Vision 2019 A Special Editorial

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Agenus is Poised for a Transformative 2019

Guest Column by Barbara Ryan

Barbara is a biopharmaceutical industry expert and a Wall Street veteran. She is a regular contributor for CNBC, a member of several advisory boards including the Prix Galien Foundation & Pharmaceutical Executive, and a faculty member at the GLG Institute, and the founder of Barbara Ryan Advisors, a life sciences capital markets strategic advisory firm. Barbara is a consultant to Agenus.

After a challenging year for equity markets, 2019 has been ushered in with a decidedly bullish tempo for health care companies. The largest pharmaceutical-company acquisition deal ever was announced in the first week of January, with Bristol-Myers Squibb's planned acquisition of Celgene for $74 billion! This was quickly followed by Lilly's acquisition of Loxo for $8.0 billion. Further, Japan-based Takeda Pharmaceutical completed its buyout of Shire plc for $62B.

Amid these M&A transactions, Agenus ended the year by announcing a partnership with Gilead Sciences, Inc. Agenus' pending partnership with Gilead, announced on December 20, 2018, is valued at $150 million upfront, which includes a $120 million upfront cash payment and a $30 million equity investment. The agreement also includes approximately $1.7 billion in potential future fees and milestones.

What do all these deals have in common? And what do they portend for 2019? They all involve highly innovative assets that offer the potential for sustainable growth, reflecting the scientific advances made in I-O. Last year, the FDA approved 59 new molecular entities, an all-time high, including new oncology therapies developed by smaller cap companies. The large biopharma companies have been flush with cash but challenged with top line growth prospects due to generic competition, and most have lacked sufficient productivity in their R&D efforts to meaningfully contribute to their top line growth.

Many of the largest companies in the industry, like Bristol-Myers and Merck, have built successful oncology businesses but recognize the need for a diverse pipeline of I-O assets to deliver optimal novel combinations. Agenus' collaboration with Gilead will give Gilead access to novel and differentiated immune modulating antibodies that complement Gilead's growing oncology portfolio and cell therapy business. In this environment, I believe that Agenus is poised to have a transformative year in 2019. I expect key data to emerge this year from its lead programs. I also expect additional novel discoveries to enter the clinic and trigger clinical and regulatory milestones, including payments from multiple existing partnerships. Agenus' portfolio includes multiple best/first-in-class immuno-oncology assets, which have already attracted validating partnerships with biopharma heavyweights like Incyte, Glaxo and Merck and most recently Gilead Sciences. New data validating the clinical potential of its various assets will make Agenus a trend-setter in I-O.

Barbara Ryan

Delivering New I-O Assets to the Clinic at Record Pace

Jennifer Buell, PhD

Dr. Buell serves as the Chief Operating Officer at Agenus and is responsible for organizational operations, including research, clinical development, manufacturing, commercial operations, communications, investor relations and external affairs.

2018 was a highly productive year for us. We set aggressive goals and delivered on all our key milestones and objectives. We made breakthrough scientific discoveries, filed 6 INDs at an industry-leading speed, confirmed our regulatory path for our target BLA filing in 2020 and delivered on our existing partnerships and our promise of an important new collaboration. We have summarized our various achievements and strengths in our previous newsletters.

We are poised to continue this momentum in 2019 with innovation and speed to advance our resolute commitment to cancer patients.

Here is what we expect to accomplish at Agenus in 2019:

Advance our Lead Assets Targeting CTLA-4 and PD-1 Towards our Target BLA Filing in 2020

In 2018, we met with the FDA and confirmed that our trials can support a BLA filing. We are positioned to take advantage of accelerated pathways for approval with a relatively small number of patients and rapidly achievable endpoints in our trials.

We expect to complete accrual of at least one of our pivotal trials by year end. We also look forward to presenting key data updates from our programs.

Advance New Discoveries to the Clinic

We have outpaced large pharma in delivering new I-O assets to the clinic, with a record 11 INDs filed between 2016-2018, 6 of which were completed in the last year alone. We anticipate continuing this momentum to deliver additional INDs this year for novel first/best-in-class discoveries made in-house. These include IND filings for our conditionally active anti-CD137 antibody (AGEN2373) and multiple other undisclosed assets.

We expect to initiate first-in-man clinical trials and generate clinical data with our novel antibodies - including our next generation anti-CTLA-4 antibody, AGEN1181, and our first-in-class bispecific antibodies. We will also file INDs for our first-in-class off-the-shelf vaccines targeting shared phosphor-neoantigens.

In addition, we anticipate filing our first cell therapy IND through AgenTus and advancing our differentiated allogeneic cell format towards IND.

Deliver on Partnerships

In 2019, we expect to achieve important milestones in our partnered programs, including the initiation of multiple clinical trials, triggering additional payments. We will also continue to pursue new partnerships with companies that have synergistic portfolios or platforms to accelerate our innovations.

Jennifer Buell