Pharma VOICE

THERAPEUTIC DIGEST

INFECTIOUS DISEASES

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INFECTIOUS DISEASES

Introduction

Despite the rapid development and widespread usage of monoclonal antibodies to treat COVID-19, and then subsequently vaccines to inoculate against COVID-19, the pandemic remains a global threat, having started nearly two years ago. Filling an unmet need for anti-COVID-19 treatments for people in the earlier stages of disease, forthcoming new oral antivirals from Merck and Pfizer have the potential to further arrest the virus' path of destruction.

Both agents, the result of the last Administration's Operation Warp Speed initiative, are presently on the cusp of approval, giving hope of accelerating the world's getting back to normalcy. The focus of this report on important new developments in the Infectious Diseases treatment category will be on the rapidly unfolding, real-time saga of two highly anticipated anti-viral candidates that are greatly needed, particularly now that COVID-19 cases are rising in the US and across the world, as scientists anticipate a fifth surge of the pandemic.

On the HIV/AIDS front, a major trend covered in this report is the transition from three to two drug antiretroviral (ARV) regimens, as well as from daily to long-acting ARV regimens. While ViiV Healthcare has pioneered the two-drug regimen (2DR) category, forthcoming entrants from Merck and Gilead Sciences have the potential to further accelerate the mainstream standard of care towards long acting 2DRs. Several companies that market today's ARVs for HIV treatment also are striving to gain approval for their medications for HIV prevention, potentially adding more convenient alternatives to the pre-exposure prophylaxis or "PrEP" roster.

While there continue to be significant advancements in the field of anti-viral medications, industry experts still lament the dearth of development of new treatments against serious nosocomial infections. As this report will show, this often is a function of the way in which new antibiotics are adopted and utilized by physicians in hospitals. Nonetheless, there are several examples of companies who are striving to muster innovative treatments in the battle against serious infections, one of which we spotlight in this report: Entasis Therapeutics.

Effective Anti-Covid Oral Medicines Are Almost Here

The COVID oral medication market is evolving rapidly and in real time. Friday, October 1, 2021, was the day that the world started to learn about Merck's Molnupiravir, an orally administered nucleoside analog polymerase inhibitor against SARS-CoV-2 that was originally licensed by Ridgeback Biotherapeutics from Emory University. Incidentally, Molnupiravir was christened by the researchers at Emory after Mjölnir, the hammer of Thor. Ridgeback, a Miami-based company, originally planned to develop it before partnering with Merck to fast-track its journey to market.

The news that was broadcasted that day in early October is that, based upon the Phase 3 MOVe-OUT trial, Molnupiravir reduced the risk of hospitalization or death by approximately 50% in non-hospitalized patients with mild-to-moderate COVID-19. The results of this interim analysis triggered a halting of the clinical trials as Merck pivoted to preparing and subsequently submitting its application for Emergency Use Authorization (EUA) just eleven days later. While an updated review of the data showed a relative risk reduction of 30% in the study endpoint, this still represented a statistically significant benefit to using Molnupiravir versus placebo. The FDA advisory committee meeting is slated to review Merck's EUA on November 30.

At the same time, European Medicines Agency (EMA) officials announced that they have initiated their review of Molnupiravir's marketing authorization, and are expecting a decision within weeks, according to a press release as of November 23. Indeed, on November 4, Merck earned its first regulatory go-ahead when the UK's Medicines and Healthcare products Regulatory Agency (MHRA) granting Molnupiravir (the EU brand name of which is Lagevrio) approval for people diagnosed with mild to moderate COVID-19 who are at increased risk of developing severe disease.

Over the subsequent two months, and concurrent with the flurry of further positive news about Molnupiravir, governments started lining up to advance purchase and stockpile large quantities. The US government announced that it would be procuring over 3 million courses at a cost of $2.2 billion, while Japan has agreed to buy about 1.6 million courses. Merck also signaled its commitment to affordable access when it inked a voluntary licensing agreement with The Medicines Patent Pool (MPP), an UN-backed organization that facilitates the distribution of life-saving therapies to lower- and middle-income countries.

Just over a month after the Merck news splash, Pfizer announced on November 5 that its oral antiviral regimen, Paxlovid, demonstrated a reduction in the risk hospitalization and death by 89% versus placebo in non-hospitalized patients treated within 3 days of symptom onset. Paxlovid combines PF-07321332, a SARS-CoV-2-3CL protease inhibitor, with ritonavir, which is also a protease inhibitor but one that serves as a pharmacokinetic (PK) booster. Based upon an interim analysis, Pfizer also halted its clinical trial due to "overwhelming efficacy" (according to the press release) and started to prepare its filing.

While Pfizer's candidate delivers a relatively higher efficacy percentage, the regimen requires a second drug – ritonavir – to slow the metabolic breakdown and allow it to stay in the blood longer. Originally developed by Abbott Laboratories and branded as Norvir, ritonavir is a powerful CYP3A4 enzyme inhibitor that has been employed in combination with protease inhibitors in the treatment of HIV/AIDS and Hepatitis C to boost their PK profiles and lessen adverse events – but at the expense of certain drug-to-drug interactions (DDIs).

On November 16, Pfizer announced that based upon its trial, it too was seeking an EUA in the US for Paxlovid and has filed a similar application in the European Union. Like Merck, Pfizer also has governments lining up for advanced purchases: according to a press release, the US will secure 10 million courses of Paxlovid for $5.29 billion assuming it receives the FDA nod. And Pfizer is reportedly in talks with the German health ministry about possible procurement of Paxlovid according to a press release.

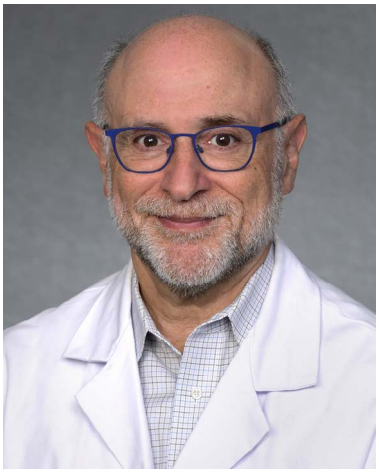
Dr. Timothy Kanter

As an expert in infectious diseases practicing in New York, Dr. Timothy Kanter is enthused about the availability of both agents and expects broad usage, including both vaccinated and unvaccinated individuals. He points to the emerging Delta variant of COVID-19 and the fact that many Americans still are unvaccinated as the two main gaps these new oral antivirals will address: **"It's very exciting to see both agents coming out of the Warp Speed initiative. While we now have the vaccinations, our growing concern is Delta – and people are still getting COVID-19 even if they're vaccinated. Both antivirals seem to be showing decreased hospitalization and death."**

With both agents becoming available within months if not potentially weeks, the question then becomes which one will be preferred. In Dr. Kantar's estimation, Pfizer will be used in more cases due to its numerically higher efficacy as well as the solid corporate track record and name

recognition the Company has established during the pandemic through its COVID-19 vaccine, Comirnaty. At the same time, he wonders about the dosage of ritonavir that will be needed as part of the Paxlovid regimen since there potentially could be interactions with patients' existing treatments. **"From the topline number, you might lean towards Pfizer, but we haven't seen the details of the dose of Norvir. The Merck drug is unboosted. With only 5 days of therapy, the Norvir may not be a big deal. We'll have to see once they are approved."**

The bigger question with both drugs will be how to convince patients with mild symptoms to get into see their physician, or into an urgent care center, within a few days. Previous oral antivirals whose effectiveness depends on early initiation after first symptoms, such as Tamiflu, Relenza and Xofluza for influenza, faced a similar challenge. **"Treating people early in the course of their COVID infection is going to be key,"** states Dr. Ian Frank, an Infectious Disease specialist and Director of Antiretroviral Clinical Research at the University of Pennsylvania **"I think there will need to be efforts to educate people, to make sure that they get tested as soon as they develop symptoms – and get referred into care."** Dr. Frank also foresees that the availability of oral antivirals is likely to divert patients away from the usage of monoclonal antibodies, which have been many hospitals' go-to in patients with mild to moderate COVID symptoms. **"I think Pfizer or Merck drugs are easier to administer options than the monoclonal antibodies. I think they will replace the monoclonal antibodies as early therapy in non-hospitalized patients."**



Dr. Ian Frank

Putting aside their upcoming marketing showdown, both Merck and Pfizer are expected to benefit significantly going into 2022. In a pre-Thanksgiving note to clients, investment banking analyst Geoffrey Porges of SVB Leerink reckons that Paxlovid is among the catalysts that could propel Pfizer's worldwide revenue north of $100 billion in 2022 as countries line up to purchase and squirrel it away. Another investment bank, Barclays, expects Merck to garner approximately $7 billion in Molnupiravir revenue in 2022, particularly when comparing the size of the deals that each company is brokering with governments, particularly the U.S. government.

Both drugs will be arriving at a critical time as many parts of the US and other countries are witnessing alarming surges in COVID-19 infections. Recent reports from the US CDC indicate that several northern US states are seeing a seasonal increase in the rate of COVID related hospitalizations, even now as booster vaccinations are recommended and are being made available. Even certain southern states are reporting a spike in COVID-19 cases. According to the CDC, there

are still an average of nearly 90,000 new COVID-19 cases per day, which represents an increase versus the prior two-week period; indeed, there are still over a thousand deaths a day, and now the total number of COVID-19 deaths in the US is on its way to 800,000.

At the same time, experts fear an erosion of vaccinated patients' immunity, underscoring the imperative for those who already are vaccinated to get their booster shots. And last week, the emergence of the new Omicron (B.1.1.529) variant discovered in South Africa sent a shock through the media and financial markets.

Outside of the US, many other countries are seeing increases in the number of COVID-19 cases and are striving to get their populations fully vaccinated, and for those who have been vaccinated, to get their boosters. Austria, for example, saw its new infection rate hit record levels and therefore instituted a controversial lockdown for people who are not vaccinated. Hospitals in parts of that country reportedly are overcrowded to the point of not being able to take in new patients.

During the conversation with Dr. Frank, we asked about the impact of the oral antivirals from Merck and Pfizer, and how they might contribute to ending the pandemic – or helping transition it to an endemic stage. **"With these new agents, and those we already have, the tools now exist for early treatment and prevention. But for individuals who present later with the disease, there aren't a lot of great therapeutic options. In the people who I've seen with severe respiratory disease, the lungs have become pretty fibrotic and I'm not sure what's going to reverse that. I don't know if we have medications that could prevent or reverse fibrosis once it starts. There will remain a need for better therapeutics for folks with more severe and advanced disease."**

HIV Therapy Is Being Simplified Even Further

In the treatment of HIV, according to experts we interviewed for this report, the major trend that has been taking place over the past few years has been the shift to antiretroviral regimens (ARVs) with improved safety, tolerability and drug-drug interactions (DDI) profiles, especially Gilead Sciences' Biktarvy and ViiV Healthcare's Dovato. There also has been a growing migration from 3 drug ARV regimens (3DRs), which have been the standard of care in HIV since the mid-1990's, to 2DR ARVs, including the first long-acting 2DR, ViiV's Cabenuva.

The major driver of this shift has been to ensure that patients' viral load is suppressed to non-detectable levels while at the same time promoting and ensuring optimal tolerability and safety,

since people living with HIV must remain on ARV medications indefinitely (at least based upon the current therapeutic paradigm/armamentarium). The experts we spoke to expect that the 3DR to 2DR transition trend will continue and accelerate as more data emerges to support the usage of Dovato, and as other new and novel 2DRs come to market.

Dr. Kanter, an Infectious Disease and HIV expert working in the South Bronx, observes that the shift from 3DRs to 2DRs has been talked about considerably within the HIV treatment community. **"The 2DRs now have a 144-week study, so we are more convinced about their efficacy. Before, when they had only 24 or 48 weeks of data, I think we were all concerned as to whether the efficacy could hold up. But it has held up and we have not seen the resistance that we were initially very concerned about."**

Dr. Kanter referred to data presented by ViiV Healthcare this past fall, namely the three-year results from the TANGO study. This study, presented at IDWeek 2021, demonstrated that Dovato is non-inferior to 3DRs in stable patients – and without any mutations in the virus that could inactivate either of the 2 constituents of Dovato, dolutegravir and lamivudine.

During our conversation, Dr. Kanter also expressed his enthusiasm for ViiV's Cabenuva, the first long-acting ARV regimen – which also is a 2DR. Cabenuva combines an HIV integrase inhibitor, cabotegravir, with a non-nucleoside reverse transcriptase inhibitor (NNRTI), Rilpivirine, and is administered once monthly via an IM injection given by a health care provider. **"The injectable is incredible. Not only have I had several patients come back to me and say, 'I feel better,' but they get to take a medication that does not remind them that they have HIV every single day. People can feel better about themselves. It helps to alleviate the stigma they feel."**

Dr. Frank from the University of Pennsylvania agrees with this assessment. **"The main trend that we are expecting is towards longer-acting therapy. As we are seeing more patients in the office again, I think there will be more of an uptake of Cabenuva."** He too feels that patients will benefit not only from the opportunity to take their medications less frequently, hence potentially enhancing adherence, but also relieving the daily thought of their having HIV. **"There are some people for whom taking a pill every day is a psychological hardship. It's being constantly reminded of the disease and is a stigmatizing moment for people in their daily life. For some, even just popping a pill every morning will not be as difficult of a task, but some individuals will prefer to get an injection once a month."**

Despite their enthusiasm, both note that Cabenuva has faced significant headwinds, including

challenges imposed by the dynamics of the pandemic. During the pandemic, both doctors held off on switching many of their patients' ARV regimens because they were not able to see their patients in the office – instead, many patients were seen via telemedicine – which slowed their transitioning patients to newer ARVs such as Cabenuva. Cabenuva also faces a challenge of patients having to present at the doctor's office or infusion clinic once a month to receive the shot, rather than to self-administer at home. **"I attended a CME talk… from Clinical Care Options that reviews some of the operational difficulties [with Cabenuva]," recounts Dr. Kanter. [They were] talking about the operational issues of getting the drug and having staff to [administer it]. The centers who do have people on [Cabenuva] had to do a lot of work to get people on the drug."**

In terms of ARV medications in the pipeline, the two candidates that both Dr. Frank and Dr. Kanter have their eyes on are Merck's **Islatravir** and Gilead Sciences' **Lenacapavir**, both of which are expected to be incorporated into long-acting regimens. Islatravir is a new type of ARV medication that has been referred to by members of the HIV treatment community as a "super nuke," in the sense of its being similar to but more potent than today's set of nucleoside analog reverse transcriptase inhibitors (NRTIs). Unlike other NRTIs, Islatravir works to defeat the virus through multiple mechanisms of viral inhibition, including hindering the process of translocation. As a result, Islatravir works against both the native form of the virus as well as virus that has mutated to include common NRTI resistant variants. In clinical studies, Islatravir also has proven to be well-tolerated.

Merck is currently developing Islatravir for different indications, and in different combinations. First, it is being studied in combination with the NNRTI Doravirine as a simpler 2DR for HIV treatment. Doravirine is currently sold by Merck under the brand name Pifeltro as a stand-alone NNRTI, and under the brand name Delstrigo as a fixed-dose combination that includes Doravirine plus lamivudine and tenofovir disoproxil fumarate (TDF). Similar to Islatravir, Doravirine has exhibited the ability to impede both the wild-type virus as well as virus laden with NNRTI mutations. A long-term study with the 2DR combination of Islatravir and Doravirine thus far have been encouraging in terms of its efficacy, but particularly its tolerability and safety profile. According to Dr. Frank, Islatravir also is being studied as a long-acting oral product and there are efforts to look at other modes of delivery, including implantation. Further, Islatravir is being evaluated in the prevention of HIV, or PrEP.

Dr. Kanter is particularly keen about the Islatravir/Doravirine combination because of an increasing phenomenon and challenge in his population which is that of weight gain. While definitive research has not been able to pinpoint the culprit – whether a particular ARV or ARV combination, or simply the isolation and inactivity imposed by pandemic itself – he sees a clear need for 2DRs that are

more metabolically friendly and weight neutral. **"For us, one of the recent things that has come up is weight gain – this is definitely an issue in my practice since many people have high BMIs to start with, some are well over 30."** He is eager to see how Islatravir/Doravirine performs in terms of its short and long-term metabolic effects relative to other frequently employed regimens, particularly Biktarvy and Dovato. **"This is going to be of particular interest in urban areas like the place I practice, here in the Bronx, or Chicago, Atlanta… other cities where we see people who have a large BMI to start. You start to think, 'Do I want to put patients onto something that will cause them to gain weight, and their A1C is already borderline?' So, I think there's a real opportunity for this idea of Islatravir/Doravirine. These are two products that have the … opportunity to be good teammates."**

Gilead's Lenacapavir is the other investigational ARV that both Dr's Frank and Kanter are excited about. Lenacapavir represents a new and unique category of ARV, specifically capsid inhibitors. According to a press release, Gilead submitted an NDA for Lenacapavir this past June for the treatment of highly treatment-experienced patients. Lenacapavir already has garnered a Breakthrough Therapy Designation from the US FDA due to its potential benefit in people living with HIV who have multi-drug resistant virus, thus fewer treatment options.

This past March, it was announced that Gilead and Merck will be collaborating in the development and commercialization of long-acting ARVs that combine the two medications, Lenacapavir and Islatravir, into both oral and injectable long-acting 2DR regimens. While top financial analyst Umer Raffat of the EvercoreISI characterized the intent of the partnership as forming potentially the **"best-in-class HIV regimen post 2025" with the "highest barrier to resistance,"** the study of the two drugs in combination hit a speedbump last week as the two companies announced a pause in their clinical trial. Raffat is keeping a close eye on how this pause will play out for both companies.

Turning now to pre-exposure prophylaxis of HIV, the medical community has been extremely pleased with the existing options but – in a trend that is mirroring the evolution of HIV treatment – is collectively looking forward to longer acting medications to boost persistency. According to University of Pennsylvania's Dr. Frank, **"PrEP has made a huge difference. However, my own clinical experience for PrEP is that many individuals don't stick with it for long periods of time."** In response to this need, several companies are bringing to market longer acting PrEP variations, with ViiV being potentially first to market. ViiV has filed an NDA with the US FDA for cabotegravir (a constituent of Cabenuva) as a long-acting agent for PrEP in people at risk of sexually acquired HIV; approval could come as early as January of 2022.

Merck is also studying an implantable formulation of Islatravir that potentially could provide protection against HIV for up to a year, utilizing a similar delivery platform as its contraceptive implant, Nexplanon. And Gilead's Lenacapavir is in clinical testing as a PrEP option for specific at-risk, vulnerable populations such as adolescent girls, young women and cisgender women.

The challenge in increasing the usage of PrEP also will be in widening its usage to include more primary care physicians, and not just specialized HIV-treating providers. **"I think PrEP is ideally prescribed by PCPs and not HIV physicians,"** states Dr. Frank. **"We need to destigmatize it. These days, it's easy to prescribe PrEP and there's not a lot of complicated management. And I think the outcomes will be better if they are prescribed by their PCP where they have an ongoing relationship with, and not requiring a referral to a 'PrEP specialist.'"**

He continued: **"I don't take care of a lot of young people because I've been doing HIV care for a long period of time. Many of my patients are older, as are my PrEP patients. It may be a different experience for adolescent medicine providers, and it may be that a more centralized place that is used to providing gender sensitive HIV prevention services would be a better site for some patients compared to their PCP's office or a provider may not have quite the same sensitivities."**

Antibiotics for Hospital-Based Infections: New Options Desperately Needed

According to Fishawack Healthcare's Dr. Dan Zaksas, new treatments for hospital-based infections are an exceedingly "impoverished" space in the pharmaceutical development pipeline as a function of certain market dynamics inherent to the adoption and utilization of new antibiotic therapies. He characterizes it as a market conundrum: the better the drug, the less it will be used.

Dr. Dan Zaksas

"The more effective and targeted the drug, the less that physicians will use it empirically due to the greater likelihood of resistance. Hence a crisis of innovation." One potential way around this will be better rapid diagnostic techniques that could help doctors to more quickly identify the cause of the pathogen. While several of these assays exist, they are only used in limited capacity and infection types. Part of the challenge also is that hospitals tend to be cost-conscious with protocols that encourage the usage of cheaper generic agents first.

Anna Diaz Triola

When asked about companies that are active in the space, Dr. Zaksas pointed to **Entasis Therapeutics**, a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of novel antibacterial products to treat serious infections caused by multidrug-resistant Gram-negative bacteria. *PharmaVOICE* had the opportunity to meet with and interview Entasis' Chief Commercial Officer, Anna Diaz Triola about their mission and focus as they advance their portfolio from clinical development stage to commercialization. Ms. Triola is a highly experienced marketing leader with a unique confluence of experience and skills that bridges the antibiotics, chronic, and rare diseases spaces, having served in a range of high-level positions within Boston-area biotech companies. Following is an abridged transcript of our conversation with her.

Please describe Entasis' mission and purpose as an organization.

ADT: "We were founded about 6 years ago as a spin-out from AstraZeneca. At that time, AZ had several early-stage assets in the pipeline that became Entasis' portfolio. What is unique about Entasis is our specific pathogen-targeted pipeline focused on addressing the high medical need to treat serious multidrug-resistant infections. The first proof of concept is sulbactam-durlobactam, or SUL-DUR and we just announced strong, positive topline data from the ATTACK trial focused on carbapenem resistant *Acinetobacter baumannii* (CRAB), a rare pathogen. SUL-DUR was designed and developed to treat *Acinetobacter* specifically. This may be a first in the antibacterial field, but the idea of tailoring a clinical study to provide clear efficacy and safety in the appropriate patient population is not new. This personalized medicine approach has already made a difference in other therapeutic areas, like oncology and rare diseases. So here we are, on the cusp of submitting our NDA in mid-2022, and potentially this could be a precedent-setting label that is focused on a rare pathogen. By following this rare pathogen in clinical development, we are able to create a streamlined commercialization strategy that is focused on sites of care where *Acinetobacter* is a problem that costs time, money, and lives."

What are the big challenges in commercializing antibiotics in today's marketplace?

ADT: "Many companies have tried and unfortunately failed in commercializing their first asset. We prioritized learning from the failures of the past and rewriting the commercial playbook for developing

new antibiotic therapies. Sometimes it's the product, other times it is the commercialization strategy itself. Sometimes what companies run into is taking a product that is not sufficiently differentiated from a labeling perspective, or which is not addressing an unmet need. By going back into history, you can evaluate the best practices and the tough lessons learned, and it's on us who are focused on commercializing these assets to imagine a different commercialization model that is inspired by the focused clinical development pathway – one that is intentional, very specific and extremely laser focused on this rare pathogen. And when you have that as inspiration, I think inspiration plus innovation and creativity allows you to imagine a different, commercialization strategy."

Tell me more about the unique approach that you are taking.

ADT: "As you know, anti-infectives is a space that has not received a lot of attention and resources – partly because of the development pathway, but also due to the complexities of the commercialization strategy. How do we solve for that in a new way? We are going to pull from the rare disease model. When you focus on a rare disease, you focus your investment on educating professionals about that specific patient population. When you think about the unmet need, you ask: is it clearly defined? Are your efforts targeted on the types of providers or the institutions where this problem exists today, or where patients have risk factors that could accelerate this nosocomial infection? Therefore, in designing our strategy we are striving to identify these hot spots where *Acinetobacter* is a problem and engaging in disease awareness efforts around that unmet need. We can then engage the stakeholders where this pathogen is relevant, and who are or should be interested in *Acinetobacter* infection. Recent publications have cataloged the cost of CRAB in terms of time, money, and lives. CRAB can increase hospital length of stay, increase cost per case of treating a weak, vulnerable, immunocompromised patient, and can cost lives. Doctors treating these hospitalized patients have about a 50/50 shot to get it right. Do they want to fiddle with a cocktail of generic agents that were not studied to treat specifically CRAB? Or do they reach for something that was designed specifically for CRAB? Engaging the right clinicians and decision-makers in the right geographic territories where this problem exists today is really critical – and that's what we're excited to do."

Are there companies that you're looking to as a model in rethinking the playbook?

ADT: "Instead of specific products, there are therapeutic areas where we've done our due diligence to understand and extract the best practices and lessons learned to inform our commercial go-to-market strategy. In rare diseases, there's always a focused effort on the unmet need, on promoting disease awareness and education, and on proper patient identification. The other discipline we have

looked closely at is oncology. Oncology used to involve a broad, scattershot approach that had many unintended consequences. It's been remarkable to see how precise cancer therapy has become and how this can benefit the patient. Future antibiotics need to follow that same arc of evolution. In the beginning, we use generic broad-spectrum agents like vancomycin… literally for everything! There is a consequence for using a blunt instrument, like broad- spectrum vancomycin and we see it today in the management of *C. difficile*. Taking our inspiration from oncology, we need to evolve from a broad spectrum to a more targeted approach. That is when you can create value for a company or hospital institution, community practice, and most importantly for the patient who has a very specific need and where we can address that need in a very specific way. That is the inspiration behind the commercialization plan for SUL-DUR.

Five years from now, what has Entasis accomplished?

ADT: "Five years from now, we have brought potential life-saving therapies to patients with high unmet need. For those who have CRAB, we hopefully have helped them get out of the ICU, out of the hospital, and back home to enjoy their activities of daily living. Also, we have helped our critical care institutions – hospitals – by providing a new treatment option for *Acinetobacter* infection and thus freeing them to use their scarce healthcare resources in better ways. Regarding the pipeline, zoliflodacin, in collaboration with GARDP and currently in a global Phase 3 clinical trial against *Neisseria gonorrhea*, the causative bacterial pathogen of gonorrhea, continues to move forward enrolling patients in at least four continents. With support from our partners CARBX and the NIH, we are continuing development of our earlier pipeline assets that introduce new first-in-class candidates, like ETX0462, a novel diazabicyclooctane with antibacterial activity against multiple Gram-negative pathogens including *Pseudomonas aeruginosa* as well as several high priority biothreat pathogens. In the future, we are executing on the company's mission to commercialize SUL-DUR and progress a pathogen-targeted pipeline focused on addressing the high medical need to treat serious multidrug-resistant infections that impact people's lives.

PharmaVOICE

THERAPEUTIC DIGESTS

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