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Delivering Innovation with Speed

Drug development timelines in oncology have shortened while product obsolescence rates are climbing. Continued innovation with speed is critical for future dominance. Fully integrated capabilities, including GMP manufacturing, are not a luxury, but rather are essential for delivering innovation with speed. Agenus' fully integrated capabilities have enabled our delivery of 5 INDs in 18 months before 2018. This year we have already enabled 3 INDs and are on track for 3 more in 2018, with plans to file 2 additional INDs in the first half of next year.

Speed Is Critical For Success In I-O

We continue to deliver innovation with speed. In fact, in one analysis, Agenus ranked first for the number of INDs filed for I-O assets in the period between Jan 2016 – Aug 2018. The analysis included ~25 companies having three or more I-O candidates in clinical development. Agenus filed 8 INDs compared to the median of 3 INDs in I-O within this group.

What makes us this efficient? How do we continue to deliver innovation reproducibly and with industry leading speed? This is made possible by our integrated end-to-end capabilities, including our cell line development platform and our own GMP manufacturing facility, which we will focus on within this issue.

Agenus' In-house GMP Manufacturing Facility Sets Us Apart Amongst Peers

Our in-house GMP manufacturing facility in Berkeley, CA is leading the industry for efficiency and speed. Today we can deliver clinical grade material from research cell bank in ~4 months, which is 3-4 times faster than industry average of 12-18 months.[1]

[1] Reference: https://www.contractpharma.com/issues/2010-04/view_features/cmc-activities-for-development-of-mabs

Forward-Looking Statements: This Agenus News Brief includes forward-looking statements, including statements regarding Agenus' clinical development plans and timelines and anticipated IND filings. These statements are subject to risks and uncertainties. Please refer to this link for more details.

Agenus West, Berkeley, CA

Acquired from XOMA in 2015, Agenus' GMP manufacturing facility (Agenus West) is run by a team with 20-30 years of experience in technology transfer, process development and manufacturing of antibodies. Including its time with XOMA, the team has delivered over 50 antibodies (many isotypes) for various pharma companies and the US defense department and is uniquely positioned to overcome any manufacturing challenges. The Agenus West team works closely with our cell line development team in Cambridge, UK, to ensure cell lines are developed with the required product quality attributes and commercial manufacturability. The availability of desired cell lines for commercial production shortens manufacturing time. Coupled with this fully integrated approach, Agenus West thrives on the latest cutting-edge technology platforms in-house, making us self-reliant and giving us the advantage of manufacturing speed, cost efficiency, operational flexibility and manufacturing technology transfer to commercial scale partners—all with desired product quality, to ultimately benefit patients.

Agenus' In-house Cell Line Development Platform Beats Industry Standards

Cell line development (CLD) is a critical first step towards a successful IND. Agenus has established a cutting-edge facility in-house to develop cell lines that are monoclonal, stable and have commercial grade yields. Bringing CLD in-house has provided assurance of quality, flexibility with production schedules, reduced timelines and reduced cost of development.

At our CLD facility in Cambridge, UK, we have established an efficient system starting with high throughput screening and selection of clones, to developing robust and reproducible cell lines that are viable for commercial scale production. Using a parallel workstreams approach and ensuring close collaboration with our GMP production facility,

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we can now efficiently deliver high yielding, stable monoclonal cell lines within ~ 4 months. This integrated approach helps us with downstream lower cost, high efficiency manufacturing and ensures fast delivery of high quality cell lines to our GMP manufacturing facility. These capabilities culminate into faster INDs with seamless supply of product which is essential for clinical and commercial success. Currently, we are in the process of further improving our CLD process to be less labor intensive and more automated, which may shrink timelines further.

Chemistry, Manufacturing, and Control (CMC) activities are critical to a successful IND filing. Today, the industry average is ~18 months to complete these steps at an estimated cost of $7 million, via external CMOs.[1] At Agenus, we have achieved a much faster pace (7–12 months) and at lower costs, through our state-of-the-art cell line development, process development and manufacturing units.

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