agenus news

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Innovative Clinical Development with Record Speeds

Agenus Trials Continue to Accrue Despite COVID-19

Paulo Moreira joined Agenus as the Global Head of Clinical Operations in February 2019. Paulo has 29 years of experience in Clinical Development and Operations. He joined us from EMD Serono after 18 years there. Paulo was named to PharmaVoice's 100 Most Inspirational Leaders in both 2015 and 2017 recognizing his industry leadership around patient centricity and the advancement of clinical trials. He was named by CenterWatch as 2018 Top Innovator for his work around the Clinical Trials Registry of the Future. Paulo holds a Visiting Scholar appointment at Boston College.

At Agenus, Paulo is practing clinical innovation to save lives.

At Agenus, we innovate with a high sense of urgency. The updated count for the number of INDs filed from Agenus discoveries now stands at 14 INDs in the last 4.5 years, more than any peer in immuno-oncology, including large biopharma. Propelled by our commitment and expertise, **Agenus has brought these therapies to patients in as little as 65 days following IND clearance, ~2.5 times faster than the industry standard of 168 days.** Our determination to push beyond the limitations of industry standards drives us, because of our commitment to deliver our unparalleled pipeline of innovative agents to patients. To this end, we rapidly completed accrual of two clinical trials in cervical cancer in under 18 months. We are planning to submit our first ever BLA in the coming months.

We Manage our Own Clinical Development and Operations to Minimize any Suprises

Our capabilities include full Clinical Operations, Program Management, Data Management, Biostatistics and Programming, Clinical Monitoring, Medical Monitoring as well as Regulatory Operations. Our proprietary, Artificial Intelligence (AI) based R&D platform helps us predict optimal therapeutic combinations, potential responders to new treatments and define biomarker signatures, which we expect to lead to smaller and quicker clinical trials with higher impact for patient benefit.

2 Cervical Cancer Trials for Potential BLA Filings
Fully Accrued in <18 months

2.5X Faster vs. Industry Standards
IND Clearance → Site Activation → Patient Dosing

8 Studies Open

~440 Patients Treated

25 Countries

120 Sites

Forward-Looking Statements: This Agenus Newsletter includes forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding anticipated BLA filings and anticipated efficiencies from our clinical operations strategy. These statements are subject to risks and uncertainties, including those described in our SEC filings.

Our Key Clinical Trials are Advancing Despite COVID-19

Even with the challenges the world is facing, wherein major clinical trial centers and hospitals have been converted to COVID-19 treatment centers, we are continuing to enroll patients in our clinical trials. In fact, in some of our trials such as with AGEN1181 (our next generation, multipurpose CTLA-4), we actually have a queue of patients who are being evaluated for enrollment. Our investigators, who are affiliated with major cancer immunotherapy centers with deep clinical trial expertise, expect to continue accruing patients.

Importantly, we have **fully accrued** patients into our balstilimab (anti-PD-1) trials, as monotherapy or in combination with zalifrelimab (anti-CTLA-4) in second line cervical cancer, and remain on track for our planned BLA filings in the coming months.

The Agenus team is managing patient safety and logistics to ensure that they receive their potentially life saving treatments and are able to continue follow-ups. We make sure that patients are provided secure transportation to visit sites safely and that site staff are also protected from potential exposure. We have supplied sites with protective gear to overcome any gaps in the system and to ensure everyone's safety and well being. We have also instituted remote monitoring and telemonitoring where possible, to continuously maintain oversight of our clinical trials. During the early phase of the pandemic spread, in anticipation of potential supply chain disruptions, we collaborated with our colleagues from Global Supply Chain, and strategically supplied our regional depots with enough study drug to ensure uninterrupted treatment to our patients.

COVID-19 has Paved The Way for Innovative Clinical Trial Practices

In addition to repurposing some of our research capabilities to advancing potential COVID-19 treatments, the pandemic has also driven high efficiencies in the way we conduct clinical trials. We are designing more patient and site centric studies without compromising the scientific merit of clinical trials. COVID-19 has paved the way for the increased adoption of practices such as telemedicine for patient monitoring, or home visits for collecting blood samples / taking vital signs. Since the visit/ data collection is done remotely, we are helping the system by not exposing the patients and sites to potential infection.

While these may seem like simple practices in theory, they are new in the world of clinical trial operations and may continue to exist post COVID-19. It is something that many innovators in the clinical development community have tried for so long, but there were no guidelines from regulatory agencies to define good clinical practice (GCP) compliant telemedicine. Hence, they were rarely practiced. In March 2020, the FDA issued guidelines for the conduct of clinical trials during COVID-19, accommodating these practices. At Agenus, we swifly implemented these practices to facilitate the continuation of our clinical trials. We will continue to bring innovative therapies and best trial practices aimed to maximize patient comfort and increase efficiencies at treatment centers.