agenus news

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A New Progressive Environment in Drug Regulatory Affairs offers opportunities for Agenus to rapidly advance its novel therapies

Agenus poised to become one of the fastest companies to advance from discovery to approval

These are exciting and rapidly changing times for Regulatory Sciences and Drug Development with the objective being to expediate access to new drugs for patients with life threatening and rare diseases such as cancer. In the last 10-15 years the global pharmaceutical regulatory environment, particularly in the U.S., has evolved to accelerate time to market through speedier regulatory review programs and enable manufacturers to employ alternative trial designs and endpoints to obtain approval. These changes have been most pronounced in oncology innovation, where novel therapeutic filings doubled compared to the late 2000s and have outpaced historically large therapeutic categories such as endocrinology[1]. We at Agenus are excited for the planned filing of our first BLAs for cervical cancer with access to more favorable regulatory tools than those that were available to oncology companies in the recent past.

At Agenus our lead assets, balstilimab (anti-PD-1) as monotherapy and in combination with zalifrelimab (anti-CTLA-4), are in pivotal trials to treat patients with relapsed/refractory cervical cancer. We are planning to submit BLA applications in 2020 for accelerated approvals based on a surrogate efficacy endpoint, which would help Agenus evolve into a fully commercial company by 2021. Moreover, we intend to take advantage of other expedited regulatory pathways such as breakthrough therapy designation (BTD), Fast Track designation, rolling review and Priority Review designations as we progress the rest of our pipeline.

Agenus plans to utilize several new initiatives by the U.S. Food and Drug Administration's (FDA) Oncology Division to assist in expediting the development, review and approval of new drugs. These new initiatives by FDA include collaboration with the National Cancer institute (NCI) and several oncology professional societies to adopt adaptive clinical trials and basket trials, and foster collaboration between pharmaceutical companies by encouraging platform trials. The FDA has introduced several regulatory designations that expedite drug review and approval, including use of surrogate markers for Accelerated Approval, Orphan Drug status, Fast Track designation, Priority Review designation, rolling reviews, and most importantly, Breakthrough Therapy designation (BTD). In fact, the average approval time for cancer drugs was 48% shorter than for non-cancer drugs between 1999-2018 as most oncology filings leveraged these programs[2].

How will Agenus leverage FDA guidance for rapid approval of novel combination therapies?

The future success of antibody-based cancer therapy lies in developing combination therapies of two or more treatment modalities to overcome the resistance pathways that cancer cells develop with single-agent treatments. We have designed our pipeline to enable such rational combinations that can therapeutically benefit patients with immune sensitive and cold tumors, by addressing multiple pathways in the cancer immunity cycle. We are leveraging the FDA guidance on development of novel-novel combination agents for our combination programs at Agenus. For example, our pathways to faster registration include development in indications where treatments do not exist or are unsatisfactory (unmet medical needs), as well as the use of biomarkers to select patients who are most likely to benefit from a specific combination. Most importantly, to reduce development and regulatory risk, we receive external feedback through collaborations with thought leaders who have been pioneers in driving clinical development of novel immuno-oncology drugs. We continually strengthen our regulatory strategy by consulting with experts who have abundant experience in closely interacting with the FDA and other regulatory agencies to drive the rapid approval of paradigm changing oncology drugs.

How else has Agenus accelerated pipeline development?

Agenus is uniquely positioned with a diverse pipeline of I-O assets, vaccines and adoptive T-cell therapy candidates all under one roof. Our I-O pipeline includes a substantial number of new IND submissions to the FDA in 2016-2019. From a regulatory perspective, we have advanced 13 I-O discoveries to INDs in a span of 3.5 years, which is unprecedented even when compared to big pharma. This has been largely due to the dedicated work of our scientists at Agenus Cambridge and Lexington, the product development team at Agenus West in Berkeley and the Clinical team who have practiced innovation, speed and quality concurrently.

In this climate, I am excited to lead the execution of Agenus' regulatory strategy and bring to life medicines to improve a cancer patient's life. We are highly encouraged by the decreased time frames to bring life-saving drugs to patients and know that in this new progressive environment these time frames will continue to decrease.

Sunil Gupta,

Vice President, Head of Regulatory Affairs and Pharmacovigilance

[1] CDER New Drugs Program: 2019 Update (https://www.fda.gov/media/133187/download)

[2] Analysis & Insight into critical drug development issues; Volume 21, Number 5, September/October 2019 (Tufts Center for the Study of Drug Development)