseline characteristics yet of what you've seen in RESOLVE-IT? And how that might be in line or different relative to your expectations?

M. Pascal Prigent, Genfit SA - CEO [18]

Mayank. Thanks for being also so early in the web call. So regarding your question about safety and the question -- if your question is related to the discussion with the FDA on the key secondary elevation or key secondary, including safety, the answer is no. But I'm not clear -- like what was your question exactly, sorry? We're working...

Mayank Mamtani, B. Riley FBR, Inc., Research Division - Research Analyst [19]

Yes. I mean, anything -- like have you had a recent DSMB review, for example? And obviously, with the context of [B power class], has there any conversation been with the agency on safety since you've engaged the agency recently?

M. Pascal Prigent, Genfit SA - CEO [20]

Yes. So the last DSMB review was in November '19. And in 2020, we'll have once in every 6 months, right? So we haven't had one in 2020 so far, but we will have one. So 6 months of November will be May.

Mayank Mamtani, B. Riley FBR, Inc., Research Division - Research Analyst [21]

Okay. And the baseline...

M. Pascal Prigent, Genfit SA - CEO [22]

Do you want to add something to this, Dean or Carol?

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [23]

No, I don't have much to add to that, Mayank. I think we have to realize that we had a very robust protocol in place, both from the efficacy as well from a safety standpoint, okay? So there is no additional safety parameters, which were requested from the FDA whatsoever. I think we have a lot of bases covered from a safety standpoint. In terms of the DSMB, of course, Mayank, as you know, it's every 6 months, as Pascal just said, and considering what we have been hearing back as recommendation that DSMB, the elafibranor continues to be a drug candidate that is generally well tolerated and no issues whatsoever. So the recommendation has been consistently continue to trial without any amendments or any change, and that has been -- always been the case with elafibranor throughout the different trials. And I think with the ongoing trial and with RESOLVE-IT, to your point, Mayank, the last one was, I think 42 months, which is quite considerable. So we are very comfortable moving forward that we should not have any issues, but time will tell, but I think it's a -- that's a very achievable safety profile for elafibranor.

Mayank Mamtani, B. Riley FBR, Inc., Research Division - Research Analyst [24]

And could you address the question on baseline characteristics? Have you looked at that or?

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [25]

Yes. Well, we've looked -- we've had some look at the baseline data. So in terms of what's the baseline characteristics from the [NIS4] activity score, for example, as you know, comparing the RESOLVE-IT trial, the Phase IIb RESOLVE-IT does not have the problematic early-stage NASH patients. So when you think about the NIS4 activity score, the baseline value is a little bit higher than what we saw in the Phase IIb.

Mayank Mamtani, B. Riley FBR, Inc., Research Division - Research Analyst [26]

Great. And just on the European agency dialogue, is that also something you're having as if like you had with the FDA? And if yes, what is the color on the time line for that? And how that might differ relative to what you may have heard from FDA?

M. Pascal Prigent, Genfit SA - CEO [27]

So right now, the dialogue has been more focused with the FDA. We are forming a meeting just later with regard to development in Europe.

Operator [28]

Our next question is coming from Ed Arce from H.C. Wainwright.

Antonio Eduardo Arce, H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst [29]

I'm glad to see that you now have a very specific time line for the resulted data. So I wanted to go back on a couple of questions, if I may, that were asked earlier. Firstly, given that you've now received feedback from the FDA on these secondary endpoints around lipid lowering, could you comment at all on perhaps the perspective from the FDA? And how that may still be an important consideration in the overall risk-benefit evaluation for NASH drugs?

M. Pascal Prigent, Genfit SA - CEO [30]

Yes. Ed, thanks for your question. I really cannot comment at this point that I cannot speculate about the FDA position and they should be done discussing secondary endpoints of (inaudible). I think right now, in discussion about label, I think that, that will be premature, honestly, but I cannot say much, maybe at later stage.

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [31]

But just to add to that, Ed, I think it's important that all the key stakeholders in the NASH space realize the importance of the metabolic aspect of NASH patients. I mean, globally, NASH is considered as the liver manifestation of metabolic disease. And with that in mind, whether it's the regulatory agencies or the key opinion leaders, real experts in the NASH field, realize that for the management of NASH patients, considering their metabolic state, is going to be very important, especially keeping in mind that the leading cause of mortality in NASH base is cardiovascular event. So I think, again, all the keystone counters are cognizant of that. And I think following the metabolic parameters and if a drug is able to have a positive impact on that, I think that is going to be something that's going to be important to track and very important for the clinical management of the patients. And of course, the health care providers would be looking to that and taking that into account, when they think about how they want to address and manage their patients from a holistic point of view.

Carol L. Addy, Genfit SA - Chief Medical Officer [32]

And Dean, this is Carol. I'll go ahead and add to that and just acknowledging the comprehensive care of patients with NASH, many of whom have associated metabolic conditions and certainly, metabolic parameters, such as lipids and changes in glucose parameters are critical in terms of optimizing the care of these patients. And so certainly, the data readout from RESOLVE-IT will be a driver for Genfit in terms of ongoing and future discussions with FDA when we prepare our NDA dossier. And ideally, of course, we would like to be able to elevate the extent to which we can include these data in the label. Of course, we've not engaged in those discussions at this point in time, that will clearly be a review item at the time that we engage with FDA during the review of the NDA process.

Antonio Eduardo Arce, H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst [33]

Okay. Great. Then just a follow up, how long will these additional NDA-required Phase I studies take? And is this the driver behind pushing back the NDA submission time line to the first half of '21? And other than these Phase I studies, are there any other requirements that are gating factors to the submission?

M. Pascal Prigent, Genfit SA - CEO [34]

Thank you. So I'll let Carol comment on the exact time. Those studies are usually very short studies and also they're ongoing. So it's not like we have to start from scratch. We can just sort of resume where we left off. But indeed, we are sort of on the critical path for the NDA filing, and that is the reason why we pushed out to the first half of 2021 on NDA filing. Now the reason why it's very difficult to give a more precise guidance is because it obviously depends on the length of the COVID-19 pandemic, which, obviously, I don't think anybody has a clue at this point on how long it's going to take. So when we said first half, we were kind of thinking had probably take for the time during which everybody was compliant and probably add a month to that because we don't expect sites will be able to, sort of, resume the next day. There will, obviously, be some sort of disruption. And it will take them a little bit of time to sort of get back on their feet. And then we were thinking -- and again, what form of (inaudible) and what sort of working view for or thought process, we were thinking maybe it's a quarter or 2 quarters based on the fact that in China, it appeared to last for about 3 months, and then add another month to that. So it's about -- that was our thought process. I don't know, Carol, if you want to provide more details?

Carol L. Addy, Genfit SA - Chief Medical Officer [35]

Right. I think in light of COVID, certainly, I think we all wish we had a crystal ball in terms of better understanding the magnitude of impacts for clinical development programs such as for elafibranor. I think the good news for our Phase I program and the studies that are necessary for the NDA submission is that these studies are being conducted in healthy individuals. And so our ability to reinitiate these Phase I studies, I think the bar, in some ways, is a little bit lower than when we give consideration to, for example, the start of our PBC study, who are in -- that study being conducted, obviously, in individuals with a chronic liver condition that may put them at greater risk for COVID-19 infection complications. So I think we're going to be following closely with our study sites, many of which have closed down because of the COVID-related situation. And so we're monitoring the situation very closely with the intention being that we'll be poised to reinitiate as soon as we have a higher level of certainty in terms of the evolution of the COVID-19 crisis.

Operator [36]

Our final question today is coming from Jean-Jacques Le Fur from Bryan Garnier.

Jean-Jacques Le Fur, Bryan Garnier & Co Ltd, Research Division - Analyst [37]

Okay. Good. So the first one is also on the timing for the NDA filing. So assuming, let's make the [ASI] hypothesis that's the normal situation for clinical trials, comes back in, let's say, during the summer or early September, what does that mean in terms of H1 2021 filing? Does that mean middle of the first half or by the end? So this is my first question about the early semesters. And the second one is, do you anticipate any advisory committee following the NDA filing?

M. Pascal Prigent, Genfit SA - CEO [38]

Jean-Jacques, thanks for your question. Look, I mean, it's not that I don't want to answer, but it's really difficult to say, to be more precise than first half of '21 because that's so much (inaudible) with the COVID-19 situation, which is the first uncertainty, but is also how quickly will the different sites get back on their feet, which is another unknown that we do not control. And as I just stated the unknown that really -- I don't want to be more precise than H1 because I think both of the other (inaudible) of being wrong.

In terms of possibility of outcome, again, too early to say. I really don't have the information. There will be an outcome for -- but at the time, you'll see what we're seeing discussed there. But as far as we're concerned, again, at this point, I really don't know.

Jean-Jacques Le Fur, Bryan Garnier & Co Ltd, Research Division - Analyst [39]

Okay. And if I may, a quick financial one. Regarding the marketing and selling and G&A expenses since they increased significantly in '19 and because of the sort of short delay for the filing, approval and launch of elafibranor, do you -- do we have to anticipate or to take the same level of expenses for these 2 lines in 2020 for this year? Or should these 2 lines decline a bit because you have a sort of delay in the launch date for elafibranor?

M. Pascal Prigent, Genfit SA - CEO [40]

No. So first of all, you're right. It increased potentially in '19 because we did a lot of work on the research, market research. It's also a fact that we hired a lot of folks either directly or indirectly and directly is for changing personnel and directly with all program and the level of the people we hired were both quite senior people. So all of that contributed to that, that increase you talked about. As far as year 2020, also I think we said in the preliminary remarks, it really depends on the -- with all these results. So right now, we are really sort of going full speed ahead in terms of preparation and launch readiness. And then after we get the results, we adjust accordingly.

Dean W. Hum, Genfit SA - COO & Chief Scientific Officer [41]

So Jean-Jacques, thank you for your questions. And just before you leave, I just want to remind of the French-speaking audience that this call will be translated and scripted into French. So please look up for that.

(foreign language)

Operator [42]

We've reached the end of the question-and-answer session. I'd like to turn the floor back over to management for any further or closing comments.

M. Pascal Prigent, Genfit SA - CEO [43]

Okay. Thank you, everyone, for joining. So I realize that we were not able to take all the questions, but, of course, the management will be happy to make themselves available to take further questions on one-on-one meeting.

So to conclude, I would say that I'm very proud of what the Genfit team has delivered across all programs over the past year. We are well positioned to build on this momentum in 2020, and there is a great deal to look forward to this year. We have formulated a clear strategy for success, and we will be very gratifying to have our next corporate update, the interim results of the RESOLVE-IT study. Thank you very much.