Fast ramp-up based on KojoX[™] regulatory filing

Using our KojoX[™] operating philosophy our partners benefit from our modular manufacturing approach, maximizing operations and design through:

• Alignment across scales and technologies providing fast scalability and de-risking the supply chain

• Expedited regulatory approval fueled by broad experience supporting the entire product life cycle

• Supply chain agility, redundancy, and scalability with Tech Transfers across our integrated network

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What We Provided What We Did How We Did It Results Image: Construction of the second s

Supply Demand

FUJIFILM Diosynth Biotechnologies' partner has significant demand for a specific therapeutic and faces supply shortage. The partner wants to ramp up production quickly to address unmet demand.

Regulatory Bottleneck

FUJIFILM Diosynth Biotechnologies has available capacity in existing facilities and the ability to guickly configure excess manufacturing square footage to accommodate production demands. Recognizing the potential bottleneck presented by regulatory requirements, FUJIFILM Diosynth Biotechnologies' depth and breadth of regulatory and validation experience needed to overcome the challenges served as a solution.

Alignment Meeting

FUJIFILM Diosynth Biotechnologies and the partner together agreed to bring completely new assets online, pursuing expedited regulatory approval based on the KojoX concepts of modular processes, equipment, and procedures.

Regulatory Approach

Together with the partner chose the following:

- Provided data and comparability studies to the regulatory authorities
- Reached an agreement with the authorities to downgrade the filing requirements
- Identified potential activities to be shortened or omitted to reduce the timeline including Process Performance Qualifications and filing updates

We anticipate

Time Saved

reducing the regulatory timelines by 5 months, allowing this vital therapeutic to reach patients in need more quickly.

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Partners for Life